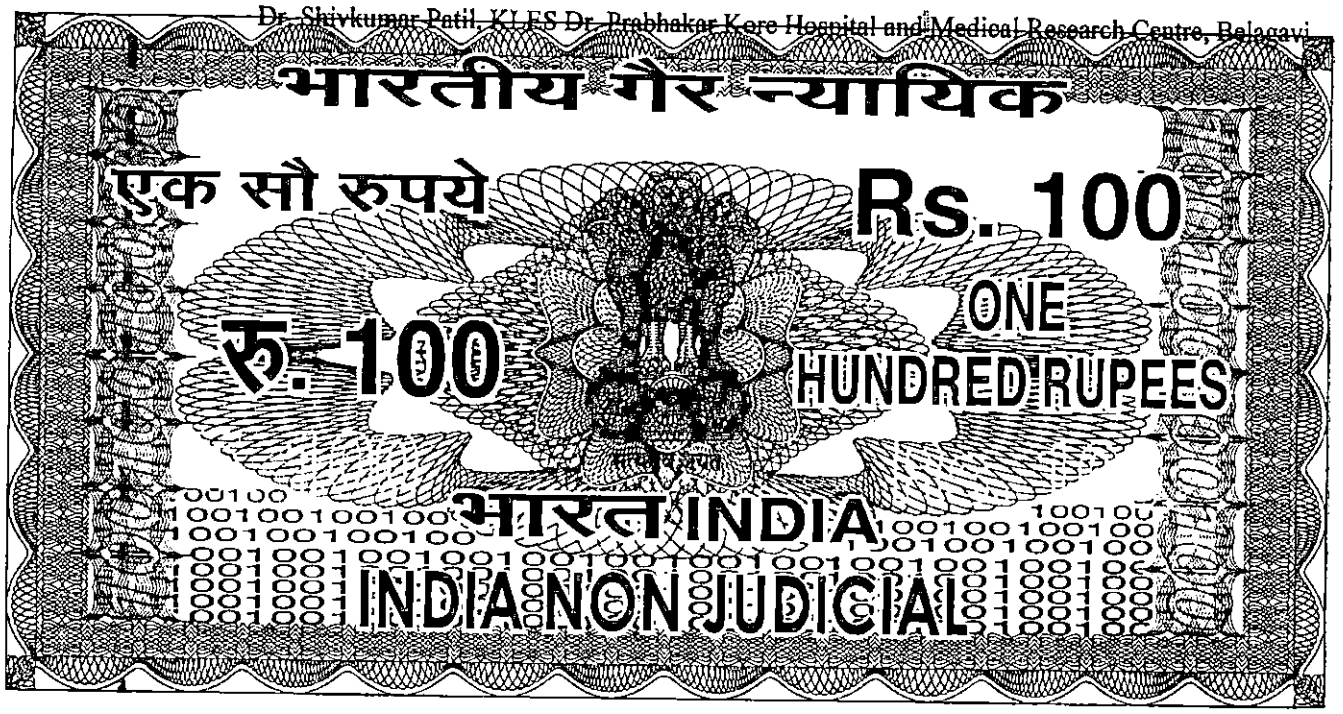

ગુજરાત गुजरात GUJARAT

નંબર : 7372 રૂ. ૧૦૦ BK 282530

તારીખ : ૨૫ માર્ચ ૨૦૧૮

નામ : Cliantha Research Limited
Opp. Pushparaj Towers,
Nr. Judges Bunglows,
ઠેકાણું : Bodakdev, Ahmedabad-380054
Ph.:+91-79-26853088-92
Fax:+91-79-26853093

કે. ડી. ફોલરીયા

લા. નં. એસ.બી. ૪૨૮, ૪૨૯/૧૯૯૯
એ-૪, સ્નેહા ફ્લેટ, મેમનગર, અમદાવાદ ના સાર્વભૌમ
સેનારની સહી.....

CLINICAL TRIAL AGREEMENT

PROTOCOL CRL011812

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date fully executed by the Partics (the **"Effective Date"**) and entered into by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Opp. Pushparaj Towers, Near Judges Bungalows, Bodakdev, Ahmedabad – 380 054, Gujarat, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its employees, assignees, nominees, agents and successors-in-interest)

AND

Dr. Shivkumar Patil whose principal place of work is **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka** (hereinafter referred to as the **"Principal Investigator"**or **"PI"** which expression, unless repugnant to the subject or context therein, shall mean and include his administrators, executors and permitted assigns)

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

AND

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre located at Nehru Nagar, Belagavi-590010, Karnataka (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

AND

CMS Clinical Research Pvt. Ltd., Inox Tower, Plot No-17A, Sector-16, Noida -201301, Uttar Pradesh (hereinafter referred to as the **"SMO"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

CRO, Principal Investigator, Institution and SMO are referred to herein individually as a "**Party**" and collectively as "**Parties**".

Whereas, Encube Ethicals Private Limited, Unit 24, Steelmade Industrial Estate, Marol Village, Andheri (E), Mumbai - 400 059, India(Hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study topical administration of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below).

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

The study of topical administration ofClindamycinPhosphate 1.2% and Benzoyl Peroxide 5% Gel(the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment ofsubjects with Acne Vulgaris (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. CRL011812 and entitled **"A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris"** a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of the Sponsor by the CRO.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board).

2. THE STUDY SCHEDULE

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

ATTESTED

Dr. S. A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010, Karnataka

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for cheques shall be:

Address: KLES Dr. Prabhakar Kore Hospital and Medical Research Centre,
Nehru Nagar, Belagavi-590010, Karnataka

The further details for the payments to **PI/Institute** should be provided as:

Cheque in the favor of	**SHIVKUMAR K PATIL**
PAN Number	**BJJPP7382P**
Name of Bank	**Syndicate Bank**
Branch	**Nehru Nagar, Belagavi**
Account No	**05042180015470**
Branch Code	**000504**
IFS CODE	**SYNB0000504**

The further details for the payments to **Site Management Organization (SMO)** should be provided as:

Cheque in the favor of	**CMS Clinical Research Pvt. Ltd.**
PAN Number	**AAFCC8457M**
Name of Bank	**HDFC Bank**
Branch	**Nacharam, Hyderabad**
Account No	**50200007478582**
Branch Code	**000368**
IFS CODE	**HDFC0000368**

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** Sponsor will pay only **Rs. 2000 (Two thousand only) per subject for screen failure**. The maximum ratio for screen failure Subjects shall be **5:1** i.e. maximum one screen failure per five randomized Subjects.

G. **Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

ATTESTED

V.A Kothiwale
Registrar
KLE Academy of Higher Education and Research
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Belagavi-590 010,Karnataka

eight (48) hours of the telephonic notification. The Institution and the Principal Investigator shall ensure that the announced or unannounced audit/inspection is getting conducted on the planned dates confirmed by the auditors/inspectors, and no request is raised for change in schedule of the audit/inspection without prior approval from the sponsor. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

E. **Supplies.**

a. The Sponsor or Sponsor's designee shall supply to the Principal Investigator/Institution, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived there from and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

F. **Study Records, Reports, and Data.**

i. *Study Records*. The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **fifteen (15) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

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Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

6. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. **PUBLICATION**

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems

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policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**

A. **Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify"**). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

ATTESTED

Dr. V.A.Kothiwale
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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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officers, and employees fully cooperate with the Sponsor and its legal representatives in the investi-investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns (**"Sponsor Indemnities"**) from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnity.

F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. INSURANCE

A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of **One (1) year** thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations in the amount of **INR 3,00,00,000/- (INR Three Crore Only)**in the aggregate. Sponsor will provide evidence of its insurance upon request and will provide to the Institution, **thirty (30) days** prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 12 shall survive termination of this Agreement.

ATTESTED

Dr. V.A.Kothiwale
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effective date of termination, all other Study activities; provided, however, upon the Spon-Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 8, 9, 10, 11, 12 and 13 shall survive any termination of this Agreement for any reason.

14. MISCELLANEOUS

A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

Any notice to the **Sponsor** shall be addressed as follows:

Address: Encube Ethicals Private Limited,
Unit 24, Steelmade Industrial Estate,
Marol Village, Andheri (E), Mumbai - 400 059, India.

ATTESTED
Dr. V.A.Kothiwale
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KLE Academy of Higher Education and Research,
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I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. **Covenant Not to Hire**. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs and also any follow-up queries from the regulatory authorities to the Sponsor. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports should be faxed / emailed to the Medical Affairs

Department of CRO for onward transmission to SPONSOR:

Name:	Dr. Ankesh Barnwal
SAE Fax number:	+91-79-66219549
Telephone numbers:	+91-79-66219545
Cell number:	+91-9909019497
E-mail:	abarnwal@cliantha.in

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety

Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

ATTESTED

Dr. V.A.Kothiwale 88
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KLE Academy of Higher Education and Research,
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Belagavi-590 010.Karnataka

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows:

Overall Per Patient Budget

Visit Number	**Visit 1 (Screening)**	**Visit 2 (Randomization)**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Safety Follow up (Tel)**
Investigator Fee	1500	1500	1500	1500	1500	1500	500
Lesion Count & IGA Assessment	200	200	200	200	200	200	
CRC Payment	1600	1600	1600	1600	1600	1600	600
Total	3300	3300	3300	3300	3300	3300	1100

Summary Table	
Investigator Fee	9500
Archival Charges	800
Lesion Count & IGA Assessment	1200
PI Grant	11500
IOH (20%)	2300
CRC Payment	10200
Grand Total	**24000**
Patient Reimbursement	3000

Note 1: Approximate Hospitalization charges in ICU in case of AE/SAE assumed to be INR 2500/- or as per actual for one day, however other charges like medications, any procedure(s), Lab investigations, consultant(s) etc. will be as per actual.

Note 2: Sponsor will pay only INR. 2000/- amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 {i.e. maximum one screen failure per five randomized patients}.

Note 3: AE/SAE compensation as per Regulatory Requirement Management as per applicable regulatory guidelines. During SAE management, consultant charges, if any, will be provided only in case the consultant is not a part of study team. The reimbursement of the consultant charges would not be applicable to the Consultant who is part of study team.

Note 4: PI Grant includes all investigation required as per protocol. The PI grant including IOH (20%) will be paid to Investigator whereas the CRC payment will be made to SMO

Note 5: All the study related documents will be archived at site under the supervision of investigator as per regulatory and/or sponsor requirement.

Note 6: Grand Total includes all necessary charges incurred for the conduct of clinical study at site as per protocol.

Note 7: Patient Travel Reimbursements based on actual (not more than Rs 500 per visit) will be paid to SMO in condition to the submission of receipts

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Budget notes, payment schedule, conditions of payment and payment directions

1. All amounts above are in Indian Rupee (INR).
2. The study site payment (PI grant, Lesion Count & IGA Assessment, CRC Payment, Patient Reimbursement etc.) would be made visit wise (upon completion of visits at site by the patient).
3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.
4. Please note that approx. 20 % of the amount for one randomized patient only i.e. INR 4800 will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.
6. Service Tax will be deducted and applicable as per current government rules and regulations (i.e. on date of invoice).
7. A service tax (as applicable) will be considered on total grant subject to availability of service tax registration number with service provider. Service tax will be paid and applicable to service provider, provided to reflect the service tax registration number on Invoice / Bills."
8. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.

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The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Schedule for the other payments is as follows:

Sponsor will pay only **INR 2000/-** amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within **thirty (30) days** after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have **forty five (45) days** after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:

Send invoices to	:	Cliantha Research Ltd .
Contact Person	:	Mr. Vidhu Shekhar Mishra
Address	:	Cliantha Research Ltd., Garden View Corporate House No. 08, Opposite AUDA Garden, Bodakdev, Ahmedabad - 380054, Gujarat

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

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(Deemed to be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Dr. V.A.Kothiwale
Registrar
K.L.E Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)

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CRO will be responsible to notify on time the health authorities in India.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

INSTITUTION

By: _____

(Signature & Date)

Dr. M. V. Jali
Medical Director

SITE MANAGEMENT ORGANIZATION

By: _____ 10/May/2018

(Signature & Date)

Ms. Nidhi Singh
Head-Clinical Operation

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: _____ 8.5.18

(Signature & Date)

Dr. Shivkumar Patil
Principal Investigator

CLIANTHA RESEARCH LIMITED

By: _____ 30 Apr 18

(Signature & Date)

Dr. Dharmesh Domadia,
Associate Vice President - Global Clinical Operations

EXHIBIT A: PROTOCOL

Already shared with Principal Investigator

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : **Dr. Shivkumar Patil**

Site Address : KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka

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Belagavi-590 010,Karnataka

Attention: **Dr. Brijesh B. Wadekar**
(Phone): +91-22-6264 7000

Any notice to **Institution** shall be addressed as follows:
Address: KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka
Attn: **Dr. M. V. Jali (Medical Director)**

Any notice to **Principal Investigator** shall be addressed as follows:
Address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi-590010, Karnataka
Attn: **Dr. Shivkumar Patil**

Any notice to **SMO** shall be addressed as follows:
Address: CMS Clinical Research Pvt. Ltd., Inox Tower, Plot No-17A, Sector-16, Noida-201301, Uttar Pradesh
Attn: **Ms. Nidhi Singh**

Any notice to **CRO** shall be addressed as follows:
Cliantha Research Limited.
Opp. Pushparaj Towers, Nr. Judges Bungalows,
Bodakdev, Ahmedabad - 380 054, Gujarat, India
Attention: Dr. Dharmesh Domadia
Associate Vice President - Global Clinical Operations
+91-79-66219 555 (phone); +91-79-66219 549 (fax)

E. **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. **Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.

G. **Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

H. **Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

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13. TERM AND TERMINATION

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(*iv*), above, unless earlier terminated in accordance with this Agreement.

B. **Termination.**

i. Either Party may terminate this Agreement immediately upon written notice to the other if:

a. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

c. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 13(B) upon thirty (30) days' prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation there from, Sponsor will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by Sponsor, to the extent medically permissible.

vi. **Immediate Termination by the CRO.** The CRO may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the CRO, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the

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B. **Of the CRO.** The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

CRO on behalf of Sponsor represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. **No Other Representations or Warranties.** Except for the limited representations and warranties given in this Clause 9, none of the CRO, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. **Of the Institution:** Institution will ensure that the Principal Investigator remits to the Sponsor / CRO all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the Sponsor / CRO immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Ahmedabad, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Ahmedabad, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Ahmedabad, India.

11. INDEMNIFICATION

A. **Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnities**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in Clause 12 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors,

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appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

8. **OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES**

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.** All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived therefrom shall be the exclusive property of that Party.

i. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

ii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.

iii. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

iv. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer

All the source documents pertaining to clinical conduct of the study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

ii. *Case Report Forms.* The Principal Investigator shall complete full clinical evaluations and CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.

iv. *Final Reports.* Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome (**"Final Report"**) to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.

v. In case the Principal Investigator is no longer associated with the Institution, Institution Head or authorized designee will be responsible for maintenance and retention of Study Records.

G. **Reporting of Serious Adverse Event.** The Institution and Principal Investigator shall notify CRO/Sponsor of any Serious Adverse Event encountered in the Study within **twenty four (24) hours** of awareness of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax / mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements.

5. CONFIDENTIALITY

Confidential Information. The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A) (*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

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4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. **IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notify the Sponsor and/or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor.

C. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator/Institution withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the Sponsor may terminate this Agreement as set forth in Clause 13(B) below.

D. **Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty**

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B. **Enrollment.** Principal Investigator will enroll **minimum30 Subjects** (as per the randomization schedule) and **not more than 80 subjects** (as per the randomization schedule) (the "**Site Maximum**") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than five days after the last Subject visit.

3. PAYMENT

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque payable to **SHIVKUMAR K PATIL (PAN No.: BJJPP7382P) AND CMS Clinical Research Pvt. Ltd. (PAN No.: AAFCC8457M).** Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule shall be subject to prior written approval of the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the protocol based on the inclusion and exclusion criteria described in the protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the Sponsor's clinical and/or medical monitor identified in the protocol prior to entry of any such subject into the Study.

The foregoing notwithstanding:

ATTESTED

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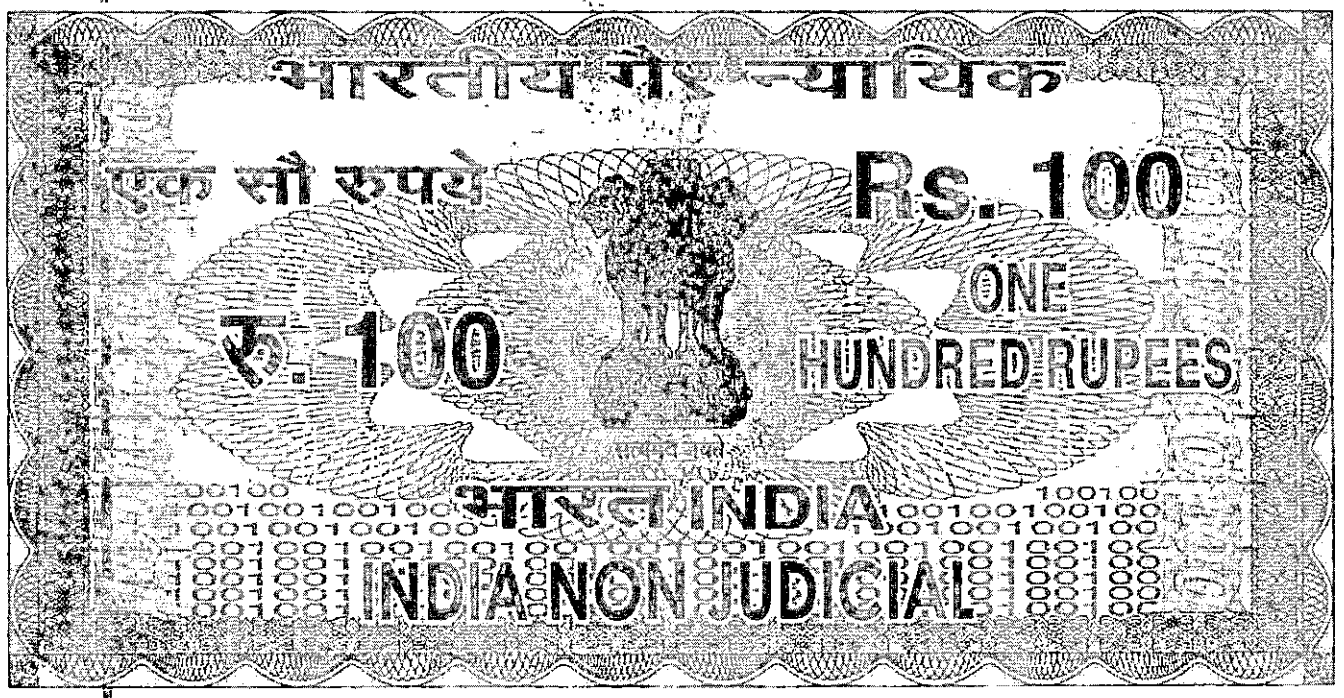
ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to-be University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TM 686654

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.वि.क. ८०००००८
22 MAY 2018
सक्षम अधिकारी

श्री. वि. क. गवई

PRODUCT CODE:	**Sotagliflozin/SAR439954**
STUDY CODE:	**EFC14875**
STUDY NAME:	**THE SCORED TRIAL**

INVESTIGATOR/INSTITUTION/SMO CONTRACT

Site Name: KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi

Study Code/ Name: EFC14875 / The SCORED Trial

Initials SPONSOR Initials INSTITUTION ATTESTED Initials INVESTIGATOR Initials SMO

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This Contract (hereinafter "the Contract") is made on 12th day of June 2018, by and among:

DOCTOR PRASAD M. R., Consultant Cardiologist having his address at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India

Hereinafter the "**INVESTIGATOR**",

AND

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India represented for the purposes hereof by **DR. M. V. JALI, Medical Director and Chief Executive**,

Hereinafter the "**INSTITUTION**",

AND

Ardent Clinical Research Services a private Site Management Organization, having its registered office at 154/155, Level-1, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, India represented for the purposes hereof by **Chandu Devanpally, Managing Director,**
Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function", (hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin**/SAR439954 (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled [The SCORED Trial, EFC14875] and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care, and

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Cardiology, and

WHEREAS, the SMO is a site management organization which is taking care of site management activities for studies of the INVESTIGATOR and is responsible for clinical trials/clinical activities/coordination etc. at the INSTITUTION and has accordingly provided the SPONSOR a certificate dated 30th May 2018, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the

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Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India** (hereafter the «Study Site»). The The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical

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Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR, the INSTITUTION and the SMO agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 4. TERM.

This Contract is being entered into force from **29th June 2018 ("the Effective Date")** and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately **51 (fifty one) months** from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

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5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (Thirty)** Subjects (the «Subjects »), within **approximately 17-18** months. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of

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each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION and the SMO agree to keep confidential and not to disclose the

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Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection

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imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

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15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

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(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

17.3 As soon as either the INVESTIGATOR, the INSTITUTION or the SMO is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR, the INSTITUTION or the SMO to the SPONSOR.

17.4 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

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ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other

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Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

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IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		THE INVESTIGATOR	
[Signature]		[Signature]	
[Name]	Dr. Chirag Trivedi	[Name]	Dr. Prasad M R
[Title]	Clinical Study Unit, Director	[Title]	Prinicipal Investigator
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	Y. J. Cama	[Name]	Shruti . H

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre (INSTITUTION)		Ardent Clinical Research Services (SMO)	
[Signature]		[Signature]	
[Name]	Dr. M. V. Jali	[Name]	Chandu Devanpally
[Title]	Medical Director and Chief Executive	[Title]	Managing Director
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	Namit A. Kamble	[Name]	Pranjal Nandode

ATTESTED

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EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 29th June 2018

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

   Such amount is divided as follows:

EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees**	**Site Coordinator Fees***	**Subject reimbursement (for travel, meals during site visit)**
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500

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EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees**	**Site Coordinator Fees***	**Subject reimbursement (for travel, meals during site visit)**
Close-out visit	14,900	3,100	1,500
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) SPONSOR will pay one time lump sum of Rs.300,000 (Rupees Three Lakhs only) after the Study Closure to INVESTIGATOR for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

9) A onetime start-up fee of Rs.60,000/- (Rupees Sixty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

10) All the payments for the study will be as per the break-up mentioned in **Annexure 1**.

11) All the devices or instruments provided by the SPONSOR will be returned to the SPONSOR at the time of closeout.

12) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

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13) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the Sponsor to the Payee against presentation by the Payee of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION/PAYEE on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

1) For payments related to INSTITUTION:

Bank Name & Branch:	Syndicate Bank, Nehru Nagar, Belagavi
Bank IFSC	SYNB0000504
Account No.:	05042010031362
PAYEE:	Medical Director and Chief Executive, KLE
PAN No.:	AAATK2644N
GST No.:	29AAATK2644N6Z3

2) For payments related to INVESTIGATOR:

Bank Name & Branch:	Canara Bank, KLES Hospital Medical Research Centre
Bank IFSC	CNRB0008515
Account No.:	8515101045816
PAYEE:	Dr. Prasad M.R.
PAN No.:	AHJPR6660F
GST No.:	Not Available

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3) For payments related to SMO:

Bank Name & Branch:	HDFC Bank, B.T. Kawade Road, Ghorapadi, Pune
Bank IFSC	HDFC0003708
Account No.:	50200007013912
PAYEE:	Ardent Clinical Research Services
PAN No.:	APQPD7081M
GST No.:	27APQPD7081M1Z9

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

ATTESTED

Dr. V.A.Kothiwale
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Annexure 1

KLES
PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELAGAVI-590 010
KARNATAKA - INDIA

Dr.Prasad M R
MBBS, M.D, DM (Cardiology)
Consultant Cardiologist
KLES Dr. Prabhakar Kore Hospital & MRC
Nehru Nagar, Belagavi-590010
Assistant Professor, J.N. Medical College, Belagavi
Mobile: 9243245777
Email: drprasadmr@gmail.com

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CONFIRM that, Ardent Clinical Research Services is taking care of site management activities of my studies at our centre who is going to manage clinical trials/ clinical activities/coordination at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, KARNATAKA. For the services being provided by the Ardent Clinical Research Services, the budget will be made as follows:

The breakup of the budget is as follows:

1. 60 % grant of total PI fees paid to PI
2. 40 % grant of total PI fees paid to SMO
3. Institutional Overhead 25 % paid to Institution
4. 100 % grant of CRC fees paid to SMO
5. Archival fees will be paid to Institution
6. Study start up payment paid to SMO
7. Subject travel reimbursement paid to SMO
8. SAE reimbursement, Lab tests cost and others on actual paid to Institution and PI.

Thanking you,

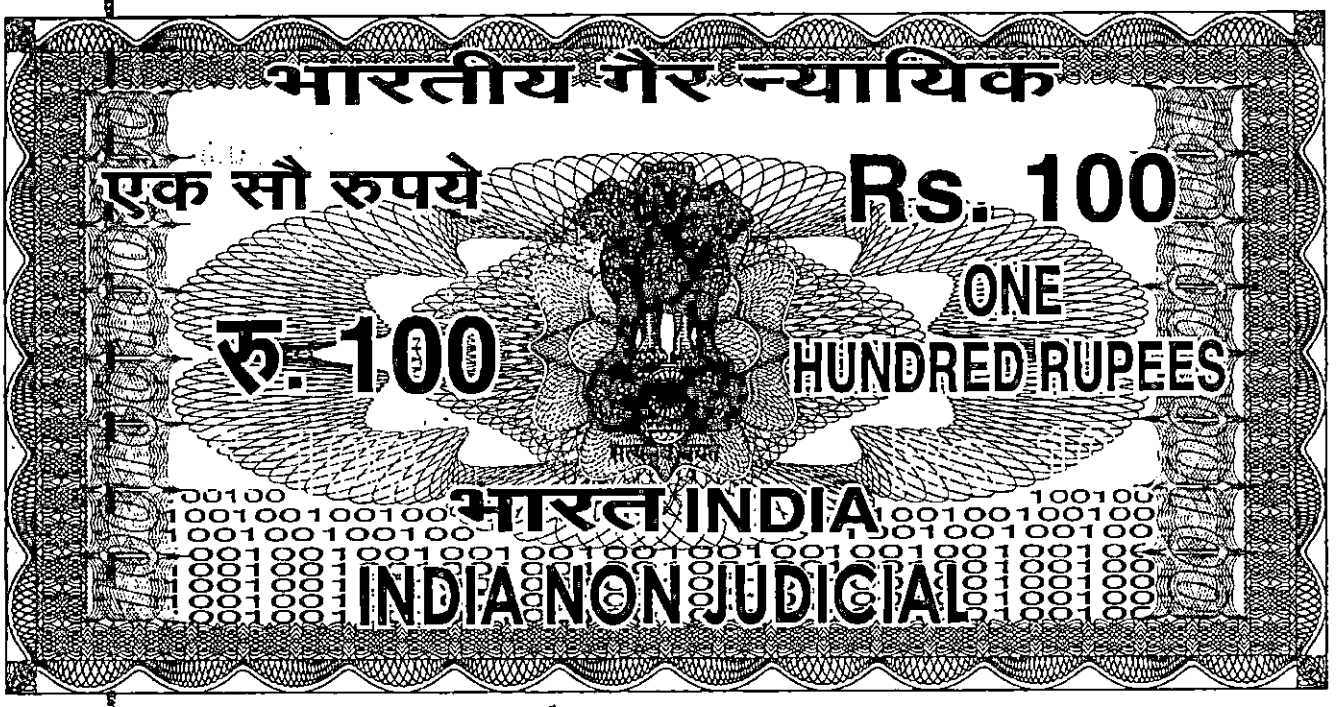
30/May/2018

Dr. Prasad MR
(Principal Investigator),
K.L.E.S. Dr. Prabhakar Kore Hospital &
Medical Research Centre,. Nehru Nagar,
Belagavi-590 010, KARNATAKA, INDIA

Dr. Prasad M. R.
MBBS,MD,DM (Cardiology)
KMC Reg No. 64022
INTERVENTIONAL CARDIOLOGIST
KLES Heart Foundation
BELGAUM - 590 010

ATTESTED

Dr. V.A.Kothiwale
Registrar



महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TG 496585

जिल्हा कोषागार कार्यालय, ठाणे
- 8 JUN 2018
मुद्रांक प्रमुख लिपीक / लिपीक
08/6/2018

PRODUCT CODE:	**SAR439977/Efpeglenatide**
STUDY CODE:	**EFC14828**
STUDY NAME:	**Amplitude – O**

INVESTIGATOR/INSTITUTION/SMO CONTRACT

Site Name & City : KLES Dr. Prabhakar Kore Hospital and MRC , Belagavi

Study Code/ Name: EFC14828 / Amplitude-O

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

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Belagavi-590 010,Karnataka

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This Contract (hereinafter "the Contract") is made on this 15th day of June 2018, by and among:

DOCTOR PRASAD MURIGENDRAPPA RENUKA, Consultant Cardiologist. having his address at KLES Dr. Prabhakar Kore Hospital and MRC, Nehru nagar Belagavi - 590010, Karnataka

Hereinafter the "**INVESTIGATOR**",

AND

KLES Dr. Prabhakar Kore Hospital and MRC, Nehru nagar Belagavi - 590010, Karnataka represented for the purposes hereof by Dr. M V Jali, Medical Director and Chief Executive

Hereinafter the "**INSTITUTION**"

AND

Ardent Clinical Research Services a private Site Management Organization, having its registered office at 154/155, Level-1, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, India represented for the purposes hereof by Mr. Chandu Devanpally, Managing Director

Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial **EFC14828/Amplitude-O** (hereinafter the «Study») to evaluate Sanofi drug **SAR439977/Efpeglenatide** (hereafter the «Investigational Medicinal Product ») in accordance with a protocol **A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk** and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care, and

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Cardiology,and

WHEREAS, the SMO is a site management organization which specializes in providing the services of clinical research coordinators, management of funds of the INSTITUTION at the clinical studies/trials sites and has accordingly provided the SPONSOR a certificate dated 30th May 2018, a copy of which is attached hereto as "**Annexure 1**", and

ATTESTED

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WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **KLES Dr. Prabhakar Kore Hospital and MRC, Nehru nagar Belagavi - 590010, Karnataka** the INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ATTESTED

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ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR, the INSTITUTION and the SMO agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 4. TERM.

This Contract is being entered into force from **14th June 2018** (**"the Effective Date"**) and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately **36** (thirty six) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

ATTESTED

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The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **25 (twenty five)** Subjects (the «Subjects »), within **11 (eleven)** months. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., __ x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

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ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s) »). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

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ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION, the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION, the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

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ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

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ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

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(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

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The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR, the INSTITUTION or the SMO is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR, the INSTITUTION or the SMO to the SPONSOR.

17.4 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

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19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

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ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between

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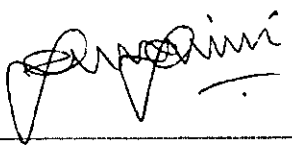
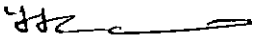
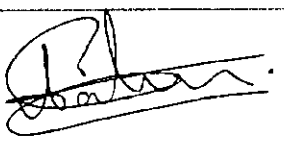
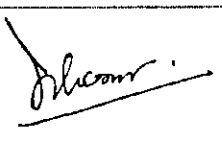
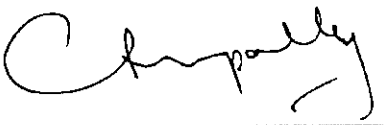
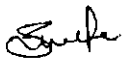
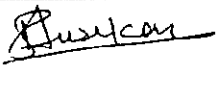
them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**Dr. Prasad Murigendrappa Renuka**
[Title]	**Clinical Study Unit Director**	**[Title]**	**Consultant Interventional Cardiologist**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**Y. J. Cama**	**[Name]**	Amey A Caonkar.

KLES Dr. Prabhakar Kore Hospital and MRC (INSTITUTION)		**Ardent Clinical Research Services (SMO)**	
[Signature]		**[Signature]**	
[Name]	**Dr. M V Jali**	**[Name]**	**Mr. Chandu Devanpally**
[Title]	**Medical Director and Chief Executive**	**[Title]**	**Managing Director**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	Swefa Kurrani	**[Name]**	Pranjal Nandode

ATTESTED

Dr. V.A.Kothiwale
Registrar

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 14th June 2018

1) The SPONSOR will pay **Rs.3,56,000/- (Rupees Three Lakhs Fifty Six Thousand only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

Such amount is divided as follows:

EFC 14828 - Per Subject Cost Details				
Visits	**Investigator Fees (60%)**	**SMO fees (40%)**	**Site Coordinator Fees* paid to SMO**	**Subject reimbursement (for travel, meals during site visit) paid to SMO**
Screening (V1)	6000	4000	5,000	1,500
Training visit(V2)	9000	6000	5,000	1,500
Randomization(V3)	21000	14000	5,000	1,500
Week 12 (V4)	10200	6800	5,000	1,500
Week 24 (V5)	7200	4800	5,000	1,500
Week 36 (phone) (V6)	6000	4000	5,000	
Week 48 (V7)	7200	4800	5,000	1,500
Week 60 (phone) (V8)	6000	4000	5,000	
Week 72 (V9)	7200	4800	5,000	1,500
Week 84 (phone) (V10)	6000	4000	5,000	
Week 96 (V11)	7200	4800	5,000	1,500
Week 108 (phone) (V12)	6000	4000	5,000	
Week 120 (V13)	7200	4800	5,000	1,500
Week 132 (phone) (V14)	6000	4000	5,000	
Week 144 (V15)	7200	4800	5,000	1,500
Week 158 (phone) (V16	6000	4000	5,000	
Close-out visit	9000	6000	5,000	1,500
Follow-up visit	9000	6000	5,000	1,500
Unscheduled Visit (if done)**	3000	2000	2,500	1,500
Total Per Subject Cost	**1,46,400**	**97,600**	**92,500**	**19,500**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

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**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.15,000/- (Rupees Fifteen Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) Sponsor will pay one time lump sum of Rs.3,00,000/- (Rupees Three Lakhs only) after the Study Closure to INVESTIGATOR for archival and document storage for a period of 15 years from the date of site closure.

7) A onetime start-up fee of Rs.50,000/- (Rupees Fifty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

8) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

9) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

10) All the payments for the study will be as per the break-up mentioned in Annexure 1.

11) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

12) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

    The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

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The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

1) For payments related to INSTITUTION:

Bank Name & Branch:	Syndicate Bank, Nehru Nagar, Belagavi
Bank IFSC	SYNB0000504
Account No.:	05042010031362
PAYEE:	Medical Director and Chief Executive, KLE
PAN No.:	AAATK2644N
GST No.:	29AAATK2644N6Z3

2) For payments related to INVESTIGATOR:

Bank Name & Branch:	Canara Bank, KLES Hospital Medical Research Centre
Bank IFSC	CNRB0008515
Account No.:	8515101045816
PAYEE:	Dr. Prasad M.R.
PAN No.:	AHJPR6660F
GST No.:	Not Available

3) For payments related to SMO:

Bank Name & Branch:	HDFC Bank, B.T. Kawade Road, Ghorapadi, Pune
Bank IFSC	HDFC0003708
Account No.:	50200007013912
PAYEE:	Ardent Clinical Research Services
PAN No.:	APQPD7081M
GST No.:	27APQPD7081M1Z9

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5)

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Annexure 1

KLES
PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELAGAVI-590 010
KARNATAKA - INDIA

Dr.Prasad M R
MBBS, M.D, DM (Cardiology)
Consultant Cardiologist
KLES Dr. Prabhakar Kore Hospital & MRC
Nehru Nagar, Belagavi-590010
Assistant Professor, J.N. Medical College, Belagavi
Mobile: 9243245777
Email: drprasadmr@gmail.com

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CONFIRM that, Ardent Clinical Research Services is taking care of site management activities of my studies at our centre who is going to manage clinical trials/ clinical activities/coordination at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, KARNATAKA. For the services being provided by the Ardent Clinical Research Services, the budget will be made as follows:

The breakup of the budget is as follows:

1. 60 % grant of total PI fees paid to PI
2. 40 % grant of total PI fees paid to SMO
3. Institutional Overhead 25 % paid to Institution
4. 100 % grant of CRC fees paid to SMO
5. Archival fees will be paid to Institution
6. Study start up payment paid to SMO
7. Subject travel reimbursement paid to SMO
8. SAE reimbursement, Lab tests cost and others on actual paid to Institution and PI.

Thanking you,

30/May/2018

Dr. Prasad MR
(Principal Investigator),
K.L.E.S. Dr. Prabhakar Kore Hospital &
Medical Research Centre,. Nehru Nagar,
Belagavi-590 010, KARNATAKA, INDIA

[illegible]
MBBS,MD,DM (Cardiology)
KMC Reg No. 64022
INTERVENTIONAL CARDIOLOGIST
KLES Heart Foundation
BELGAUM - 590 010.

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Belagavi-590 010,Karnataka

CLINICAL TRIAL AGREEMENT

PROTOCOL TITLE	A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery
PROTOCOL NO:	DMPL/P05-2017/CT/VN
DATE OF AGREEMENT:	12-06-2018
SPONSOR	
Company Name:	**DATT MEDIPRODUCTS PRIVATE LIMITED**
Address:	56, Community Centre, East of Kailash, New Delhi – 110065
PRINCIPAL INVESTIGATOR	
Name:	**Dr. Shama Bellad**
Address:	Department of ENT, SMO Office G+2 Near Psychiatry ward, K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India
Contact Details:	+91-8765848001
INSTITUTION	
Name:	**Dr. M.V. Jali** K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre,
Address:	K.L.E.S. Dr. PrabhakarKore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India

(PRINCIPAL INVESTIGATOR) **(INSTITUTE/ HOSPITAL)** **(SPONSOR)**

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Belagavi-590 010, Karnataka

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL37368510622557Q
Certificate Issued Date	:	12-Jun-2018 04:28 PM
Account Reference	:	IMPACC (IV)/ dl889803/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL88980378655927270077Q
Purchased by	:	DATT MEDIPRODUCTS PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DATT MEDIPRODUCTS PRIVATE LIMITED
Second Party	:	DR SHAMA BELLAD AND OTHERS
Stamp Duty Paid By	:	DATT MEDIPRODUCTS PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

This clinical trial agreement ("**Agreement**") is made between **DATT MEDIPRODUCTS PRIVATE LIMITED**, (hereinafter referred to as "SPONSOR") a company incorporated under the **Companies Act 1956**, having registered Office at Gajraj Chambers, 2B, Second Floor, 86 B/2, Topsia Road (South), Kolkata 700046 and corporate office at **56, Community Centre, East of Kailash, New Delhi – 110065**, on the First Party:

(PRINCIPAL INVESTIGATOR) **(INSTITUTE/ HOSPITAL)** **(SPONSOR)**

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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AND

K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre,(*Institution or Hospital Name*) (hereinafter referred to as **"Investigation Site"**), whose is located at Nehru Nagar, Belagavi-590010, Karnataka, India (*Institution or Hospital Address)* on the **Second Party;**

AND

Dr.ShamaBellad (Investigator *Name*),whose designation is ENT surgeon at *K.L.E.S. Dr. PrabhakarKore Hospital & Medical Research Centre,*Nehru Nagar, Belagavi-590010, Karnataka, India *(Institutional or Hospital Address)*(hereinafter referred to as **"Principal Investigator" (PI),** which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executors, administrators and successors) of the **Third Party;** Sponsor, Principal Investigator (PI) and Institution shall individually be referred to as a **"Party"** and collectively as the **"Parties".**

RECITALS:

WHEREAS,

A. **SPONSOR** is, inter-alia, engaged in the business of manufacturing and marketing of medical device along with research, product development and clinical research;
B. The **Investigator** is engaged in the treatment of subjects with potential exposure to the indication intended for treatment, at an Institution/ hospital/;
C. The **Institution** is the facility where the clinical trials and study will be conducted ethically and as per the approved protocol;
D. Sponsor is willing to engage the Principal Investigator and Institution to conduct theClinical trial and the Study on non-exclusive basis and Institution and Principal Investigator are willing to carry out the Study on the terms and conditions set out in this Agreement.
E. The purpose of this agreement is to agree on terms and conditions, as well as procedures, according to which the clinical trials and the Study will be conducted, and on the division of duties and responsibilities between the parties conducting the said trials/Study.
F. The Sponsor is desirous of conducting the Study as per IEC approved protocol.
G. The Clinical Trials/Study will be initiated at the site only after an approval from the Drugs Controller General (India) and registered Ethics Committee of the institute.
H. On the faith and strength of the aforesaid representations and warranties, the **SPONSOR** has agreed to appoint the Institution and Investigator for the conduct and supervision of

(PRINCIPAL INVESTIGATOR) **(INSTITUTE/ HOSPITAL)** **(SPONSOR)**

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the Study/Trials in accordance with the approved Protocol subject to the terms and conditions hereinafter appearing.

NOW THEREFORE, the Parties agree as follows:

1. **DEFNITIONS:**

1.1. **"Affiliate"** of a Party means any entity that controls, is controlled by or is under common control with such Party, where "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, through ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests, by contract or otherwise

1.2. **Applicable Law** means the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945 with its amendments and any other law or rules for the time being in force in India;

1.3. **Case Record Form** means a printed, optical or electronic document or database designed to record Subject information.

1.4. **Confidential Information** means any and all data or information whether oral, written or in electronic form disclosed by Sponsor and its Affiliates to Principal Investigator and/or to the, Institution including (i) all information collected in the course of, resulting from, or arising directly from the Study; (ii) Protocol, brochure, Study Materials and Investigational Product, business plans, sales or marketing methods; (iii) information, ideas, concepts, IPR, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Sponsor and its Affiliates; (iv) know-how, methodology, trade secrets, sequences and structure of the Study; and (v) information concerning the business affairs or clients of the Sponsor and its Affiliates.

1.5. **Fees** shall mean the milestone payments agreed by the Parties for the Study.

1.6. **Force Majeure Event** shall mean circumstances beyond reasonable control of a Party, including but not limited to, change in government policy, fire, flood, epidemic, act of god, war and riot;

1.7. **GCP** means good clinical practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India

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and under Applicable Laws;

1.8. **GLP** shall mean good laboratory practices guidelines issued by the Central Drugs Standard Control organization (CDSCO), Directorate General of Health Services, Govt. of India and under Applicable Laws;

1.9. **ICH-GCP** shall mean International Conference on Harmonization – Good Clinical Practice guidelines; is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects;

1.10. **IEC** shall mean Institutional Ethics Committee of the Institution;

1.11. **Investigational Product** shall mean a medical device (VELNEZ), which will use, as a nasal pack.

1.12. **IPR** shall mean patent, copyright, trademark, service mark, service name, trade name, internet domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, Study Materials and Investigational Product and all confidential or proprietary information obtained by Principal Investigator and Institution from Sponsor or generated or created by Principal Investigator and Institution as a direct and sole result of performing the Study under this Agreement, including, without limitation results of the Study, data generated, confidential proprietary, commercial, scientific, medical or technical information.

1.13. **Party** shall individually mean Sponsor or Principal Investigator or Institution

1.14. **Parties** shall collectively mean Sponsor, Principal Investigator and Institution

1.15. **Protocol** shall mean a document that states the background, objectives, rationale, design, methodology and statistical considerations of the Study.

1.16. **Regulatory Authority** means the Drugs Controller General of India, Directorate General of Health Services, Ministry of Health and Family Welfare, Drug Advisory Committee and relevant governmental authority having jurisdiction under Applicable Law.

1.17. **Representatives** shall mean the employees, directors and officers of a Party;

(PRINCIPAL INVESTIGATOR) **(INSTITUTE/ HOSPITAL)** **(SPONSOR)**

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1.18. **Serious Adverse Event** means any untoward medical occurrence that results in death, is life-threatening and requires inpatient hospitalization or prolongation of existing hospitalization.

1.19. **Study Site** shall mean the Institution facility located at **Department of ENT, K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India(Site Address)**

1.20. **Study** means the clinical study and detailed study in eligible subjects to be conducted by the Principal Investigator and Institution to test the efficacy of the Study Device.

1.21. **Study Completion** occurs when the final Clinical Study Report (CSR) is signed by Principal Investigator and Institution and Sponsor. Clinical trials data generated in the Study has been locked and provided to the Sponsor, including a copy of the approval letter of IEC acknowledgment of final report.

1.22. **Study Material** means the Medical Device (VELNEZ- Nasal Pack)

1.23. **Subject** means patients enrolled in the said Study;

2. **SCOPE AND CONDUCT OF THE STUDY**

2.1. Sponsor hereby engages the Principal Investigator and Institution to conduct the clinical trials/Study on non-exclusive basis.

2.2. Institution agrees to provide all the facilities to the Principal Investigator and confirms that the Study shall be conducted at the Study Site under the direction of Principal Investigator.

2.3. Principal Investigator shall conduct the Study in accordance with the Protocol, GCP and Regulatory Authority requirements including ICH-GCP, Institution standard operating procedures and Applicable Law.

2.4. Institution shall perform the Study under the direct supervision and control of Principal Investigator. If Principal Investigator is unwilling or unable to perform the Study, Institution shall refer alternative investigator to Sponsor as replacement of Principal Investigator and based on Sponsor's written approval, such investigator shall be engaged as Principal Investigator for the Study. If a mutually acceptable Principal Investigator is not referred by the Institution, then the Study may be continued with

(PRINCIPAL INVESTIGATOR) (INSTITUTE/ HOSPITAL) (SPONSOR)

ATTESTED

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Dr. ShamaBellad (Investigator Name)until the Sponsor suspends or terminates the Study or till completion of the Study.

2.5. Sponsor will not accept the Study until relevant milestones are achieved as identified in the Protocol. In the event of any actual or anticipated failure by Site to perform the Study in strict compliance with the standards specified in the Protocol or otherwise described in this Agreement for any reason other than Sponsor's acts or omissions, Sponsor shall be entitled to, at its sole option, require the Principal Investigator and Institution to re-perform the relevant milestone in the Study without any cost to Sponsor within the timelines specified by Sponsor or refund the Fees paid by Sponsor for the Study.

3. **SUBJECT RECRUITMENT:**

3.1. Principal Investigator shall enroll the Subjects in the study after IEC approval.

3.2. Principal Investigator shall ensure that all Subjects comply with Protocol requirements.

3.3. It shall be the responsibility of the Institution and Principal Investigator to notify Sponsor and IEC of any significant deviation from Protocol and/or Applicable Law and Regulatory Authority guidelines including without limitation to Serious Adverse Events within twenty-four (24) hours.

3.4. Principal Investigator and Institution shall enroll around **20 Subjects** in their Study. Should enrollment of the Subjects exceed the identified strength, additional Subjects may be recruited only upon Sponsor's prior written consent?

3.5. Principal Investigator and Institution agrees that Sponsor can limit or stop Subject inclusion in the Study at any time for any reasons. If Sponsor limits Subject inclusion in the Study, milestone Fees under the payment schedule shall be paid by Sponsor based on the milestones achieved by the Principal Investigator and Institution as defined in **Annexure - I**. Should there be no Subject enrollment or there is no Study kick-off by Principal Investigator and Institution in accordance with the Agreement, entire milestone Fees paid by Sponsor shall be refunded immediately.

3.6. If a Subject suffers with any Study related injury, Principal Investigator and Institution shall notify Sponsor within 24 hours, however, Principal Investigator and Institution shall be responsible to provide complete medical treatment to the Subject. Sponsor will bear actual medical expenses incurred by the Principal Investigator and Institution for the Subject as a result of any Study injury. In case of death of Subject due to Study

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related injury, Principal Investigator and Institution shall immediately notify the Sponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. **RESPONSIBILITY OF PARTIES:**

4.1. **Principal Investigator (PI) and Institution:**

4.1.1. Principal Investigator and Institution shall be responsible to conduct the said Study at the Study Site.

4.1.2. Principal Investigator and Institution shall not subcontract the Study to any third party, except with prior written consent of Sponsor.

4.1.3. Principal Investigator and Institution shall provide preliminary and final detailed reports to Sponsor as per the timelines specified in the Protocol.

4.1.4. Principal Investigator and Institution shall be responsible to provide daily updates in respect of Serious Adverse Events, milestones pending, completed and safety issues.

4.1.5. Principal Investigator and Institution agrees that the Investigational Product and Study Materials are owned by Sponsor and all unused Investigational Product and Study Materials shall be returned to Sponsor on Study Completion. However, Institution is responsible to maintain full and accurate records for the use of Investigational Product and Study Materials in the Study.

4.1.6. Principal Investigator and Institution shall be responsible to notify Sponsor and IEC if there is a requirement for change in Protocol. Principal Investigator shall carry out the modifications and/or amendments in the Protocol based on the approval of IEC and Sponsor.

4.1.7. Principal Investigator and Institution agrees that Sponsor can monitor the Study and advise Principal Investigator and Institution on cessation of the Study or withdrawal of Investigational Product and Study Materials for safety reasons.

4.1.8. Principal Investigator and Institution shall maintain all Study Materials, including copies of signed consent forms, Case Record Forms, Protocol and information relating to Investigational Product and Study Materials in safe custody locked at all times.

4.2. **Principal Investigator (PI) :**

4.2.1. Principal Investigator thoroughly familiarizes himself with the appropriate use of Study Materials / Investigational Product (VELNEZ) and as described in the Protocol, informed

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consent documents and Case Record Form.

4.2.2. Principal Investigator shall be responsible to coordinate with the research staff and Institution and deliver all reports, data, statement and deliverables of the Study to the Sponsor.

4.3. **Institution:**

4.3.1. Institution is responsible to ensure that Principal Investigator conducting the Study under this Agreement is not debarred by the Regulatory Authority or under Applicable Laws.

If Principal Investigator leaves the Institution or otherwise ceases to be available, then the Institution must consult with the Sponsor and use reasonable endeavors to nominate as soon as practicable a replacement reasonably acceptable to both parties; and The Sponsor may require recruitment into the Study by the Institution to cease, or move the Study to a different study site

4.3.2. The Institution shall be responsible for ensuring sufficient, appropriate and necessary facilities, equipment and resources for the conduct of the trials/Study, and all other resources reasonably required to complete the Study and that no other than legal obligations or commitments of the Institution cause unreasonable damage to or delay in conducting the said trial/Study as set forth in this agreement.

4.3.3. Institution will ensure that the Study is subject to the continuing oversight of the Principal Investigator and IEC throughout the Study Completion.

4.3.4. Institution shall be responsible to retain archival records of the Study including the original or a copy of all Subject consent forms in conformance with applicable regulations for a minimum free storage period of 15 (fifteen) years.

4.3.5. Institution shall notify Sponsor before destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Sponsor at the mutually agreed costs after completion of free storage period of fifteen (15) years.

4.4. **SPONSOR**

4.4.1. Sponsor will provide Study Materials to the Principal Investigator and Institution for the purpose of conducting the Study.

4.4.2. Sponsor will share relevant information of Study Materials and Investigational Product with Principal Investigator and Institution.

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5. **REGULATORY AUTHORITY**

5.1. Principal Investigator and Institution shall obtain IEC approval and Sponsor will obtain regulatory authority clearance under Applicable Law as specified in the Protocol.

5.2. If Principal Investigator and Institution fails to obtain the IEC and Regulatory Authority approval within the agreed timelines stated in the Protocol, Sponsor shall at its sole option, immediately suspend or terminate the Study and terminate this Agreement as per **Section 13**and claim refund of entire Fees paid by the Sponsor together with appropriate damages from Principal Investigator and Institution.

5.3. Principal Investigator and Institution shall notify sponsor within twenty-four (24) hours upon receipt of written communication from Regulatory Authority inspection or inquiry related to the Study.

5.4. Principal Investigator and Institution shall cooperate with Sponsor from time to time in inquiry, investigation, audit or proceedings of Regulatory Authority without additional cost to Sponsor.

6. **REPRESENTATION AND WARRANTIES**

6.1. Parties represent and warrant that they are authorized to execute this Agreement and that the terms of this Agreement are not in violation of any contract to which they are a party.

6.2. Principal Investigator and Institution represents and warrants that they have relevant skill, experience, expertise, regulatory approvals/licenses and facilities to conduct the Clinical Trials/Study as required by Sponsor from time to time.

6.3. Institution represents and warrants that the processes and clinical tools used by Principal Investigator to perform the Study herein does not infringe any Intellectual Property Rights including patent, copyright, trade secret, industrial rights or other proprietary right of any third party.

6.4. Institution warrants that Principal Investigator, and all Representatives deputed for performing the Study shall possess relevant skills and qualifications and the Study shall be rendered in a professional and workmanlike manner.

6.5. Principal Investigator and Institution shall diligently and timely respond to all Study queries and requests of Sponsor.

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6.6. Principal Investigator and Institution shall comply with all Applicable Laws including data privacy, confidentiality and data security policies from time-to-time.

7. INTELLECTUAL PROPERTY

7.1. All rights, title and interests resulting from the said Clinical Trials/Study, Study Materials and Investigational Product including IPR whether created, developed, generated, modified or improved by Principal Investigator and/or Institution shall be the exclusive property of Sponsor. Principal Investigator and Institution agrees that Sponsor owns the right, title and interest in any inventions, designs, discoveries, improvements, developments, innovations and works of authorship produced as a result of the Study. Principal Investigator and Institution shall irrevocably transfer and assign all rights, title and interest in IPR in favor of Sponsor.

7.2. Principal Investigator and Institution shall not use the Confidential Information and IPR and/or data generated from the study directly or indirectly for any purpose other than the study.

7.3. Principal Investigator and Institution agrees that all inventions, data, works, discoveries, technology and innovations or improvements in relation to the study and IPR, whether or not subject to any protection by statute which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by PRINCIPAL INVESTIGATOR and/or Institution either alone or in combination, in the course of the performance of study under this Agreement including modifications or improvements to any proprietary technology, information or materials provided by Sponsor to PRINCIPAL INVESTIGATOR and Institution shall be the exclusive property of Sponsor. The Inventions are to be promptly reported to Sponsor. Sponsor is free to use the results of the Study without any further communication to Principal Investigator and Institution.

7.4. Principal Investigator and Institution agrees to cooperate with Sponsor and its nominees to obtain patents or register copyrights in any and all countries for the inventions and IPR and to execute all documents for use in applying for and obtaining such protection thereon as Sponsor may desire, together with assignments thereof to confirm Sponsor's ownership. In the event that any improvements, innovations or developments do not qualify to be work for hire, Principal Investigator and Institution hereby irrevocably transfers, assigns and conveys, all rights, title and interest in such improvements or developments to Sponsor free from all encumbrances and agrees to

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execute, and shall cause its Representatives to execute, all necessary documents in favor of Sponsor.

8. **FEES**

8.1. Principal Investigator and Institution shall submit any invoice to the Sponsor for conducting the said Study/Clinical Trials. Principal Investigator and Institution agrees that the payments made by Sponsor for conducting the Study is fair as mutually agreed by the Parties as per **Annexure I**

8.2. Principal Investigator consideration of the Study, Sponsor will pay the Fees/ charges to the Institute on completion of relevant milestones as specified in **Annexure I.**

8.3. If there is any delay in performing the Study, Institute shall be liable to refund the entire Fees to the Sponsor as mentioned in **Section 2.5 and 5.2.**

8.4. Institute shall submit to Sponsor the invoices for Study completed till the relevant milestones. All invoices shall be approved by the Sponsor representative. Principal Investigator shall give supportive documents upon successful completion of deliverables within the agreed timelines. Sponsor will make payments against undisputed invoices within thirty (30) business days from the date of receipt of invoice. If there is any discrepancy in the invoice submitted by the Institute, Sponsor will notify Institute within fifteen (15) business days from the date of receipt of such invoice and withhold disputed invoice amounts until resolved by the Parties. However, pending resolution of any dispute under this Agreement, Principal Investigator and Institution shall proceed diligently with its performance of the Study and complete the Study during dispute proceedings, unless otherwise instructed by Sponsor.

8.5. All made by Sponsor to institute shall be subject to tax deduction at source, Service tax and payments other applicable taxes as per there applicable rates, shall be paid extra by Sponsor.

8.6. Institute has provided the NEFT/ RTGS / wire transfer details to the Sponsor for processing the payments and subject to undisputed invoices, payment will be processed by the Sponsor

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All invoices to be sent to:

Sponsor:	**DATT MEDIPRODUCTS PVT LTD**
Billing Address:	Datt Mediproducts Private Limited 56, Community Centre, East of Kailash, New Delhi -110065, India.
Attention of:	Dr. Rajan Datt
Telephone:	+91 (11) 47191777
Email:	rajan.datt@dattmedi.com

All invoices will be sent to the Sponsor via e-mail and the electronic version of the invoices will be considered as the original and hard copies of the invoices if required by Sponsor will be generated by institute without any additional expenses.

9. PUBLICATION:

9.1. Principal Investigator and Institution shall not, without the prior written consent of the Sponsor, report or publish or make available the data, results or any report of the Study conducted under this Agreement to any third party or in any journal, book, magazine, etc.

9.2. Accordingly, Study results may be published in medical journals or presented at a public forum such as conferences only after Sponsor's written consent and Sponsor has determined that such publication will not compromise IPR issues and/or confidentiality issues associated with the Study and approved or consented in writing that the Principal Investigator and Institution may publish or report the data, results or any report of the Study

The Principal Investigator and Institution shall declare that Sponsor has provided her/him with funding for the Study whenever she/he writes or speaks in public about a matter that is the subject of this Agreement or about any other issue relating to Sponsor.

9.3. In all publications, the Sponsor's support of the Study shall be acknowledged. The Study will be clinically and statistically evaluated collaboratively by the Sponsor, Principal Investigator and on behalf of Institution and manuscript shall be prepared for submission to a peer-reviewed journal, subject to written approval of Sponsor.

9.4. Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a

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journal without further obligation to the Principal Investigator and Institution or discloser. All communications in relation to the Study such as press releases or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

10.1. Principal Investigator and Institution agrees that Confidential Information shall be used only for rendering the Services. Principal Investigator and Institution shall keep Confidential Information strictly confidential, protect from unauthorized use, reproduction, access and damage or destruction and employ the same degree of care as it would employ to protect its own confidential information.

10.2. Principal Investigator and Institution shall limit disclosure of Confidential Information only to its Representatives who necessarily require access to render the Services, provided that (a) Principal Investigator and Institution first require each of them to agree in writing, either as a condition of their service to Principal Investigator and Institution or in order to obtain Confidential Information, to be bound by terms and conditions substantially similar to those terms and conditions applicable to Principal Investigator and Institution under this Agreement, and (b) Principal Investigator and Institution shall maintain a record of Confidential Information disclosed to the Representatives and such record shall contain the name, designation of the Representatives and details of Confidential Information disclosed, which shall be made available to Sponsor upon request. However, Principal Investigator and Institution shall, under all circumstances, continue to be liable as a principal party.

10.3. In the event Principal Investigator and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, Principal Investigator and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek protective order or other appropriate remedy to minimize disclosure and Principal Investigator and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

10.4. All Confidential Information is provided "as is", without any warranty, express, implied or otherwise, regarding its accuracy or performance and in no event shall Sponsor be liable to Principal Investigator and Institution for disclosure of Confidential Information under this Agreement.

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10.5. Upon the first written request of Sponsor at any time during the term or immediately upon expiry or earlier termination of the Agreement, Principal Investigator and Institution shall return within fifteen (15) days all Confidential Information to Sponsor, by registered mail/courier of international repute, and/or destroy such Confidential Information as per the directions and instructions of Sponsor and provide written certification to Sponsor. Principal Investigator and Institution may, however, retain one copy of such Confidential Information in its legal archives solely for legal compliance purposes, under strict obligations of confidentiality as stated in this Agreement.

10.6. All obligations contained in the Agreement shall however survive the expiry or early termination of this Agreement and the Parties shall remain bound by the same at all times.

11. INDEMNITY:

11.1. Principal Investigator and Institution shall indemnify and hold Sponsor, its Affiliates and/or their respective Representatives and assigns harmless against all notices, claims, demands, actions, suits or proceedings given, made or initiated against Sponsor on account of or arising out of any and all liabilities, damages, injuries, cause of action and expenses including attorney's fees suffered or incurred by Sponsor for (a) breach of responsibility of Parties; (b) loss or damage caused to Investigational Product and Study Materials; (c) willful negligence, misconduct and misrepresentation (d) breach of representation and warranties and confidentiality obligations under this Agreement; (e) any third party claims for infringement of IPR and (f) injury and/or death of Subjects.

The Institution and Principal Investigator agrees to indemnify and hold harmless the Sponsor from any and all liability of trial subjects, loss, or damage it may suffer as a result of either the institution's negligence or breach of contract of the Principal Investigator during the Study.

11.2. Sponsor's only liability to Principal Investigator and Institution for conducting the Study shall be the payment of Fees not exceeding relevant milestone mentioned in **Annexure I**, provided Principal Investigator and Institution have satisfactorily achieved the relevant milestone and/or completed the Study.

12. TERM

12.1. This Agreement shall commence from the Effective Date and shall be valid for a period of five (5) years or on Study Completion or unless sooner terminated by Sponsor in

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accordance with **Section 13**, whichever is earlier. Parties may renew this Agreement upon mutually agreed terms and conditions.

13. TERMINATION

13.1. Sponsor shall be entitled to terminate this Agreement in the following circumstances:

13.1.1. Without cause at any time by giving seven (7) days' prior written notice to the Principal Investigator and/or Institution.

13.1.2. In the event of breach by Principal Investigator and Institution that is not cured within thirty (30) days from the date of written notice by Sponsor.

13.1.3. Immediately, if Principal Investigator and Institution fails to obtain Regulatory Authority clearance;

13.1.4. Immediately, if Institution becomes insolvent or files for bankruptcy.

13.1.5. In the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

13.2. If this Agreement is terminated by Sponsor and/or Principal Investigator, Institution:

13.2.1. Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.

13.2.2. Principal Investigator and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.

13.2.3. Should Sponsor retain a third party for completion of the Study, then Principal Investigator and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

14. INSURANCE

14.1. Sponsorshall secure and maintain in full force and effect throughout the performance of the Study, insurance coverage from a reputed insurance company to cover its obligations including the Principal Investigator and Representatives and all the Subjects injury and/or death.

14.2. Copy of Institution insurance certificate shall be handed over to Sponsor, prior to commencement of the Study.

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15. **NOTICE**

15.1. Any notice given under this Agreement shall be in writing and signed by or on behalf of the Party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or by E-mail or fax to the address and for the attention of the relevant Party. Any change in address shall be notified by a Party to the other.

15.2. Any such notices be deemed to have been received;
-If delivered personally at the time of delivery;
-In the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt;
-In the case of fax, at the time of transmission

The addresses, Email IDs and fax number of Parties for the purpose of any written notice is as follows:

For Sponsor	For Institution
Datt Mediproducts Private Limited 56, Community Centre, East of Kailash, New Delhi -110065, India. Telephone: +91 (11) 47191777 email : rajant.datt@dattmedi.com	**K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre,** Nehru Nagar, Belagavi-590010, Karnataka, India Telephone No : 0091-0831-2473777 FAX : 0091-0831-2470732 Email:medicaldirector@klehospital.org

GOVERNING LAW AND DISPUTE RESOLUTION

15.3. This agreement and the Parties rights and obligations hereunder shall be governed by and interpreted in accordance with the laws of India.

15.4. All disputes arising under this Agreement shall be mutually settled by the Parties within thirty (30) days, failing which, shall be finally resolved by arbitration under the Rules of Delhi International Arbitration Centre situated at the Delhi High Court, Sher Shah Road, New Delhi - 110503 by one/sole arbitrator appointed in accordance with its Rules. The language of the arbitration proceedings shall be English. The place of arbitration shall be the Delhi International Arbitration Centre at Delhi. Award passed by the arbitrator shall be final and binding on the Parties.

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15.5. Principal Investigator and Institution will be extremely detrimental to Sponsor and would cause irreparable harm to the business of Sponsor which cannot be adequately compensated by monetary damages. Therefore, in addition to any other rights or remedies available to Sponsor under contract or at law, Sponsor shall be entitled to immediate return of Confidential Information and to equitable relief, including injunction and/or specific performance from any court of competent jurisdiction.

16. **General Provisions**

16.1. The relationship between Sponsor and the Institution is of independent contractor.

16.2. A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by a Force Majeure Event provided that the affected Party promptly notifies the other of the occurrence of Force Majeure Event.

16.3. Principal Investigator and Institution shall not assign this Agreement to any person, without prior written consent of Sponsor.

16.4. Any waiver by a Party of any provisions of this Agreement shall not operate or be construed as a waiver of any subsequent breach of such provision or any other provision hereof by such Party.

16.5. The invalidity or unenforceability of any provision of this Agreement shall not in any way affect, impair or render unenforceable this Agreement or any other provision contained herein, which shall remain in full force and effect.

16.6. No amendment to this Agreement shall be valid unless mutually agreed in writing and executed by the Parties.

16.7. This Agreement represents the entire agreement between the Parties and supersedes all prior negotiations, understandings and agreements, written or oral, relating to the subject matter herein

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In Witness, Whereof, the Parties hereby sign and execute this Agreement as of Effective Date.

For Datt Mediproducts Private Limited

Signature _____
Name: Dr. Rajan Datt
Title Managing Director

For Institution

Signature _____
Name: Dr. M.V. Jali
Title : Medical Director

By Principal Investigator

I, Dr. Shama Bellad (***Investigator Name***), acknowledge that I have read and understood the terms and conditions of this Agreement and accept to be bound personally as agreed in this Agreement. I, also agree to use all reasonable endeavors to enable the Institution to comply with its obligations under this Agreement.

Signature: _____

Dr. Shama Bellad,
Address
Department of ENT
K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehru Nagar, Belagavi-590010, Karnataka, India

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ANNEXURE I

1. **Project Timelines**

S. No.	Task	Tentative Date
1.	IEC submission	30-04-2018
2.	Site Initiation visit	15-06-2018
3.	First Patient In	Third week of Jun 2018
4.	Last Patient In	Last week of Sep' 2018
5.	Last Patient Last Visit	Last week of Oct' 2018
6.	Site Closeout Visit	Last week of Nov'2018
7.	Signing of Study Report	Last week of Nov'2018
8.	Proposed Principal Investigator Involvement	Dr. Shama Bellad

2. **Payment Milestones**

Inst. No	Time of payment of the grant	% of Total Grant
1.	IEC review charges at the time of EC submission (A)	Rs75,000 +GST (excluding TDS)
2.	Screening of first Patient	25 %
3.	First patient first visit	20%
4.	Last patient follow-up visit	30%
5.	Final report submission	25%

3. **Allocated study budget** (B)

Particular	Total Cost for 20 patients
Investigator Fees (PI and CI's) + Institutional Fee (20%)	**50,000**
Site Coordinator charges	**50,000**
Study Specific test	**As per actual**
Total	**1,00,000/=**

4. Total amount (A+B) = **175,000/-** (One lakh Seventy Five Thousand Only) + taxes

5. **Bank details for payment transfer: PI**

Beneficiary Name	Dr. Shama Bellad
Bank Name	Syndicate bank
Bank Address	Nehru Nagar Belagavi
Account No.	05042010065280
Account Type	Saving
NEFT/ IFC / RTGS code	SYNB0000504

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6. **Bank details for payment transfer: CRC**

Beneficiary Name	Prashant Banduni
Bank Name	OBC Bank
Bank Address	Nehru Nagar Belagavi
Account No.	12112011007420
Account Type	Saving
NEFT/ IFC / RTGS code	ORBC0101211

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Datt Mediproducts Pvt. Ltd.

First Addendum to Clinical Trial Agreement between Datt Mediproducts Pvt. Ltd and Department of ENT, K.L.E.S. Dr. Prabhakar kore Hospital & Medical Researchdtd 12 June 2018

PROTOCOL TITLE	A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery
PROTOCOL NO:	DMPL/P05-2017/CT/VN V1.0, Date-10-04-2017: Revised- DMPL/P05-2017/CT/VN V2.0, Date-30-03-2018, Rev1.0, wef 01-05-2018
DATE OF AGREEMENT:	12-06-2018
SPONSOR	
Company Name:	**DATT MEDIPRODUCTS PRIVATE LIMITED**
Address:	56, Community Centre, East of Kailash, New Delhi – 110065
PRINCIPAL INVESTIGATOR	
Name:	**Dr. Shama Bellad**
Address:	Department of ENT, SMO Office G+2 Near Psychiatry ward, K.L.E.S. Dr. Prabhakar kore Hospital & Medical Research Centre, Nehru Nagar, Belgavi-590010, Karnataka, India
Contact Details:	+91-8765848001
INSTITUTION	
Name:	**Dr. M.V. Jali** Medical Director
Address:	K.L.E.S. Dr. Prabhakar kore Hospital & Medical Research Centre, Nehru Nagar, Belgavi-590010, Karnataka, India

The aforementioned agreement is hereby amended as follows:

Clause 3. Subject recruitment

1.4. Principal Investigator and Institution shall enrol 40 Subjects in the current Study. Subjects may be recruited only upon Sponsor's prior written consent

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Belagavi-590 010,Karnataka

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KLES
Dr. PRABHAKAR KORE HOSPITAL
MEDICAL RESEARCH CENTRE
NEHRU NAGAR BELAGAVI-590010

Datt Mediproducts Pvt. Ltd.
Delivering Next-Gen Sensing Solutions Globally

In Witness. Whereof, the Parties hereby sign and execute this Agreement as of Effective Date.

For Datt Mediproducts Private Limited

Signature
Name: Dr. Rajan Datt
Title Managing Director
Date:
23 SEP 2019

For Institution

Signature
Name: Dr. M V Jali
Title: Medical Director
Date: 10/10/19

Acknowledgement by Principal Investigator:

I, Dr Shama Bellad, acknowledge that I have read and understood the **First Addendum to Clinical Trial Agreement between dtd 12 June 2018 on Sept 23rd 2019** and accept to be bound personally as agreed in this Agreement. I, also agree to use all reasonable endeavours to enable the Institution to comply with its obligations under this Agreement.

Signature:

Date: 23/09/2019

Department of ENT.
SMO Office G+2 Near Psychiatry ward.
K.L.E.S. Dr. Prabhakar kore Hospital & Medical Research Centre, Nehru Nagar, Belgavi-590010, Karnataka, India

This addendum to Clinical Trial Agreement between dtd 12 June 2018 is executed on dtd._____September, 2019 in two copies.

ATTESTED

Dr. V.A.Kothiwale
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THE AJARA URBAN CO-OP. BANK LTD
THE AJARA URBAN CO-OP BANK LTD
N.M.JOSHI MARG
MUMBAI-400 011
Authorised Signatory

भारत 62092 SPECIAL ADHESIVE महाराष्ट्र
106925 JUN 15 2018
10:28
Rs.0000200/- PB6508
STAMP DUTY MAHARASHTRA

D-5/STP(M)/C.R.1072/02/07/663-665/2007

Clinical Trial Agreement

ARTICLES OF AGREEMENT made at Mumbai, this 15th day of June 2018

BETWEEN:

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai 400018, hereinafter referred to as "Sponsor" (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and assigns) of the First Part;

Dr. Saroja A O designation being Prof and ~~HOD~~ Dept of Neurology and having his/her address at KLES Dr Prabhakar Kore hospital and MRC Belagavi karnataka hereinafter referred to as "Investigator", (which expression shall, unless it be repugnant to the context ore meaning thereof, be deemed to mean and include his or her heirs, executors, administrators and successors) of the Second Part;

AND

KLES Dr Prabhakar Kore hospital and MRC Belagavi, Karnataka represented by Dr. M. V. Jali whose designation is Medical Director and Chief executive ; and registered under the provisions of Bombay Public Trust Act, 1950 and hereinafter referred to as "Institution", (which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee and permitted assigns) of the Third Part.

AND

Ardent Clinical Research Services, Office No. 154/155, Level-1, Connaught Place, Bund Garden Road, Pune-01, MH, India. Represented by Mr. Chandu Devanpally whose designation is Founder & Managing Director; and registered under the company act 1961 and having its registered office at 154, 155, level-1, Connaught place, bund garden road, Pune-411001, MH, India and hereinafter referred to as "SMO", (which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee and permitted assigns) of the Fourth Part.

(Sponsor, Investigator, Institution and **Ardent Clinical research Services** may be individually referred to as Party and collectively as Parties)

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B. The Sponsor is interested in conducting the following clinical trial as per protocol namely **Protocol No.** CAMG334A2302 ;

Protocol Title: A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER)

as may be amended from time to time by the Sponsor at its sole discretion (hereinafter referred to as "**Protocol**") and has approached the Investigator for the conduct and supervision of the Clinical trial in accordance with the Protocol.

C. The Investigator is a qualified medical practitioner inter alia, engaged in medical research and clinical practice of Neurology in KLES DR PRABHAKAR KORE HOSPITAL & MRC , the Investigator has agreed to conduct the above clinical trial as per the Protocol and has represented to the Sponsor that it shall obtain the approval of the Ethics Committee where the clinical trial shall be conducted;

D. The Institution has agreed to provide all the necessary infrastructure including but not limited to laboratory investigations, ECG etc. with a view to facilitate and enable the Investigator and Sponsor to perform the clinical trial in accordance with the Protocol.

E. The Drugs Controller General (India) granted his no objection to the conduct of the Trial vide his letter CT/79/17-DCG(I) dated 19th Feb 2018 (copy attached as Annexure C) and the same is presently in full force and effect;

F. **Ardent Clinical research Services** is responsible for clinical trial operations/coordination as per protocol GCP and applicable regulatory requirements.

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G. Basis the above representations and warranties, the Parties have agreed to enter in to this Agreement on the terms and conditions hereinafter appearing.

NOW THIS AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS :

1. Based on the representations of the Investigator specified in the recitals (which are incorporated herein by reference), the Sponsor hereby appoints the Investigator and the Investigator hereby agrees to perform, conduct and supervise the clinical trial in accordance with the Protocol at the Institution and the Institution and **Ardent Clinical research Services** agree to facilitate and enable the Investigator to perform the clinical trial in accordance with the Protocol.

2. The Sponsor agrees:

   (a) to provide all supplies of clinical trial investigation product, the placebo, the case report forms ("CRFs") and other materials such as eCRF laptops, ECG machine as may be necessary to conduct the clinical trial . It is clarified that such supplies shall at all times remains the property of the Sponsor;

   (b) to convene and conduct the initiation meeting for the training and familiarization of the Investigator and such other persons who are identified by the Institution as being involved in the clinical trial such as the sub/co-investigators, assistants, nursing staff and other personnel with the clinical trial ;

   (c) to periodically monitor the progress of the clinical trial ;

   (d) to perform periodic checks as to whether drug accounting / reconciliation has been properly carried out by the Investigator;

   (e) to verify that the data in the CRFs conforms to hospital source data.

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3. Clinical trial supplies etc. will be issued by the Sponsor only after the Sponsor has:

(i) received a duly executed set of this Agreement; and

(ii) received the true copy of the approval of the Ethics Committee of the Institution to the Protocol, the informed Subject consent document ("ICD") and other appropriate clinical trial documents;

4. The Investigator shall:

(a) Obtain the approval of the Ethics Committee for the Protocol, ICD and other appropriate clinical trial documents as well as re-approvals by the Ethics Committee should the Sponsor amend the Protocol and to make available copies of the re-approvals for inspection of the Sponsor and to keep the Sponsor informed in writing of re-approval completion;

(b) Recruit required Subjects (refer to Annexure A) who would be the subjects of the clinical trial (the "Clinical trial Subjects") and to ensure their completion of the clinical trial as per the Protocol;

(c) Carry out the clinical trial in accordance with :

(i) the Protocol; and

(ii) the approval of the Ethics Committee; and

(iii) the approval of the regulatory authorities; and

(iv) Including but not limited to Schedule Y of the Drugs and Cosmetics Act, 1945 as amended, Good Clinical Practice (GCP) guidelines and Standard Operating Procedures (SOP) of the Sponsor that have been provided to the Investigator;

(d) Administer the Sponsor-approved ICD to each clinical trial Subject and ensure that it is signed by the clinical trial Subject after a co-investigator has interviewed the clinical trial Subject, who must

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also co-sign and date the ICD before administration of the clinical trial investigational product;

(e) Provide written/oral information about the Clinical trial to all staff members involved with the Clinical trial or with other elements of the Subjects' management;

(f) Supervise the working of co-investigators and other personnel connected with the conduct of the clinical trial and ensure compliance with the Protocol and the Clinical trial;

(g) See and evaluate the clinical trial Subjects as required by the Protocol and to sign the eCRFs. To ensure the data completed on CRF is true, complete and correct and accurately reflect the results of the clinical trial with respect to each person participating as a subject ("Subject"). The Investigator may perform special tests, hospitalize the Subject, unblind the therapy or prescribe new drugs subject to the consent of the Sponsor. The Sponsor will be available to consult the Investigator about Subject problems and care;

(h) Keep accurate records and accounts of the receipt, dispensing, and return of the Products including the eCRF laptops, ECG machine as may be provided by the Sponsor or to destroy the clinical trial investigational products on termination of the Clinical trial Agreement, all in accordance with the instructions of the Sponsor and the terms of the Protocol;

(i) Provide access, inspect and copy all data and documents relating to the clinical trial to and co-operate with the clinical trial monitors and/or the clinical trial bio-statisticians as the case may be;

(j) Maintain and keep safe and secure for fifteen (15) years from the end of the trial, properly organized clinical trial records, Subject files and source data (eg. ECG, lab results etc.) and to provide

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access to the Sponsor to such records for regular monitoring and audits by the Sponsor and regulatory authorities;

(k) Permit the Sponsor and/or its nominees to conduct an audit (at such intervals as required by the Sponsor) of all services to be provided by the Investigator under and in accordance with the terms of this Agreement including inter-alia of all records and documents relating to the clinical trial, equipment supplied and/or maintained by the Investigator in connection therewith and the Investigator shall provide such assistance as reasonably requested by the Sponsor in connection therewith.

(l) Monitor each clinical trial Subject for the development of clinical or laboratory evidence of adverse events and to immediately notify (and in any event no later than the statutory timelines provided therefor) Serious Adverse Events as hereinafter defined in writing to the Sponsor and notify as appropriate the Ethics Committee and other relevant authorities;

(m) Obtain the written consent of the Sponsor of any action which would require unblinding of the treatment by the Investigator, except in an emergency situation;

(n) Scrutinize and approve the final report for submission to the regulatory authorities;

(o) Refrain from using the clinical trial investigational product for any purpose other than the performance of the clinical trial and not to make the Product available to any third party other than as specified in the Protocol without Sponsor's prior written consent.

(p) Render timely support in registration process of the Clinical trial with the CTRI (Clinical trial Registry of India).

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5. The Institution shall:

(a) Provide well trained and skilled personnel as may be appropriate and all Institution facilities necessary to carry out the clinical trial;

(b) Permit the Sponsor and/or its nominees to conduct an audit (at such intervals as required by the Sponsor) of all services to be provided by the Institution under and in accordance with the terms of this Agreement including inter-alia of all records and documents relating to the Clinical trial, equipment supplied and/or maintained by the Institution in connection therewith and the Institution shall provide such assistance as reasonably requested by the Sponsor in connection therewith.

(c) Refrain from using the clinical trial investigational product for any purpose other than the performance of the clinical trial and not to make the clinical trial investigational product available to any third party other than as specified in the Protocol without Sponsor's prior written consent.

(d) Supervise the working of co-investigators and other personnel connected with the conduct of the clinical trial and ensure compliance with the Protocol and the clinical trial;

(e) Provide access to and co-operate with the clinical trial monitors and/or the clinical trial bio-statisticians as the case may be;

(f) Maintain and keep safe and secure for fifteen (15) years from the end of the clinical trial, properly organised clinical trial records, Subject files and source data (eg. ECG, lab results etc.) and to provide access to the Sponsor to such records for regular monitoring and audits by the Sponsor and regulatory authorities;

6. The Investigator shall not make any changes whatsoever in the applicable procedures under the Protocol without the prior written approval of the

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Sponsor except when necessary to eliminate apparent immediate hazard to a particular Subject, in which event the Investigator shall immediately notify the Sponsor and the Ethics Committee .

7. (a) The Investigator undertakes to document all Serious Adverse Events on the CRF. Any Serious Adverse Event which is serious as defined herein below shall be reported immediately (within 24 hours of its occurrence) by written communication to the sponsor, chairman of the Ethics Committee and other authorities as prescribed in Schedule Y of the Drugs & Cosmetics Act 1945 as amended from time to time.

(b) An event is considered as a Serious Adverse Event if it fulfills at least one of the following criteria :-

(i) Untoward medical occurrence during clinical trial that is associated with death;

(ii) Inpatient hospitalization (in case the clinical trial was being conducted on outpatients);

(iii) Prolongation of hospitalization (in case the clinical trial was being conducted on inpatients);

(iv) Persistent or significant disability or incapacity;

(v) A congenital anomaly or birth defect or is otherwise life threatening.

8. (a) In consideration of the Institution , Investigator and **Ardent Clinical research Services** fully and faithfully performing all their obligations hereunder, the Sponsor shall pay the set out in Annexure – A hereto. At the request and upon the instructions of the Investigator and the Institution for reasons of administrative convenenience, which request and instructions have been confirmed and acknowledged by **Ardent Clinical research Services** Novartis shall pay such entire consideration to **Ardent Clinical research Services,** only. Such payment of the amounts mentioned in Annexure A hereto, **Ardent Clinical research Services** shall

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constitute a valid and binding discharge Novartis of its payment obligation under this Agreement.

(b) Payments made by the Sponsor to **Ardent Clinical research Services** only shall be only in respect of such Subject/s :-

(i) who are treated in compliance with the Protocol, and

(ii) for whom the Investigators' records contain a signed ICD that has been approved by the Ethics Committee and the Sponsor.

(iii) If another person is requested/identified to be paid by the Investigator, a letter must be provided by the Investigator which inter alia provides the scope of the work and authorises payment to such a person other than the Investigator.

(c) It shall be the Institution's responsibility to comply with all obligations in respect of taxes, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Investigator, the Institution and its employees and/or collaborators.

(d) The Sponsor will also reimburse the Institute and the Investigator for the costs of extra, unanticipated tests arising out of adverse events. The Sponsor will also reimburse the Institution and the Investigator the reasonable costs of treatment and hospitalization of Subjects arising out of adverse events which the Sponsor determines with reasonable medical certainty, to have resulted from the clinical trial investigational product dispensed or administered or in accordance with the Protocol, the same being approved by the Investigator and/or the Institution's Ethics committee. The Institution shall promptly furnish all records of such extra tests and treatments to the Sponsor.

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9. The Institution, Investigator and **Ardent Clinical research Services** agree not to pay a fee to any physician in exchange for the referral of a Subject for enrollment in the Clinical trial.

10. The Institution, Investigator and **Ardent Clinical research Services** understand, acknowledge and agree that the clinical trial investigational product provided by the Sponsor to the Investigator for the clinical trial will be used solely under the Protocol and shall not be used for any other purposes.

11. (a) The Sponsor indemnifies and agrees to indemnify, defend and hold the Investigator, the Institution only , harmless from and against any loss, damage, costs, expenses, claims, demands and suits resulting from an injury to a Subject directly caused by or attributed to the clinical trial investigational product dispensed or administered in accordance with the provisions of the Protocol and this Agreement, including the reasonable cost and expense of handling such claims and defending such suits. The Sponsor covenants and agrees to assume responsibility for clinical trial related injury and shall provide complete medical management and/or compensation in the event of injury or death of such Subject as provided under the law.

The Sponsor however shall in no event be liable to the Investigator, Institution and/or **Ardent Clinical research Services** whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof.

(b) The Sponsor's obligations of indemnification to the Investigator and the Institution shall, however, be subject to the following conditions:-

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(i) The Institution, Investigator and Ardent Clinical research Services have strictly adhered to and complied with all specifications of the Protocol and recommendations furnished by the Sponsor for the use and administration of any drug or device described in the Protocol;

(ii) The Sponsor is notified by the Institution and Investigator in writing within seven (7) days of the receipt of any claim, demand or complaint in respect of the clinical trial;

(iii) The Institution and Investigator co-operates fully in the investigation and defense of any such claim or suit;

(iv) The Sponsor's obligations of indemnification hereunder shall not extend to any loss or damage or expense arising out of the negligence, malpractice or improper statement or act of the Institution and Investigator and/or Ardent Clinical research Services in connection with the conduct of clinical trial.

(v) The Institution and Investigator has complied with all the applicable laws, regulations or rules.

(c) The Sponsor reserves the right to approve and/or disapprove all proposed settlements for damages for which it will be required to make payments hereunder.

(d) The Institution, Investigator and Ardent Clinical research Services covenant and agree to jointly and severally indemnify, defend and hold harmless the Sponsor from and against any loss, damage, costs, expenses, claims and demands suffered by the Sponsor or as a result of any third Party, Subject claims due to or arising out of the negligence, malpractice or improper acts or omissions of the Investigator or non-compliance with the conduct of the clinical trial in accordance with the Protocol or the instructions of the Sponsor or applicable laws, regulations or rules for the time being in force.

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12. Neither Party shall at any time during the continuance of this Agreement or thereafter, use the other party's name or issue any public/press/media statement about this Agreement or divulge or make known to any person, any information or data relating to the contents of this Agreement without the prior written permission of the other Party.

13. Medical information relating to a Subject participating in the clinical trial shall be treated as confidential and disclosure to third parties is strictly prohibited. Such medical information may, however, be given to regulatory authorities, the Subject's personal physician or other appropriate medical personnel responsible for the Subject's welfare on a written demand consented to by the Sponsor in writing.

14. All information and data, trade secrets, privileged records and other confidential or proprietary information provided by the Sponsor both prior to the initiation and during the course of the Clinical trial including without limitation the Protocol, the eCRF, the ICDs, the final report etc including information disclosed to, collected or developed by the Principal Investigator, the Institution or their employees in connection with this Agreement or the Clinical trial (collectively "Confidential Information") shall be treated as confidential and proprietary by the Investigator and the Institution and shall not be used for any purpose other than the Clinical trial or disclosed in any way by the Investigator or the Institution or any of his/ their staff members co-investigators, nurses etc at any time either during the continuance of this Agreement or after the termination thereof. **Ardent Clinical research Services** does not have any Confidential Information in terms of this Agreement. However, these confidentiality obligations will not apply to information which:

(i) at the time of execution of this Agreement is publicly available;

(ii) is possessed by the Investigator at the time of disclosure by the Sponsor from a source other than the Sponsor who obtained such

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information without breaching or violating any law, rule or agreement; or

(iii) is acquired from a third party which has the right to disclose such information.

15. The Institution and Investigator shall at all times provide access to the Sponsor, its duly authorized employees and/or agents to any and all information collected on behalf of the Sponsor relating to any work done in connection with the clinical trial. Any proposed publication / lecture / manuscript / poster presentation or other dissemination of any information relating to or connected with this clinical trial, or any data and results of the clinical trial by the Investigator shall be submitted to the Sponsor for its written approval at least 15 working days prior disclosure for presentation and at least 45 working days prior to its submission for publication or use provided that the Sponsor shall have the right to require amendments to any such proposed presentation / publication to ensure inter – alia, accuracy of the information contained, that proprietary information is not inadvertently divulged and to enable intellectual property rights to be secured. Authorship of any publications relating to the clinical trial shall be determined by mutual agreement in writing by all parties. The Investigator understands and agrees that the Clinical trial is a multi-center clinical trial and that a multi-center publication will be jointly prepared and published. The Sponsor may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the clinical trial are made available to the Sponsor, whichever is later. The Investigator and the Institution further understand and agree that they shall not publish the results of theirs participation in the clinical trial for a period of one year after completion of the clinical trial in its entirety, allowing for the review and analysis of the clinical trial results and the preparation and publication of the multi-center manuscript. The Investigator will be duly acknowledged in such multi-center publication.

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16. All rights, title and interests including the rights to any intellectual property in all documentation used or supplied by the Sponsor, all the data, inventions, discoveries and results arising out of or in connection with this Agreement and the clinical trial and in the know-how incidental thereto and any patent applications and resultant patents derived therefrom shall be owned and be the exclusive property of the Sponsor. The Sponsor may use this information in any way it deems fit. The Investigator, the Institution and **Ardent Clinical research Services** agree and undertake to cause their employees to execute promptly all documents and take all such other action as may reasonably be requested by the Sponsor to permit the Sponsor to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer/assignment of ownership of all data, information, documents, inventions and discoveries to the Sponsor in accordance with this Agreement, and assisting the Sponsor in the preparation and prosecution of patent applications. The Parties agree that this clause shall survive the termination/ earlier determination of the Agreement.

17. The Institution and/or Investigator and/or v shall not acquire any rights of any kind in the clinical trial investigational product or its uses as a result of participation in the Clinical trial.

18. The Sponsor reserves the right to limit entry or enrollment of additional Subjects at any time on account of the fact that sufficient Subjects have been entered by other Institution/Investigators to complete the needs of the Clinical trial, even though the maximum enrollment period has not ended. Entry or enrollment of additional Subjects may also be limited if eCRF for enrolled Subjects are not available for potential inspection within 5 days of the Subject's visit.

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19. (a) Neither the Institution nor the Investigator nor **Ardent Clinical research Services** shall sub-contract, delegate, assign or transfer in any manner whatsoever the whole or any part of its rights, benefits and obligations under this Agreement without the prior written consent of the Sponsor.

(b) The Institution, the Investigator and **Ardent Clinical research Services** acknowledge and agree to ensure compliance by the Investigator, co-investigators, nurses and other staff working on or in any way connected with the Clinical trial, with this Agreement and/or the law. Any breach of the terms of this Agreement by such co-investigator, nurse or other staff shall constitute a breach of this Agreement by the Investigator and/or Institution and/or **Ardent Clinical research Services**

20. Neither the Investigator nor the Institution, nor Ardent Clinical Research Services nor any person employed thereby nor any collaborator who is involved in the performance of the clinical trial has been debarred under any regulatory or government authority whether in India or other countries and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Sponsor. If at any time after the execution of this Agreement, the Institution or Ardent Clinical Research Services becomes aware that the Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Sponsor forthwith.

21. The Parties hereto expressly agree that the basis for all transactions between the Sponsor, the Institution, Investigator and Ardent Clinical Research Services in pursuance of these presents shall be on a principal to principal basis and any and all contracts or transactions entered into by the Institution, Investigator or Ardent Clinical Research Services with third parties in respect of any matter or matters hereunder shall be entered

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into by the Institution, Investigator or Ardent Clinical Research Services as such principal and not as an agent for and behalf of the Sponsor and in respect of any and all such contracts and transactions, the Institution, Investigator or Ardent Clinical Research Services alone shall be responsible for the due performance thereof and the Sponsor shall incur no liability, responsibility or obligation of any nature whatsoever in connection therewith.

22.

(a) This Agreement shall come into force with effect from 19-Feb-2018 (date of grant of approval of the DCGI for conduct of clinical trial) hereof and shall thereafter remain in full force and effect up to 30 Sep 2020 unless earlier terminated in accordance with clauses 23 or 24 hereof.

(b) The Sponsor may, in its absolute discretion, renew this Agreement for such further term and on such terms and conditions as are herein contained or as otherwise determined by the Sponsor, provided that written notice of such renewal shall have been given by the Sponsor to the Investigator not less than 90 (ninety) days before the date of expiry specified in sub-clause (a) hereof.

23. Notwithstanding anything to the contrary herein contained, the Sponsor shall be entitled to terminate this Agreement forthwith without being liable to pay any compensation whatsoever to the Institution or the Investigator or Ardent Clinical Research Services upon the happening of any of the following events:-

(a) upon the Institution and/or Investigator and/or Ardent Clinical Research Services committing any breach or default in the performance or observance or discharge of any of the covenants, stipulations, agreements and conditions herein contained and failing to remedy or rectify such breach or default within a period of 30 days after receiving a written notice in that behalf from the Sponsor;

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(b) if the Institution and/or Investigator and /or Ardent Clinical Research Services assigns or purports to assign its rights, obligations and benefits under this Agreement without the prior consent in writing of the Sponsor.

(c) Upon the institution and /or Investigator and/or Ardent Clinical Research Services committing any breach or default of the Sponsor guideline/s as applicable from time to time

24. The Sponsor may, in its sole discretion, terminate the clinical trial forthwith, without being liable to pay any compensation whatsoever to the Institution/ and/ or to the Investigator and/or to Ardent Clinical Research Services if in the sole opinion of the Sponsor an emergency situation or other condition requires the clinical trial to be discontinued or terminated, the inability to recruit an adequate number of Subjects, unsatisfactory progress of the Clinical trial or for any other reason whatsoever in which event, the Sponsor shall reimburse the Institution/and/ or the Investigator for all costs and non-cancelable financial/pecuniary commitments incurred prior to the termination, it is clarified that there shall be no reimbursement or payments of any nature whatsoever that shall be payable by the Sponsor to Ardent Clinical Research Services under any circumstances whatsoever; provided that the Sponsor shall not be responsible for any payments to the Institution/and/ or the Investigator that are set forth in this Agreement after such termination.

25. Institution and/or the Investigator only shall be entitled to terminate this Agreement at any time, after assigning the reasons for such termination to the Sponsor by giving three (3) months' prior notice in writing of its intention to do so.

26. The termination of this Agreement for any reason whatsoever shall be without prejudice to any claim or right of action previously accrued or acquired by either party against the other. Provided that Ardent Clinical

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Research Services shall not be entitled to terminate this Agreement for any reason for whatsoever.

27. Upon the expiration or sooner determination or purported determination of this Agreement, the Institution and the Investigator shall :-

(a) forthwith discontinue the conduct of the clinical trial;

(b) not hold itself out or permit or cause him/herself to be held out as the Investigator in any manner whatsoever;

(c) forthwith deliver up all stocks of the Products, placebo, eCRF and other materials / documents or information in his/her possession to the Sponsor or otherwise dispose of the same in accordance with the directions and instructions of the Sponsor and shall account to the Sponsor for the quantities thereof.

(d) Ardent Clinical Research Services will ensure to invoice for all the activities accruing prior to expiration or termination, and will confirm in writing for "no dues pending" in the format decided mutually, on receipt of the payment for the said invoices."

28. All consents and notices required to be given or served by either party hereto on the other shall be deemed to have been given or served in writing if the same shall have been delivered personally, left at or sent by Registered Post Acknowledgment or facsimile. Due to the other party at the registered office in the case of the Sponsor and to the aforesaid address in the case of the Investigator. Service of notice upon the Investigator shall constitute a valid service of notice upon the Institution and/or - Ardent Clinical Research Services.

29. Neither Parties shall be liable for any failure or omission to fulfill their commitments hereunder, in whole or in part, on account of force majeure conditions, including but not limited to natural calamities, such as floods, earthquakes, hurricanes or any other pestilence, strikes, lock-outs, fire,

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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break-down, war, civil disturbances, act or regulation of Govt., destruction of plant, inability to secure government authorization and/or approval or any other cause beyond their reasonable control. Such force majeure occurrence shall be immediately notified to the other party.

30. Any time, relaxation, indulgence or concession or waiver granted, made or shown by the Sponsor to or in favor of the Institution/ and/ or the Investigator and/or Ardent Clinical Research Services under this Agreement shall not in any way prejudice or affect the rights or remedies available to the Sponsor under this Agreement or at law and shall not be construed as constituting a continuing waiver, indulgence or relaxation of such provision or obligation of the Institution and/ or the Investigator and/or Ardent Clinical Research Services under this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of the Sponsor thereafter to enforce each and every provision of this Agreement.

31. The Investigator and Ardent Clinical Research Services will ensure compliance with Medical Council of India (MCI) guidelines and Professional Practices Policy (P3)as in force from time to time and shall be responsible for training its employees who are involved with performing the Services set forth in this Agreement on (P3) at its own expense. The Investigator and Ardent Clinical Research Services agrees and undertakes to comply with the Sponsor's guidelines and policies including Code of Conduct and Anti bribery policy for the time being in force, a copy of which is annexed as Annexure B.

32. The Sponsor shall have the right at any time to conduct inspection or audit of the clinical trial and its processes conducted by the Institution and/ or the Investigator and/or Ardent Clinical Research Services at such intervals as the Sponsor may deem appropriate.

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The Investigator, the Institution and Ardent Clinical Research Services shall ensure that clinical trial sites and the Investigator allows officers authorized by the Central Drug Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of clinical trial sites to inspect, search and seize any record, data, documents, books, investigational drugs etc. related to clinical trials and provide adequate replies to any queries raised by the inspecting authority in relation to conduct of clinical trial

33. This Agreement is entered into and will be deemed for all purposes to have been made at Mumbai, India and shall be governed and construed in accordance with the laws of India. Courts in Mumbai alone shall have exclusive jurisdiction to deal with any dispute, claim or controversies between the Parties arising out of or in connection with the Agreement.

34. Any amendment, modification or alteration to this Agreement shall be effected in writing wherein the parties hereto shall express their consent to such amendment, modification or alteration and thereupon the said amendment, modification or alteration shall be deemed to form part of this Agreement.

35. Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement will be construed as if such provision were not contained herein and the remainder of this Agreement will remain in full force and effect. The Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

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36. This Agreement shall be executed in four original counterparts; one each of which shall be retained by the Sponsor, the Investigator, the Institution and SMO (name) respectively and all four taken together shall constitute one and the same agreement.

IN WITNESS WHEREOF the parties hereto have hereunto set and subscribed their hands to these presents, the day and year first hereinabove written.

SIGNED AND DELIVERED for and on behalf of the within named **Sponsor, Novartis Healthcare Private Limited** by the hand of its authorized signatories, **Sachin Singh**, in the presence of:

Novartis Healthcare Private Limited

Sachin Singh

Date: 15th June 2018

SIGNED AND DELIVERED by the Within named **Investigator**, Dr. Saroja A O, Prof and HOD, Dept of Neurology, KLES Dr. Prabhakar Kore hospital and MRC, Belagavi, karnataka 590010, in the presence of :

Dr. Saroja A. O

Date: 23rd June 2018

SIGNED AND DELIVERED for and on behalf of the within named **Institution**, Dr. M. V. Jali, Medical Director and Chief executive, KLES Dr Prabhakar Kore hospital and MRC, Belagavi, Karnataka 590010, in the presence of:

Dr. M. V. Jali

Date: 7 JULY 2018

SIGNED AND DELIVERED for and on behalf of the within named **SMO** Mr. Chandu Devanpally, Founder & Managing Director, Ardent Clinical Research Services, Office No. 154/155, Level-1, Connaught Place, Bund Garden Road, Pune-01, MH, India. in the presence of:

Mr. Chandu. Devanpally

Date: 26th June 2018

Ardent Clinical Research Services Pune

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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G. JYOTHI
S.V.L.NO.2/2005, H.NO.25/3 RT.
BESIDE UDIPI HOME COMPLEX
OPP CHAITNYA COLLEGE
S.R. NAGAR
HYDERABAD - 500 038

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("The Agreement") is made and executed on **15th June 2018** by and between

Hetero Biopharma Limited (formerly Known as Hetero Drugs Ltd, hereinafter referred to as "SPONSOR",), **H. No. 8-3-166/1 & 2, 105 to 108, 1st Floor, G Block, East Wing, Challa Estates, Erragadda, Hyderabad-500018,Telangana State, India**, a company registered under the companies Act 2013, represented by its Director and hereinafter called "Sponsor" (which expression unless repugnant to the subject or context therein shall mean and include its assignees, affiliates, employees, subsidiaries, nominees, agents and successors-in-interest) of the one part

AND

Dr. Archana Uppin, Consultant at KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010 Karnataka, India Hereinafter referred to as the "Principal Investigator" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the second,

AND

KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India Hereinafter referred to as the "Institution" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the third part,

"Sponsor", ''Investigator", "Institution" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

WHEREAS

The Sponsor is conducting a clinical trial entitled, Study title: - **"A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of The Marketed Formulation of Hetero - Adalimumab".** as permitted by the Drugs Controller General India vide with its DCGI approval letter dated 06 Mar 2018. ("Confirmatory Clinical Trial")

Vide Investigator undertaking letter dated **03 May 2018**, the Principal Investigator agreed to conduct the aforesaid clinical Trial at **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India** in patients with Rheumatoid Arthritis, Axial Spondyloarthritis, Psoriatic Arthritis and Psoriasis to confirm the efficacy, Safety and immunogenicity of the aforesaid drug.

A. SPONSOR is the owner of Protocol and interested in carrying out a clinical trial, through the Principal investigator

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B. AND WHEREAS the institution is equipped and qualified to undertake the study and Institution and Principal Investigator have agreed to perform the study on the terms and conditions hereinafter set forth.

C. Institution and PI desires to engage SMO to provide qualified manpower services as required for conducting the clinical study under this agreement and rendering such services upon such terms and condition set forth herein. SMO is a site management organization has qualified and trained personnel to competently conduct the Study and is desirous of rendering such services upon such terms and conditions. SMO hereby agrees to provide its services in connection with the clinical trial and as per the approved study protocol and the terms and conditions set forth therein.

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

1.0 The Clinical Trial Period shall be approximately 24 months from the date of this agreement, which may be extended by mutual consent in writing.

2.0 The **Principal Investigator** will conduct the Clinical Trial strictly as per Protocol ID No. HCR/IV/ADALI/01/2017 (Annexure II) ("Clinical Trial Protocol") as approved by the Institutional Ethics Committee in accordance with applicable regulatory requirements.

2.1 The Principal Investigator confirms that he has studied and understood the Clinical Trial Protocol and has agreed to conduct the Clinical Trial according to the guidelines prescribed by the Drugs Controller General India.

2.2 The Principal Investigator hereunder shall perform the Study at the Clinic/ hospital/ Institution mentioned in the investigator undertaking. The following person shall be acting as collaborators if applicable, in the conduct of the study and agree to be bound by the terms of this Agreement (the "collaborators")

2.3 The Principal Investigator further represent, warrant and covenant that the Principal Investigator is and at all times, during the term of this Agreement, shall be: (a) in good professional standing, (b) in possession of all requisite professional licenses, (c) fully qualified to conduct the Study and to act as the Principal Investigator under the Agreement, (d) fully experienced and knowledgeable with respect to all matters pertaining to the study and (e) responsible for the supervision of all persons who may assist the Principal Investigator or otherwise be engaged in the study. The Principal Investigator shall be responsible for the performance of the study as per the highest standards of medical and clinical research practices. Prior to commencing the Study, Principal investigator shall require and each Collaborator engaged in the Study to complete and return to SPONSOR the Disclosure of Financial Interests and Arrangements, if any, in the study.

2.4 The Principal Investigator agrees to use his / her best efforts and professional expertise to perform the Study in accordance with the Protocol and the terms and conditions of this Agreement. In the event SPONSOR do not approve, SPONSOR may terminate this Agreement in accordance with the Termination section below and Institution shall take all necessary steps to effectuate such termination.

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2.5 The Principal Investigator agree to ensure to his best efforts that no subject in this study may participate concurrently in any ancillary study (technique, procedure, questionnaire or observation other than those set forth in the Protocol) without prior approval in writing from SPONSOR. In the event that SPONSOR approves such participation, the Principal Investigator agree that the ancillary study will be conducted in accordance with all applicable Laws, Rules and Regulations, including but not limited to Schedule Y (as amendment up-to-date) to Drugs & Cosmetics Rule 1945 under Drugs & Cosmetics Act 1940, Guidelines of Indian Council for Medical Research, India Good Clinical Practice of the Central Drugs Standards Control Organization, ICH Guidance for Good Clinical Practice (as amendment up-to-date), Declaration of Helsinki. Principal Investigator agree to provide SPONSOR periodically and in a timely manner during the term of this Agreement with all Clinical Trial results and other data called as per the Protocol on properly completed (written or electronic) Case Record Forms.

2.6 PI should prior inform the sponsor preferably before a month if planning to move out of the study for any unforeseen reasons, and PI/institution is responsible to identify suitable replacement in case where the PI change happens in the study. Approval should be obtained from sponsor for all such changes and should be as per GCP and applicable regulatory requirements

2.7 Principal Investigator agree to report to SPONSOR all SAEs and important medical events, as identified in the protocol, affecting any trial subject in the Clinical trial as per applicable regulatory guidelines (including but not limited to schedule Y guidelines). Principal Investigator further agrees to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements.

2.8 The Principal Investigator undertakes to indemnify and hold harmless the Sponsor, its directors, employees and agents from any claims, demands, costs or judgments against them resulting from their failure and/or the failure of their employees and/or the agents of **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India** to adhere to the terms of this agreement or procedures/terms of the protocol for the trial and/or failure to comply with any/all applicable laws, regulations, guidelines and/or from the wrongful/ unauthorized use of the Clinical Trial Drug and/or from the data/information/ result/reports submitted to Sponsor and/or from acts of negligence, malice, fraud by Principal Investigator and/or the employees and/or the agents of **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India**

2.9 The unspent money, if any of the completed drug trial can be utilized by the principal investigators at her/his discretion and after approval of competent authority, for patient care, academic and research activities, office infrastructure, maintenance of trial records etc.

3.0 The **Sponsor** appoints **Sheejith K,** Clinical Development & Medical Affairs as Monitor for the Clinical Trial and reserves its right to nominate any other person as Monitor.

The Sponsor will supply the aforesaid Drug to the Principal Investigator free of cost, case record forms, consent forms, patient information sheets and other stationery as may be required. The Sponsor will bear the Consultation Charges, Research Assistant Fee, Laboratory Investigation charges, other miscellaneous and sundry expenses as detailed in Annexure III. All amounts will be paid by means of crossed cheque with available payee details.

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In case of injury or death during a clinical trial, patient shall be given free medical management as long as required by the sponsor.

In case the injury occurring to the clinical trial subject is related to the clinical trial, the subject or the subject's nominee(s) shall also be entitled for financial compensation as per order of Licensing Authority defined under clause (b) of rule 21 and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

The expenses on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

The Sponsor undertakes to indemnify and hold harmless Principal Investigator, Ethics committee and other employees of **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India** who are directly involved in the Clinical Trial under their supervision, from any claims, demands, costs or judgments arising out of adverse reactions to the patients on Clinical Trial involving the Clinical trial Drug provided, however, the Sponsor shall not be responsible for any liability, loss or damages resulting from a failure by Principal Investigator, Ethics committee and/or the employees and/or the agents of **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India** to comply with the terms of this agreement or any/all applicable laws, regulations, guidelines and/or acts of malice, negligence, or fraud.

4.0 Dispute Resolution:

This Agreement shall be governed by and shall be construed in accordance with Indian Laws. The Parties agree that they shall in good faith work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be referred to Arbitration in terms of Arbitration & Conciliation Act, 1996. All disputes, controversies or claims arising out of or relating to this Agreement including interpretation thereof, or breach, termination or invalidity thereof shall be referred to arbitration to a sole arbitrator to be appointed mutually by the Sponsor and the Institution. The Venue of Arbitration at Hyderabad, Telangana and the Arbitration proceedings shall be conducted in English language. The decision of such arbitrator shall be final, binding and conclusive on the Parties.

5.0 Term. The validity of the agreement is for a period of four years from the date of the Agreement or the completion of the Clinical Trial, whichever is earlier.

6.0 Termination: This agreement may be terminated-

6.1 By either party if the other party commits breach and fails to remedy such breach within 30 days from the date of receipt of written notice detailing the same. The other party on receipt of the notice shall immediately take all steps to cease conduct of the trial as soon as possible to protect the welfare of subjects participating in the trial. Further, either party may terminate this Agreement with immediate effect by written notice to the respective party if the Investigator is no longer available and Institution and the Sponsor fail to appoint an Investigator mutually.

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6.2 By Sponsor with 30 days prior written notice:
Sponsor, in its sole discretion, shall have the right to terminate agreement and stop the conduct of the trial at any time by giving notice to the principal investigator accordingly

6.3 Termination by the Institution / Investigator:
Institution / Investigator shall have the right to terminate the conduct of the trial if necessary to protect the welfare of the subjects by giving notice to sponsor.

Respective obligation in the event of early termination: If the trial is terminated prior to its completion, the Sponsor shall pay to the remuneration detailed in the Agreement by the milestones that have been duly achieved to the date of termination. In the case of early termination of the trial for any reason, the Institution / Principal Investigator shall provide all such assistance as Sponsor shall reasonably require to ensure an efficient handover of conduct of trial to a third party and with due regard for the welfare of the subjects.

Return of Material: Principal Investigator shall return to SPONSOR any unused Study Drug and all SPONSOR Confidential Information, as defined in the Confidentiality Section of this Agreement, on the conclusion of the Study or termination of this Agreement as the case may be.

7.0 Ownership of Data, Confidentiality and Publication:

7.1 Ownership: All case report forms and other data (including without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Principal Investigator in the course of conducting the Study (the "Data") shall be property of SPONSOR, which may utilize the Data in any way it deems appropriate, subject to and in accordance with all applicable (a) Indian laws and regulations and (b) privacy and security laws of India and other countries. Any copyright work created in connection with performance of Study and contained in the Data (except any publication by the Principal Investigator as provided for hereinafter) shall be property of SPONSOR as the author and the owner of copyright in such work

7.2. All information, including, but not limited to, the Study Drug or SPONSOR operations, such as SPONSOR's patent applications, formulas, manufacturing processes, basic scientific data, prior clinical data and formulation information supplied by SPONSOR to and/or Principal Investigator and not previously published (the "SPONSOR Confidential Information") are considered confidential and shall remain the sole property of SPONSOR. Both during and after the term of this Agreement, and Principal Investigator will use diligent efforts to maintain in confidence and use only for the purposes contemplated in this Agreement (i) the information which is identified in the preceding sentence as confidential or which a reasonable person would conclude as confidential and proprietary property of SPONSOR and which is disclose by or on behalf of Principal Investigator and (ii) Data which is generated as a result of this Study. The preceding obligations shall not apply to data or information (i) which has been published through no fault of Investigator, or (ii) which SPONSOR agree, in writing, may be used or disclosed, or (iii) which is published in accordance with paragraph C of this Section 4. The provisions in this paragraph shall survive the termination or expiration of this Agreement for a period of ten years.

7.3. Publication: The Principal Investigator acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor which is disclosed to the Principal Investigator is and shall always remain the sole and exclusive property of Sponsor. The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the Principal Investigator may publish data generated at their (own) site, only after getting written approval from Sponsor and only after the first publication of such data by the Sponsor or as mutually agreed by the Parties.

7.4. Patents: All rights to any discovery or invention conceived and reduced to practice as a result of the work conducted under this Agreement shall belong to SPONSOR. The Principal Investigator agree to assign to SPONSOR, the sole and exclusive ownership thereto, upon the payment of costs by SPONSOR, if any, incurred by principal investigator in assisting SPONSOR in their filling, prosecution, or maintenance of any patent application or patent issued thereon. Such patent applications, if any, shall be filed and prosecuted by SPONSOR. Principal Investigator shall promptly disclose to SPONSOR any invention or discovery arising under this Agreement. Principal Investigator shall execute and shall have its employees execute all documents necessary to transfer all rights, titles and interests in and to any such invention or discovery to SPONSOR.

8. Data Use Agreement:

8.1 Encoding study data: Principal Investigator shall ensure that the patient identifiable information that is disclosed during the study and provided to the SPONSOR under this study fulfilled all privacy obligations under applicable legislations and regulations.

8.2 SPONSOR use of data set: SPONSOR shall not use or disclose information that would violate the requirements of any privacy legislation. SPONSOR will limit access to the data to personnel responsible for research and development function within their respective organization or within affiliated companies of SPONSOR. SPONSOR may also provide access to contract research organizations and other consultants or agents working with the research and development functions of these entities on the research activities detailed above. SPONSOR will ensure that all such parties assume the data protection responsibilities of SPONSOR as set forth in paragraph (c) of this section.

8.3 Protection of the data. SPONSOR shall, with respect to the information continued in the data (i) not use or further disclose the information other than as permitted or required by this agreement or as otherwise required by law; (ii) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) report to Principal Investigator any use or disclosure of information not provided for by this agreement of which it becomes aware; (iv) ensure that any agent or assignee, including a subcontractor, to whom it provides the information agrees to the same restrictions and conditions that apply to SPONSOR with respect to the data and (v) not identify the information or contracts of the individuals to whom it pertains.

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9. Insurance

9.1. SPONSOR shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study)

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Insurance coverage for general liability in amounts appropriate to the conduct of business activities and the services contemplated by the study.

9.2. Principal investigator and Ethics Committee shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study) Insurance coverage for medical, professional and medical malpractice liability, in amounts appropriate to the conduct of business activities and the services contemplated by the study.

9.3. Upon request, each party shall provide to the other party a copy of the insurance certificate setting forth the foregoing coverage.

10. Debarment / Financial Disclosure: Principal investigator shall not employ, contract with or retain any person directly or indirectly to perform service under this Agreement if such a person incurs any disqualification of any nature under any statute in force either in India. Upon written request from SPONSOR, principal investigator shall, within ten days, provide written confirmation that it has complied with the foregoing obligation. Principal investigator shall also provide to SPONSOR all information necessary to comply with any disclosure requirements mandated Drugs & Cosmetics Act 1940, including any information required to be disclosed in connection with any financial relationship between SPONSOR and Principal Investigator. This disclosure requirement shall require disclosure of information involving immediate family members of those involved in the study.

11. Independent Contractor: Principal Investigator act in the capacity of independent contractor hereunder and not as agents or employees of SPONSOR. The Principal Investigator will make no claim against SPONSOR for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers compensation, disability or unemployment benefits or employee benefits of any kind, including right/status as an employee of SPONSOR.

12. Publicity: None of the parties shall use the name of any other party for promotional purposes without the prior written consent of the party whose name is proposed to be used nor shall either party disclose the existence or substance of this Agreement except as required by law.

13. Agreement Modifications: This Agreement or any of its Exhibits shall not be altered, amended or modified except by written document signed by all parties Hereto.

14. Assignment: SPONSOR shall have the right to assign this Agreement to an affiliate of SPONSOR upon prior written notice to Principal investigator. In all other instances, neither party shall assign its rights or duties under this Agreement to another without prior written consent of the other party. Subject to the foregoing, this Agreement shall bind and inure to the respective parties and their successors and assigns.

15. Conflict with protocol: If any of the provisions of this Agreement conflict with any provision of the protocol, this Agreement shall take precedence.

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In witness whereof, the parties have caused this agreement to be executed by their authorized representative on the date, month and year first above mentioned

Hetero Biopharma Limited

Dr. Shubhadeep Sinha
Authorized Signatory

Hetero Biopharma Limited

18/6/2018

M.Jayapal Reddy
Authorized Signatory

KLES Dr Prabhakar Kore Hospital & Medical Research Centre

07/Jul/18

Dr. M. V. Jali
Authorized Signatory

Principal Investigator

22/6/2018

Dr. Archana Uppin

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

Annexure I

DCGI NOC

(Attached Separately)

ATTESTED

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Annexure II

CLINICAL TRIAL PROTOCOL

(Attached Separately)

ATTESTED

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Annexure III

PAYMENT TERMS AND SCHEDULE

Estimated cost per completed patients enrolled for Immunogenicity:

IM Subjects with Efficacy and Safety				
Sr. No	Head	Unit Charge	Visits	Total
1	Investigator Consultation Charges	4700	11	51700
2	Chest X-Ray	500	1	500
3	Montoux test	900	1	900
4	CRP, ESR	500	5	2500
5	12 lead ECG	500	5	2500
6	Patient Conveyance (All visits)	500	11	5500
7	Institutional Charges (1,2,3,4,5) * 25%			14525
	Total Cost Per Completed Patient (Maximum for 6/12 Doses)			78125

Estimated cost per completed patients enrolled for Safety :

Subjects with Safety				
Sr. No	Head	Unit Charge	Visits	Total
1	Investigator Consultation Charges	4700	8	37600
2	Chest X-Ray	500	1	500
3	Montoux test	900	1	900
	CRP, ESR	500	5	2500
4	12 lead ECG	500	5	2500
5	Patient Conveyance (All visits)	500	8	4000
6	Institutional Charges (1,2,3,4) * 25%			11000
	Total Cost Per Completed Patient (Maximum for Eight Cycles)			59000

Administration Budget:

Sr. No	Head	Per Month	Months/year	Total
1	Clinical Research Coordinator payment	10000*	12 months	1,20,000
		Total		1,20,000

*Till recruitment or last patient last visit at site Rs10,000/Per month paid for CRC and there after 5000/per month till Site close out visit or till 12 months (from site initiation) whichever is earlier

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1. **Payment terms:**

1. Payments will be made preferably within 30 working days from the date of receipt of correct original invoice

2. Payment of Rs. **50,000/-** will be paid as an advance after signing the agreement before or after the site Initiation visit. This amount will be adjusted in the subsequent invoices received. Research Assistant charge will be paid monthly basis as decided by the Institution prior approval from the sponsor.

3. The final payment to the site will be paid based on the number of patients enrolled, completed, Withdrawn/dropout and screen failures before the site closure visit. CRC payment will be paid per month as Rs **10,000/-** for 12 months only or till site closeout whichever is earlier

4. If the site is terminated or doesn't progress in terms of recruitment for at least 6 months after Initiation / paying the advance, then the amount paid should be returned by the PI/Institution to the Sponsor after making necessary deductions and adjustments

2. **Payee Details :**

The sponsor will make the payment after tax deduction at source. The account payee crossed Cheques will be issued in favor of

Payee Name	**Archana Shivaputra Khangavi**
Payee Address	**KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010 Karnataka India**
Tax ID Number (PAN Number)	**CSTPK3409G**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Government of National Capital Territory of Delhi

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Certificate No.	:	IN-DL40222780434344Q
Certificate Issued Date	:	20-Jun-2018 12:19 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210384323279647875Q
Purchased by	:	JSS Medical research India Private Ltd
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical research India Private Ltd
Second Party	:	NA multiple sites
Stamp Duty Paid By	:	JSS Medical research India Private Ltd
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 24 Sep 2018
JSS MEDICAL RESEARCH INDIA PVT LIMITED
12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector- 27D, Faridabad-121003, Haryana
(AS THE CRO)
DR VIKRANT GHATNATTI
KLES DR PRABHAKAR KORE HOSPITAL AND MRC
Nehru Nagar, Belgavi, Karnataka-590010
(AS THE PRINCIPAL INVESTIGATOR)
AND
KLES DR PRABHAKAR KORE HOSPITAL AND MRC
Nehru Nagar, Belgavi, Karnataka-590010
(AS THE SITE/INSTITUTION)
AND
GENESIS RESEARCH
Jadhav wadi, Kolhapur- 416211
(SMO)

CLINICAL TRIAL AGREEMENT
Page 1 of 25

Medical Research India Pvt. Ltd. JSS Faridabad

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

This Clinical Trial Agreement (the "**Agreement**") is dated: 24 Sep 2018

BETWEEN:

1. **JSS Medical Research India Pvt Ltd.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through its [Senior Vice President, Dr. Renu Razdan] being authorized to sign this Agreement (hereinafter referred to as"**JSS India**"whichexpression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

2. **Dr Vikrant Ghatnatti,** working as Consultant Endocrinologist at KLES Dr Prabhakar Kore Hospital and MRC having his residence at B6 Staff quarters JNMC campus Nehru Nagar, Belgavi-590010 (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

3. **KLES Dr Prabhakar Kore Hospital and MRC,** a [*hospital*] registered under the provisions of [Indian Companies Act, 1956 OR *any other relevant law*], having its registered office at Nehru Nagar, Belgavi – Karnataka- India being authorized to sign this Agreement (hereinafter referred to asthe"**Site**"whichexpression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

4. **Genesis Research (SMO)** registered under the provisions of [Indian Companies Act, 1956 OR *any other relevant law*], having its registered office at Jadhav wadi , Kolhapur , Maharashtra India being authorized to sign this Agreement (hereinafter referred to as the "**SMO**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns

The Sponsor, JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. The Sponsor is in the business of developing, manufacturing and/or distributing pharmaceutical products, in Dermatology.

B. JSS India is a CRO.

C. The Site is engaged in [Clinical Trial]and the PI is an *consultant*] at the Site.

D. The Sponsor desires to conduct a clinical trial in respect of the Drug, and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

E. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

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1. **Definitions and Interpretations**

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by the Sponsor.

"**Clinical trial**" shall mean a clinical trial conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"**Dispute Notice**" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by the Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and well being of all such actual and potential research participants.

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

"**Fee**" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

ATTESTED

Dr. V.A.Kothiwale
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Belagavi-590 010, Karnataka

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"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indian GCP" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research.**"Information Brochure"** shall mean the information brochure of the Sponsor.

"Informed Consent Form" or **"ICF"** shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject .

"Investigational Products" shall mean the chemical compound invented by the Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by the Sponsor.

"Invoice" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"Subject" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"Payment Milestone" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"Protocol" shall mean Protocol No. [2015-DFU-301] as provided by the Sponsor.

"Price" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'D' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"Screen Failure" shall mean the screen failure as defined in the Protocol.

"Serious Adverse Event" or an **"SAE"** includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

"Standard Operating Procedures" or **"SOP"** shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

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1.2.1 words denoting the plural number include the singular and vice versa;

1.2.2 references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

1.2.3 references to this Agreement include the Recitals and the Schedules;

1.2.4 the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

1.2.5 references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

1.2.6 references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

1.2.7 references to any Party include its successors, transferees and permitted assignees.

2. **Scope of the Agreement**

The PI agrees to perform the Clinical Trial for and on behalf of the Sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by the Sponsor.

3. **Term**

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. **Clinical Trial**

4.1 Clinical Trial Initiation: JSS India and/or the Sponsor shall provide the PI all Clinical Trial Documents. The PI and/or the Siteshall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the Sponsor and/or JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is [*as defined in the Protocolincluding follow-ups*]. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions of the Sponsor and/or JSS India.

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

5. **Responsibilities and Obligations of the Parties**

ATTESTED

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5.1 The Sponsor shall be responsible for the following:

5.1.1 Clinical Trial Documents and Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to JSS India and the PI.

5.1.2 Approvals and Consents: Procuring and providing any approvals and consents required to be taken by the Sponsor in [*the country of its jurisdiction and/or India*].

5.2 JSS India shall be responsible for the following:

5.2.1 Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of Sponsor.

5.3 The PI and/or the Siteshall be responsible for the following:

a. The PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

b. Upon request by JSS India and/or the Sponsor, the PI will provide JSS India and / or the Sponsor all information needed by JSS India and/or the Sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

c. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or the Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the Sponsor and JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or the Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

d. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.4 Regulatory Agency Audit: The PI and the Site will inform JSS India and the Sponsor within twenty four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India and the Sponsor with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India and/or the Sponsor in any such investigation, and in the implementation of appropriate action plans for such observations.

6. Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to the Sponsor as follows:

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(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause the Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Sponsor represents, warrants and covenants to JSS India as follows.

(a) Formation/Power and Authority: The Sponsor is duly formed and validly existing under the laws of the country of its origin and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Sponsor represents and warrants that it is in full compliance at all times and will continue to be in compliance at all times with all Applicable Laws of the country of its origin and the laws of India.

(c) Permits: Prior to commencement of a Project, the Sponsor shall identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of such Project, in accordance with the Applicable Laws, in the country of its origin and country where Clinical Trial has be undertaken. The Sponsor shall be solely responsible for procuring and maintaining each such permit and approval in the country of its origin. Unless impossible, expressly prohibited by Applicable Laws or otherwise requested by JSS India in writing, the Sponsor shall procure and maintain in the name of the Sponsor all permits and approvals for which it is responsible.

(d) Debar: The Sponsor certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

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The Sponsor agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term.

(e) Freedom to Use: The Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India, the PI and/or the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

6.3 The Site represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Formation/Power and Authority: The Siteis duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [13] Subjects or such higher numbers as agreed upon with JSS India and the Sponsor in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Sitein respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India and/or the Sponsor's request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

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6.4 The PI represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [9] Subjects or such higher numbers as agreed upon with [*JSS India/ the Sponsor*] in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India and/or the Sponsor's request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7. **Use of Name**

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or the Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8. **Ownership of Property and Data**

The Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of this Agreement.

9. **Record Retention and Site Audits**

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the [Drug Controller General of India], and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH) region, (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India and/or the Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India and/or the Sponsor so elect, comprise: (a) inspection of the PI's and/or the Site'sfacilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site'scompliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

ATTESTED

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10. **Publications**

JSS India and/or the Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Siteunderstand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Sitemay only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to the Sponsor and/or JSS India. The PI and the Siteagrees to delete any information that may be confidential or proprietary.

11. **Fees**

a. Budget: The Sponsor, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before [*DATE*]. The Parties shall negotiate and agree on the Budget on or before [*Date*]. The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

i. The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India and/or the Sponsor. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the Sponsor and/ or JSS India unless the PI and/or the Site have taken the written consent of JSS India and/or the Sponsor before administration of such tests or services.

b. Payment of Fees and Expenses to the PI and/or the Site: The Sponsor, or if so authorized by the Sponsor, JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol ,the consideration for their services will be pro rated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

i. Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the Sponsor and/or JSS India, if so authorized, [on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

(b) the Sponsor or JSS India, if so authorized, shall pay the invoiced amount within thirty (30) business days of the date of the invoice. The payment shall be made through wire transfer into the following account, or, through crossed cheque/DD, as applicable:

PAYEE NAME	"Genesis Research"
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	CQJPP0528D

ATTESTED

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BANK NAME & BRANCH ADDRESS	State bank of India
Account No:	36599680134
Branch Code:	01887
IFSC Code:	SBIN0001887
GST Registration No	27CQJPP0528D1ZX

ii. Taxes: Anygoods and service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or the Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

iii. Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS India and/or the Sponsor that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12. **Insurance**

a. The Sponsor shall maintain all adequate insurance coverage, which will include adequate clinical trial insurance of the study.

b. The Sponsor shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site, the PI, the Clinical Trial and JSS India.

13. **Indemnification**

13.1 Indemnity: The Sponsor agrees to indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification:The Sponsor's obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligationsto indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

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(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and/ or JSS India and/ or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 13 above, directly or due to a third party claim shall give written notice to the Sponsor, against whom such indemnification rights are claimed.

Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the Sponsor shall not relieve the Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the Sponsor or its defenses.

With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of the Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if the Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from the Sponsor; provided, however, that:

(i) the Indemnified Party shall obtain the prior written consent of the Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if

(A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the Sponsor,

(B) such settlement does not expressly unconditionally release the Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or

(C) involves criminal or quasi-criminal allegations against the Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim;

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(ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the Sponsor in connection with such claim or legal proceeding;

(iii) the Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and

(iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, the Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if

(A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party,

(B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or

(C) involves criminal or quasi-criminal allegations.

13.4.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of Sponsor in relation to the Study.

13.6 The Sponsor shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs. Sponsor shall also pay cash compensation, to subject or legal heirs of subject, awarded by ethics committee (or any court) in case of death or permanent disability. The Sponsor shall not be liable for payments for a Subjects' lost wages.

14 **Confidentiality**

a. All of the information disclosed by JSS India and/or the Sponsor or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and/or the Sponsor and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

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b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 **Termination**

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

15.2 The Sponsor may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India and/or the Sponsor that the PI and/or the Siteis not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or the Sponsor representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Siteor its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India and/or the Sponsor, to meet with JSS India and/or the Sponsor or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Siteto comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India and/or the Sponsor in writing that business or scientific considerations require termination.

h. Case Report Forms provided tothe PI and/or the Siteor its associated staff by JSS India and/or the Sponsor or its representatives for use in the Study, are not completed and forwarded to JSS India and/or the Sponsor or its designated representative, within the timelines prescribed by JSS India and/or the Sponsor.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India and/or the Sponsor.HoweverJSS India and/or the Sponsor shall have the sole right to determine the acceptability of a new PI.

15.3 In the event thatJSS India and/or the Sponsor exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the Sponsor and/or JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

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16 **Miscellaneous**

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India:

JSS Medical Research India Pvt Ltd
12/2, 6th Floor, Vatika Mindscapes, Sector 27D, Faridabad-121003, Haryana, India
New Delhi—110020, India

Attention: Dr RenuRazdan
Designation: Senior Vice President-India
Telephone: +91 129 6613 500

E-mail: renu.razdan@jssresearch.com

If to the PI:

DR Vikrant Ghatnatti
KLES Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, Belagavi
Karnataka, India – 590010
Designation: Consultant Endocrinologist
Telephone: +91-9844445598
Email: victorvikrant@gmail.com

If to the Site :

Dr. M. V. Jali
KLES Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, Belagavi
Karnataka, India – 590010
Designation: MD & CE
Telephone: +91-831 2473777
Email : medicaldirector@klehospital.org

If to the SMO:

Mr. Satyajit patil
Genesis Research, Kolhapur
Designation: Manager
Telephone: +91-9762388445
Email : info@genesisresearch.in

If the Sponsor delivers, ships, or mails materials or documents to JSS India, or requests in writing that JSS India deliver, ship, or mail materials or documents to the Sponsor or to third parties, then

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the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by the Sponsor. JSS India disclaims any liability for the actions or omissions of third-Party delivery services or carriers.

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written instrument signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by JSS India and the Sponsor.[and the appropriate Institutional Review Board (as per Indemnity Agreement Pg. 8)].

16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India and/or the Sponsor.

16.4 Assignment: This Agreement may be assigned by JSS India and/or the Sponsor to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India and/or the Sponsor.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8,9, 13, 14, 15, 16.2, 16.3 and 16.11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and the Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding

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arbitrator . The venue of arbitration will be New Delhi, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief:Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

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IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India

By: _____
Print Name: Dr. Renu Razdan
Title: Senior Vice-President

Date: Sept 27, 2018

The Principal Investigator

By: _____
Print Name: Dr Vikrant Ghatnatti
Title: Consultanat Endocrinologist

Date: 08 oct 2018

The Site

By: _____
Print Name: DR M.V Jali
Title: MD and CE

Date: 22 oct 2018

The SMO

By: _____
Print Name: Mr. Satyajit Patil
Title: Manager

Date: 28 Sep 2018

ATTESTED

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Schedule A

[List of services to be provided by the PI and/or the Site]

Sl. No.	Activities	JSS India	PI/Site
1.	Execution of Clinical Trial Agreement	☒	☒
2.	Sharing Essential Documents	☒	
3.	Review of Site Specific Informed Consent Document	☒	(☒)
4.	IEC Submission of Dossier, IEC notifications of updates/documents		☒
5.	Execution of Informed Consent Form from subjects		☒
6.	Inclusion/Exclusion Assessment		☒
7.	Medical Management		☒
8.	IP Handling, Accountability & Storage		☒
9.	IP Administration/dispensing		☒
10.	Glucometer, test strips and lancets accountability and dispensing		☒
11.	Laboratory Sample Collection and Centrifuge		☒
12.	Telephonic Contact & Follow-up with patients as per study protocol		☒
13.	eCRF Entries/ Completion on time (within 3 days of subject visit)		☒
14.	eCRF Signatures		☒
15.	Safety Reporting (e.g. AES/SAEs)		☒
16.	Randomization		☒
17.	Query Resolution (During the study; Post close-out, if any)		☒
18.	Query Signatures (During the study; Post close-out, if any)		☒
19.	Source Documentation		☒
20.	Documentation of ICF procedure including AV consenting as applicable		☒
21.	Patient diary retrieval and review		☒
22.	12-Lead ECG, X ray, MRI, CT, neurological assessment for DFU, Doppler etc.		☒
23.	Providing Clinical Supplies and Non-Clinical Supplies	☒	

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24.	Archival of study documents		☒

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Schedule B

1. Budget for Clinical Trial – Break Up

Visit 1/Screening	12,000
Visit 2/ Baseline/ Day 0	7,000
Visit3/ Day 3	6,000
Visit 4/Day 7	6,000
Visit 5/ Week 2	6,000
Visit 6/ Week 3	6,000
Visit 7/ Week 4	5,000
Visit 8/ Week 5	5,000
Visit 9/ Week 6	5,000
Visit 10/ Week 7	5,000
Visit 11/ Week 8	5,000
Visit 12/ Week 9	5,000
Visit 13/ Week 10	5,000
Visit 14/ Week 11	7,000
Visit 15/ Week 12	5,000
Visit 16/ Week 14	5,000
Visit 17/ Week 16	5,000
Visit 18/ Month 2	5,000
Visit 19/ Month 3	5,000
Visit 20/Week 52/53	5,000
Total	115,000

Total for 13 patients	1,495,000
Miscellaneous (Phone & fax bills, stationery, Scan etc.)	60,000
Administrative @ 25% of the total budget	3,73,750
Total PI Grant	1928750
Per patient Grant	148,365

PASS THROUGH	Cost in INR	Comments
EC Fee	90,000/-	Excluding TDS
EC Fees for renewal of study approval, if any	-	None
EC fees for protocol amendment	20,000/-	Per submission (Excluding TDS)
EC fees for SAE review, if any	10,000/-	Excluding TDS

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All the Investigation Charges as mentioned in the Protocol will be on actual at various visits:-	On actuals	(ABI, Neurological Assessment, X-ray, Doppler, CT/MRI,ECG)
Offloading Shoes & Wound Dressing Protector	-	Will be provided by the CRO
Temperature Logger 2/site	-	Will be provided by the CRO
Patient Travel reimbursement per visits	500 per visit*19 visits= 9500	123500
	Total	**243,500/-**

NOTE:

Expenses for AE/SAE management will be billed on actuals. SAE Compensations for related SAEs including Trial related Injury/Deaths	Applicable Taxes Present GST rate (18%) are not included in the pass-through budget	41,000/- for 15 Years Archival of document post study not included in the budget

II. Payment Schedule

A. Ongoing Payments:

- Invoice will be raised monthly for the completed visits of the enrolled subjects, after confirmation of CRA about the EDC entries completion of these visits.
- The payment schedule should be as per the SCHEDULE D
- All the payments made to site under investigator grant will be subject to TDS deduction.
- Pass through cost (ECG & Subject reimbursement) shall be based upon actuals. Site has to submit separate invoice for pass-through charges accompanying ECG bills.

B. Last Payment: 20% of last invoice will be retained & will be released at the time of the Close Out visit. This payment will be made when all the subjects for Clinical Trial have been recruited, all data have been entered in the Case Report Form and all queries resolved. In addition, any additional expense pending to be paid will be paid at this time.
In the event of any excess payment from the Sponsor/CRO to the Trial Site, the Trial Site must promptly return the excess amount to the Sponsor.

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SCHEDULE C

Estimated Budget for Screen Failure

INR 8,000/- per Screen failed subject will be reimbursed. The cap for screen failure patient is 5.

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ADDENDUM TO CLINICAL TRIAL SITE AGREEMENT FOR 0804-16 STUDY
("Addendum")

1 PREAMBLE AND INTENTION

The Parties are,

1.1 **Lambda Therapeutic Research Ltd.**, a company incorporated in accordance with the laws of India with its registered office at Lambda house, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India (herein referred to as "Lambda") (which expression shall unless repugnant to the context or meaning thereof be deemed to include its affiliates, employees, subsidiaries, nominees, successors - in - interest and assigns)

AND:

Principal Investigator, **Dr. Shiva Kumar Patil,** KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND:

KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India
(Hereinafter referred to as the "Institute")

AND:

Site Management Organization, KV Clinical Research Services Office no. 615, 6th Floor Golden Trade Centre New Rajendra Nagar, Raipur – 492001, Chhattisgarh
(Hereinafter referred to as the "SMO")

CRO, Site, SMO and Principal Investigator are hereinafter individually referred to as a "Party" and collectively as the "Parties".

WHEREAS:

1.2 Parties have entered into a Clinical Trial Site Agreement dated April 05, 2018 (herein referred to as "Agreement"), pursuant to which CRO, acting as an independent contractor on behalf of SPONSOR desires to coordinate a clinical research study, Site and Principal Investigator agreed to facilitate and carry out the Study as detailed in Agreement.

1.3 The Parties wish to amend and supplement certain of the terms of the Agreement as recorded herein ("Addendum").

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1.4 This Addendum forms part of and is to be read with the Agreement as from **June 21, 2018** ("Effective Date").

2 AMENDMENTS

As requested by Investigator to increase the "Investigator Grant" amount of **INR 49,920** (per patient) as per **attachment – A (Revised Budget);**

In addition to this LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the SMO, Institution & PI. Details of Payee are:

Payee Details:

Payee Name	:	"KV Clinical Research Services Payable" at Raipur
Payee Address	:	AAPFK7058P
PAN / TAN Number	:	MIG II /253 Sector -1, Pt. Deendayal Upadhyay Nagar, Raipur – 492001, Chhattisgarh
GST Number	:	22 AAPFK7058P1ZM

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A. Revised Budget:

FINANCE SUMMARY BOX	
Invoice Currency	INR
Study Base	Visit-based
Effective Date	The revised budget will be applicable from 21 June 2018

Sr. No.	Payment Head	Screening/Visit 01	Visit 02	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9/ EoT + EoS	Total
		Up to 14 days prior to dosing	Day 0	Day 7	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84 + 7 days	
1	Investigator Grant	3200	2250	2250	2250	2250	2250	2250	2250	3000	21950
2	Study Coordinator Grant	1500	1200	1200	1200	1200	1200	1200	1200	1500	11400
3	ECG (12 Lead)	500	[redacted]							500	1000
4	X-Ray	500									500
5	Institutional Overhead (20%)	1140	690	690	690	690	690	690	690	1000	6970
6	Target Lesion Photograph Print	[redacted]	450	450	450	450	450	450	450	450	3600
	Total										
7	Patient Compensation (actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grand/patient										**49920**
8	**Local Laboratory Investigation**										
8a	Haematology	420	[redacted]							420	**840**
8b	Blood/Serum Biochemistry	1430								1430	**2860**
8c	Immunology	1200								1200	**2400**
8d	Urinalysis	150								150	**300**
8e	Pregnancy Tests	150	UPT kit will be provided by Lambda							150	**300**
	TOTAL OF SECTION 8										**6700**
	***Local lab Investigations: Haematology, Biochemistry, Immunology, Serum pregnancy test and Urine analysis investigations will be done as per protocol requirement on Visit 1 and Visit 9 only.**										
	Note:										

1. The above referenced per patient grant will remain same throughout the study. Additionally investigator/site will get a bonus amount of INR 20,000 after enrollment of every 10th patient in the study.

2. Phlebotomist activities will be completed by site team only. No additional cost will be paid for the same.

3. Patient compensation will be provided based on actual bills only (provided is upper limit)

3 GENERAL

3.1 As of the Effective Date, this Addendum 1 shall be read together with and shall be deemed to be incorporated in the Agreement and shall be governed by the terms, conditions and definitions set forth in the Agreement, as if such terms were fully set forth herein.

3.2 Except as expressly amended hereby, the terms and conditions of the Agreement shall continue in full force and effect and are hereby confirmed and ratified.

SIGNATORIES

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

Lambda Therapeutic Research Ltd.

By: Ravesh
Printed Name: Ravesh Patel
Title: AVP - CTM
Date: 23 Jun 2018

PRINCIPAL INVESTIGATOR

By:
Printed Name: Dr. Shivakumar Patil
Title: Consultant Dermatologist
Date: 29 Jun 2018

SMO

By:
Printed Name: Kiran Kumar Patel
Title: Founder & COO
Date: 21 July 18

INSTITUTION

By:
Printed Name: Dr. M. V. Jali
Title: MD & CE, KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010.
Date: 16 Jul 2018

LAMBDA Research Accelerated

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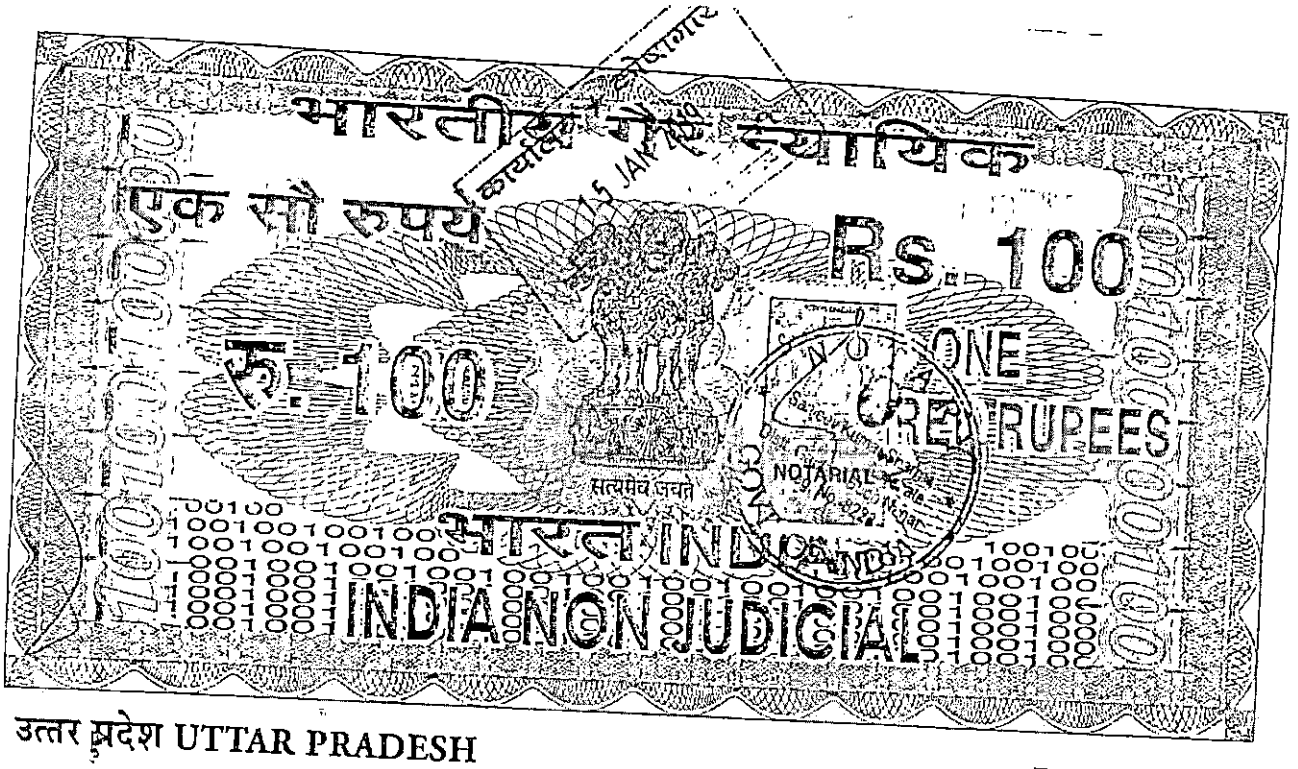

उत्तर प्रदेश UTTAR PRADESH

ER 241167

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)
And
KLE's Dr. Prabhakar Kore Hospital and MRC, Belagavi
And
Dr. Sameer Haveri (Principal Investigator)

FOR THE STUDY

Title of Study:	**A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury**
Protocol Number:	PMZ-1620/CLINICAL-2.3/2018
Version Number:	02
Date of Protocol:	05 July 2018

NOTARY Sanjeev Kumar Sharma Advocate Distt. Gautam Budh Nagar Reg. No. 6226 GOVT. OF INDIA

Dr. Sameer Haveri
Consultant Orthopaedics
KMC Reg. No. 63092
KLES Dr Prabhakar Kore Hospital n.
MRC, Belgavi

ATTESTED
Sanjeev Kumar Sharma
Advocate
Reg. No. 6226
Distt. Gautam Budh Nagar

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on 15 Feb 2019 ("**Effective Date**") at Gautam Buddha Nagar **BY AND BETWEEN:**

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Registered Office at B-4, Sarita Vihar, New Delhi-110076 & Corporate Office at H-6, Site C, Surajpur Industrial Area, Greater Noida-201307, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART;**

AND

KLE'S Dr. Prabhakar Kore Hospital and MRC an Institution having its office at **KLE'S Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar Belagavi -590010.** (here in after referred to as **"KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi",**

KLE'S Dr. Prabhakar Kore Hospital and MRC, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART;**
AND

Dr. Sameer Haveri, M.S (Orthopedics) a registered medical practitioner holding MCI registration number 68382 is the Associate Professor, at **KLE'S Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar Belagavi** (hereinafter referred to as **"Principal Investigator"**), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART;**

Pharmazz, KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi and **Principal Investigator** shall hereinafter be collectively referred to as the **"Parties"**. Each of the Parties shall hereinafter individually be referred to as a **"Party"**.

RECITALS

1. WHERE **(KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi)** is a pioneering institution of world-class investigator site in India having an exclusive set up for conducting Phase II to Phase IV clinical trials and have assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related to PMZ-1620 is a lyophilized IRL-1620 Injection, as a treatment of acute spinal cord injury.

3. Principal Investigator **Dr. Sameer Haveri, MS (Orthopedics)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

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KMC Reg No. 68382
KLES Dr. Prabhakar Kore Hospital & MRC
Belagavi

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by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled "**A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury** as defined in the Protocol.

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocol number (a copy of which is attached as **Exhibit A**) and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"Investigational Drug"** shall mean: IRL-1620 for Injection 30 µg/vial.

i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** shall means Drug Controller General of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

Dr. Sanket Hav... Consultant Orthopaedics ... KLES Dr. Prabhakar Kore ...

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d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** and Principal Investigator to complete the following -

Responsibility of the KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi & Principal Investigator

The **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** agrees to provide full support to the Principal Investigator **at KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** to conduct the Clinical Trial in **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

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2.1 The Principal Investigator and **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research (**"Applicable Laws& Guidelines"**);

c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/e-CRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other

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event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the

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Dr. Sameer Consultant Orthopaedic
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subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/ **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** throughout the period of the Clinical Trial and with third party vendor or sponsor for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Principal Investigator/ **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator of **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained from **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi.** The Pharmazz will provide the Study Drug to the Principal Investigator **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** free of

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other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

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cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** jointly and severally agree that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of Acute Spinal Cord Injury.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the full right to:

a. examine and inspect the **KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study and audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and KLE'S Dr. Prabhakar Kore Hospital and MRC, Belagavi carrying out the Clinical Trial in

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accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the Dr. Sameer Haveri in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in Exhibit B will be paid by the Pharmazz to the Dr. Sameer Haveri to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in **Exhibit B** to be paid to Dr. Sameer Haveri shall be paid by Pharmazz.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to Dr. Sameer Haveri under this Agreement.

6. REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

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7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, The Party of the First Part, **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect):

The First Party & The Second Party i.e. **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi & PI** shall be joint & severally liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

The First Party **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement. This agreement can be extended with mutual understanding, if the trial is not complete.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, Department of KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi and the **Principal Investigator** shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for viable reasons of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** and PI

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b) **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status;

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** to provide access by the Pharmazz's representatives all original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified

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and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the **Principal Investigator/ KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the **Principal Investigator/ KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees and undertake that it shall indemnify, defend and hold harmless the Principal Investigator, **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including

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Dr. Consult... KLES Dr. Prabhakar Kore Hospital & MRC, B...

employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Pharmazz in any such claims. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** ; or (v) failure of the

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Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

a) The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Pharmazz's activities and obligations contemplated in this Agreement.

b) The **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a professional indemnity liability insurance coverage from an Indian insurance company for the Study

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for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** along with its comments or viable modifications which shall be considerable by the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi.**

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

15. INTELLECTUAL PROPERTY RIGHTS

KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

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16. **CONFIDENTIALITY**

a) The Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

b) The Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall:

First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential

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Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** or their successors or assigns;

ii. by written records were in the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** receives from a third party legally in a position to provide with information to the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the

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Pharmazz, and that if there is a breach (either actual or threatened) by the Principal Investigator/ **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

17. SEVERABILITY & WAIVER AND ASSIGNMENT

a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

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c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. **MISCELLANEOUS**

a) It is agreed by the Parties that the Principal Investigator and **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi** shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

e). The governing (applicable) language to this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in English language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. **NOTICES**

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

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Pharmazz	Site Name	Principal Investigator
Mr. Sunil Gulati Chief Operating Officer	**Dr. M. V. Jali** Medical Director	**Dr. Sameer Haveri** Principal Investigator
Pharmazz India Pvt. Ltd. H-6, Site-C, Surajpur Industrial Area, Greater Noida – 201307 **Email:** sunil.gulati@pharmazz.com	KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi- 590010 **Email:** medicaldirector@klehospital.org	KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi-590010 **Email:** drsameerhaveri @gmail.com

19.2. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Gautam Buddha Nagar and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Gautam Buddha Nagar courts shall have exclusive jurisdiction in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

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22. **FURTHER ASSURANCES**

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi**	For **Principal Investigator**
Signature:	Signature:	Signature: .....
Name: **Mr. Sunil Gulati**	Name: **Dr. M. V. Jali**	Name: **Dr. Sameer Haveri**
Title: Chief Operating Officer	Title: Medical Director	Title: Principal Investigator

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Annexures-

1. Exhibit A- Clinical Trial Protocol
2. Exhibit B- Budget & Payment schedule
3. Exhibit C- Principal Investigator's Document
4. Exhibit D- Site Feasibility Questionnaire
5. Exhibit E- Insurance Policy for Clinical trial
6. Exhibit F- DCGI CT-NOC
7. Exhibit G- EC Registration Letter

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Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

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Exhibit B

(Budget and Payment Schedule)

Total duration of Study		**3 months**	
Subject enrollment duration		**12 months**	
Total number of subjects		**10**	
		Visit 1,2 3 & 4	Total
Professional Fee	**PI and CO-I**	10,000	10,000
Fees	**Coordinator Fees**	7,000	7000
Fees	**Study Nurse**	7000	7,000
Institutional Overhead	**25% of Professional Fee**	6000	6,000
Patient Related expenses	**Including Travel @1000 per visit**	1,2a,2b,3,4	5,000
Total			
Estimated Total Cost per trial Subject			35,000
Estimated number of trial Subject in 2 months			5
Estimated total of all subjects			1,75000

- The payment shall be made visit wise.
- First 8 patients enrolled in the study will be evaluated for safety at Day 15 (Visit 2a-Day 15±2) assessment visit.

Payee Details

Payee Name	**Sameer Mahammadali Haveri**
Name of the Bank & Branch	**State Bank Of India**
A/C No:	**33052509079**
IFSC	**SBIN0008789**
MICR	**590002008**
PAN No./TAN No,	**ADKPH3464L**
GST (if applicable)	**NA**

Dr. Sameer Haveri
Consultant Orthopaedics
KMC Reg. No. 68382
KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

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Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

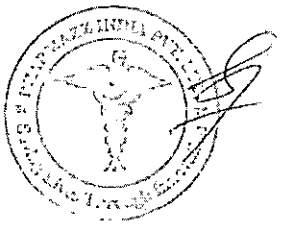

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Exhibit-D

Site Feasibility Questionnaire

REFERENCE ENCLOSED

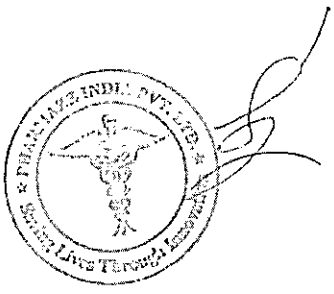

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Exhibit-E

Insurance Policy for Clinical Trial

REFERENCE ENCLOSED

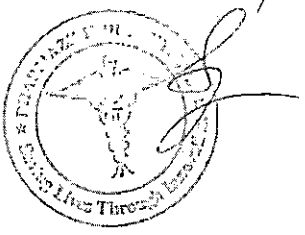

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Exhibit-F

DCGI CT-NOC Letter

REFERENCE ENCLOSED

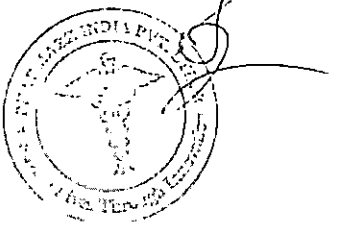

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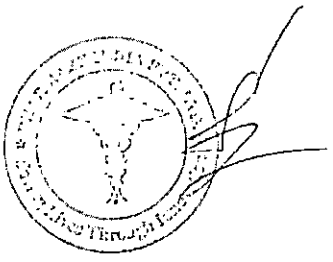
Exhibit-G

EC Registration letter

REFERENCE ENCLOSED



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Page 30 of 30

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA67316568538350R
Certificate Issued Date	:	06-Mar-2019 03:15 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM30/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0866560550075048R
Purchased by	:	Dr SAMEER HAVERI
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Dr SAMEER HAVERI
Second Party	:	MD AND CE KLES DR PRABHAKAR KORE HOSPITAL BELAGAVI
Stamp Duty Paid By	:	Dr SAMEER HAVERI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Issued by
The Judicial Employees
Co-operative Credit Society Ltd.
Dist. Court Compound, Belagavi

Authorised Signatory

Please write or type below this line

TO,

THE MD & CE,

KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,

NEHRU NAGAR, BELAGAVI-590010

SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE CLINICAL TRIALS AND RESEARCH PROJECT BY DR. SAMEER HAVERI

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid
2. The onus of checking the legitimacy is on the users of the certificate
3. In case of any discrepancy please inform the Competent Authority

Sir,

I **Dr.Sameer Haveri** the undersign is Principal investigator for the clinical trial "A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury." I have co-investigator is Dr. PrakashMahantshetti and Research Coordinator is Ms. Seema Khanagaonkar.

I hereby give an undertaking that I will conduct the investigations/clinical trials as per the agreed terms and deposit 25% of the total funds (as and when received from time to time) to the second party (Medical Director & CE KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi) to the institution as mentioned in the Judicial agreement made. The payment due will be paid within 3 to 4 working days on receipt of the payment from the sponsors.

I will maintain records of all the receipts from the third party as well as payments to the second party throughout the trial period and submit a final report about the finances including institutional charges, when I conclude the trial.

Date: 11-03-2019

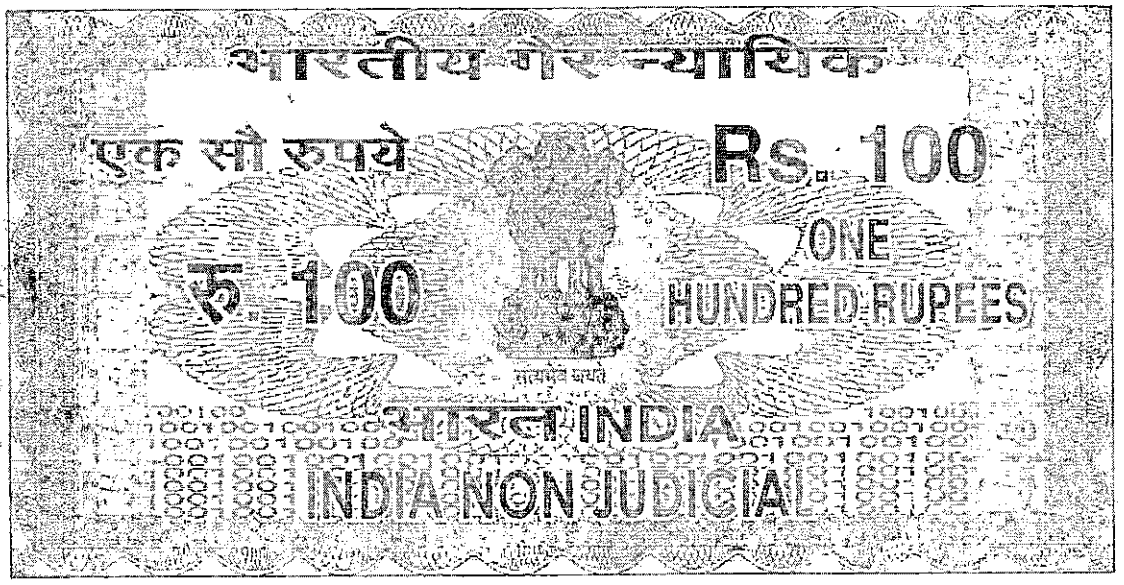
Place: Belagavi

Signature of PI

Dr. Sameer Haveri
Consultant Orthopaedics
KMC Reg. No. 68382
KLES Dr. Prabhakar Kore Hospital &
MRC, Belagavi.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



महाराष्ट्र MAHARASHTRA 2018 TR 670010

जिल्हा कोषागार कार्यालय, लातूर
25 JUL 2018
मुद्रांक प्रमुख लिपीक / लिपीक

PRODUCT CODE:	**HOE901/AVE0010–INSULIN GLARGINE/LIXISENATIDE**
STUDY CODE:	**INSLIL08556**
STUDY NAME:	**LixiLan India**

INVESTIGATOR/INSTITUTION/SMO CONTRACT

Site Name & City : KLES Dr Prabhakar Kore Hospital & Medical Research, Belgaum

Study Code/ Name: INSLIL08556 / LixiLan India

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

ATTESTED

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Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

This Contract (hereinafter "the Contract") is made on 2nd day of August 2018, by and among:

DOCTOR VIKRANT GHATNATTI, having his address at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi – 590010, Karnataka, India.

Hereinafter the "**INVESTIGATOR**",

AND

KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE, having its address at Nehrunagar, Belgaum (Belagavi) - 590010, Karnataka, India represented for the purposes hereof by Dr. M. V. Jali, MD & CEO

Hereinafter the "**INSTITUTION**"

AND

GDD EXPERTS (INDIA) PVT.LTD having its address at Ground Floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur – 440001, Maharashtra India represented for the purposes hereof by Dr. Vinod Gyanchandani, Head Clinical Operations

Hereinafter the "**SMO**",

AND

~~SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED~~, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial LixiLan-India: A **randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin** (hereinafter the « Study ») to evaluate Sanofi drug **HOE901/AVE0010–INSULIN GLARGINE/LIXISENATIDE** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol **INSLIL08556 (LixiLan-India)** and its amendments (hereinafter collectively the «Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care;

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Endocrinology, and

WHEREAS, the SMO is a site management organization which specializes in providing the services of clinical research coordinators, management of funds of the INSTITUTION at the clinical studies/trials sites and is responsible for Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management of **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belgaum.** All clinical responsibilities towards patient care has been accordingly subcontracted to the SMO who is responsible for such activities on a non-profit basis and has accordingly provided the SPONSOR a certificate, a copy of which is attached hereto as "**Annexure 1**", and

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WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE, Nehrunagar, Belgaum (Belagavi) - 590010, Karnataka, India.** The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for

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5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **17** Subjects (the «Subjects »), within **8 MONTHS**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g.,__ x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

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ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION and the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/

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INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

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ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

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(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

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(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR, the INSTITUTION or the SMO is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR, the INSTITUTION or the SMO to the SPONSOR.

17.4 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

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The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for

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public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No

variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason. IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		[Signature]	
[Name]	Dr. Chirag Trivedi	[Name]	Dr. Vikrant Ghatnatti
[Title]	Clinical Study Unit Director	[Title]	Consultant Endocrinologist
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	Y. J. Cama	[Name]	Amey A Coonkar

INSTITUTION **KLES Dr Prabhakar Kore Hospital & Medical Research**		**SMO** **Global Drug Development (GDD)Experts GDD EXPERTS (INDIA) PVT.LTD.**	
[Signature]		*[Signature]*	
[Name]	Dr. M.V. Jali	[Name]	Dr. Vinod Gyanchandani
[Title]	MD & CEO	*[Title]*	Head Clinical Operations
In presence of		In presence of	
[Signature]		*[Signature]*	
[Name]	Akshay Thombare	*[Name]*	Dr. Pradnya Mahajan

ATTESTED

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Belagavi-590 010,Karnataka

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 04th July 2018

1) The SPONSOR will pay **Rs.1,87,000/- (Rupees One Lakh Eighty Seven Thousand only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

Such amount is divided as follows:

• - Per Subject Cost Details			
Visits	**Investigator Fees**	**Site Coordinator Fees***	**Subject reimbursement (for travel, meals during site visit)**
Visit 1 (Screening Phase)	7000	5250	1200
Visit 2 (Run In Phase)	7000	5250	1200
Visit 3 (Run In Phase)	3000	2250	
Visit 4 (Run In Phase)	3000	2250	
Visit 5 (Run In Phase)	6000	4500	1200
Visit 6 (Base Line)	11000	8250	1200
Visit 7	3000	2250	
Visit 8	5000	3750	1200
Visit 9	3000	2250	
Visit 10	5000	3750	1200
Visit 11	3000	2250	
Visit 12	3000	2250	
Visit 13	5000	3750	1200
Visit 14	3000	2250	
Visit 15	6000	4500	1200
Visit 16	3000	2250	
Visit 17	6000	4500	1200
Visit 18	3000	2250	
Visit 19 (End of Treatment Visit)	12000	9000	1200
Visit 20 (Post Treatment Follow up Visit)	3000	2250	
TOTAL	**100000**	**75000**	**12000**
			187000
Admin Cost (Files, Internet, Telephone charges etc	Rs.3000 per month from SIV		
Study Set UP	Max Rs.25000	Will be reimbursed on Actuals	
Study Set Up (Initiation efforts)	Max Rs.25000		
Study Closure and Archival for 15 years	Max of Rs.200000		

In case Premature EOT visit following payment terms will be followed for all subsequent visits

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Type of Visit (On-site / Telephonic Visit)	Investigator Fees	Coordinator Fees	Patients Transport
End of Treatment Visit, Onsite	8000	6000	1200
Post Treatment Follow Up visit, Telephonic	3000	2250	0
Telephonic Visits	1500	1125	0
On-Site Visits	3000	2250	1200

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.
**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.15,000/- (Rupees Fifteen Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) A onetime start-up fee of Rs.25,000/- (Rupees Twenty Five Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

7) A close out fee of Rs.2,00,000/- (Rupees Two Lakhs only) will be paid towards close out efforts once the site close out visit has been conducted.

8) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

9) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

10) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

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In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION/PAYEE on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

Investigator's payment to be paid to:

•	Bank Name & Branch:	**Axis Bank Ltd, Nagpur**
•	Bank IFSC	**UTIB0001537**
•	Account No.:	**910020034162231**
•	PAYEE:	**GDD EXPERTS (INDIA) PVT.LTD.**
•	PAN No.:	**AADCG0363Q**
•	GST No.:	**27AADCG0363Q1ZA**

25% of Institutional Over Heads (IOH) payment to be paid to:

Bank Name & Branch:	**Canara Bank KLE Hospital Belagavi-590010 Karnataka India**
Bank IFSC	**CNRB0008515**
Account No.:	**8515106000008**
PAYEE :	**Medical Director & CE KLES Hospital Belagavi**
PAN No.:	**AAATK2644N**
GST No.:	**29AAATK2644N6Z3**

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

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<u>**Annexure 1**</u>

GDD Experts India Private Limited

[illegible]

<u>Annexure 1</u>

<u>TO WHOMSOEVER IT MAY CONCERN</u>

THIS IS TO CERTIFY that GDD EXPERTS (INDIA) PVT. LTD. is responsible for Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management for investigator fee for the trial conducted in KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belgaum. All clinical responsibilities towards patient care has been [illegible] subcontracted to GDD EXPERTS (INDIA) PVT LTD who is responsible for such activities on a non-profit basis.

All Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management related Investigator's Fees shall be credited to "GDD EXPERTS (INDIA) PVT. LTD" as per following details:

Bank Name & Branch	Axis Bank Ltd, Nagpur
Bank IFSC	UTIB0000048
Account No.	910020034162231
PAYEE	GDD EXPERTS (INDIA) PVT LTD.
PAN No.	AADCG0363Q
GST No.	27AADCG0363Q1ZA

Signed for & on behalf of

GDD Experts India Private Limited

Head Off: 1707 L ST NW, SUIT 1020, Washington, DC 20036

Site Name: KLES Dr Prabhakar Kore Hospital & Medical Research, Belgaum

Study Code / Name: INSLIL08556 \ LixiLan India

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

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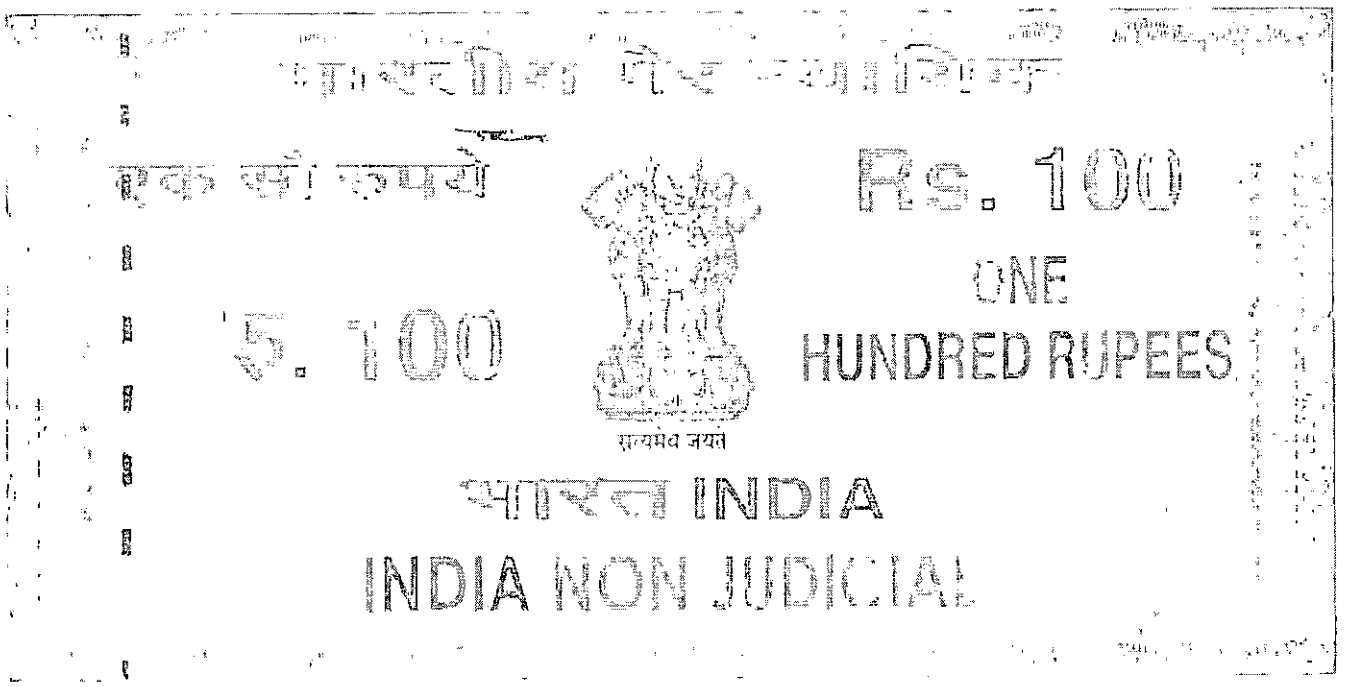

తెలంగాణ तेलंगाना **TELANGANA**

M 552677

Sl.No. 3453 Date: 04/08/2018

SOLD TO : B. Anji Reddy S/o. Obulu Reddy, R/o Hyd

FOR WHOM : M/s. Axis Clinicals Limited, Miyapur, Hyd.

MOHD ABDUL RAWOOF
LICENCED STAMP VENDOR
LIC. No. 16-04-13/2016
H.No.8-4-369/748/B, NRR Puram Colony,
Site-III, Borabanda, HYDERABAD-18.
(SOUTH) DISTRICT. Phone No..9948287671

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into as of this day of _____ (the.**66 (Part) & 67 (P** "Effective Date"), by **AXIS Clinicals Ltd having registered office situated at 1-121/1, Sy. Nos art), Miyapur, Serilingampally , Hyderabad 500049,** [hereinafter referred as **"AXIS"**] acting as an independent contractor for **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)** a company with offices located Sy No: 550,551& 552, Kolthur (Village), Shameerpet (Mandal) R,R (District) Telangana (State)-5000078- India [hereinafter referred as **"Sponsor"**].

And

Dr.Mahesh Kalloli [hereinafter referred to as **"Principal Investigator"**] employee/ affiliate of **KLE's Dr. Prabhakar Kore Hospital** [hereinafter referred to as **"Institution"**] located at Nehru Nagar, Belagavi-590 010, Karnataka, India.

And

KLE's Dr. Prabhakar Kore Hospital whose principal place of business is. at Nehru Nagar, Belagavi-590 010, Karnataka, India .**(Hereinafter** referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administration, execution, assigns & successetion-in-interest).

Investigator and institute shall hereinafter be collectively referred to as the ***"Site"***.

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WHEREAS, the Site has personnel and facilities for carrying out the Study Number: CR178-17 entitled "**A Multicentric, Open Label, Randomized, Two-Treatment, Two-sequence, Two-period, Cross-over, Multiple dose, Steady-state Clinical Bioequivalence Study of Everolimus 10 mg tablets of Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) (Test) with Afinitor® (Everolimus) 10 mg tablets of Novartis Pharmaceuticals Corporation, USA (Reference) in advanced renal cell carcinoma (RCC) patients under fasting conditions**" described in study protocol.

WHEREAS **Sponsor** is desirous of engaging the said Site for carrying out the Study through **AXIS**

NOW, THEREFORE, in consideration of the premises and the covenants and agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

DEFINITIONS

"Study" means the clinical study of the test for the SPONSOR conducted through and under control of AXIS and conducted at Site as specifically identified in this Agreement.

"SPONSOR'S Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of **SPONSOR or SPONSOR's** Affiliates that are: (1) provided to Sites in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigation, or Study Staff in connection with the Study (except for a Study patient's medical records); and (3) cumulative Study data, results, and reports generated from all sites conducting the Study.

"Investigator/s" means the individual(s) responsible for the conduct of the Study at Site and for direct supervision of Study Staff.

"Study Staff" mean the individuals providing services on behalf of Site with respect to the Study at Site, including without limitation sub-investigator, study coordinator, and other Site employees, agents, or subcontractor.

"Invention" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigator, or Study Staff: (1) in connection with the Study; or (2) which incorporate **SPONSOR** Confidential Information.

"Study Timelines" means the Enrollment date, End Date, the Visits Completed Date and the eCRF Target Date set out in Section I of this Agreement.

"Study Supplies" means Study drug(s) and related devices, equipment (if required), or other trial supplies provided by AXIS/Sponsor for the conduct of the Study.

"Protocol" means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

"eCRF or Electronic Case Report Form" means electronic document designed to record all of the protocol required information to be documented and reported on each patient.

"Test" means **A Multicentric, Open Label, Randomized, Two-Treatment, Two-sequence, Two-period, Cross-over, Multiple dose, Steady-state Clinical Bioequivalence Study of Everolimus 10 mg tablets of Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) (Test) with Afinitor® (Everolimus) 10 mg tablets of Novartis Pharmaceuticals Corporation, USA (Reference) in advanced renal cell carcinoma (RCC) patients under fasting conditions.**

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"Data" shall mean all information, reports, records, and document provided and /or generated under this agreement excluding patient hospital medical records (case sheets). Data shall be the sole and exclusive property of **Sponsor.**

1. STATEMENT OF WORK

The Site has study staff, other personnel and facilities for carrying out the Study in strict compliance with any and all applicable Central, State, and Local laws, Regulations and Guidelines, Good Clinical Practices, all requirements of the host institution or facility, and any other relevant professional standards, and specifically to conduct the Study in accordance with the 'Undertaking by the Investigator' and Protocol, which Principal Investigator has read, gone through in detail, discussed with AXIS signed, and delivered to AXIS prior to the commencement of the Study at the Site.

The Principal Investigator shall use his or her best efforts to recruit only qualified participants as per Inclusion and Exclusion criteria and shall not knowingly enroll any participants, which in his or her best professional judgment do not adequately meet the criteria for qualified participants.

The following plan will apply to the Study:

(1) The maximum allowed enrollment at a site is 5 Patients with Advanced Renal Cell Carcinoma (as mutually agreed between Axis and Site) shall be completed on or before four (4) months from the date of site initiation. However, if the Site is unable to enroll patients for the study within one month of initiation, AXIS will be having the authority to determine the enrollment number in a unilateral manner.
(2) Institution or Investigator may enroll more study patients than Institution's allotted Enrollment number after having a written communication with AXIS. .
(3) All patient visits will be completed no later than Five (5) months from the date of site initiation. This condition may be relaxed in case of exceptional circumstances which may be the sole discretion of AXIS / Sponsor.
(4) Source Documents, Electronic Case Report Forms ("eCRF") and other information associated with a patient's visit must be satisfactorily completed. If applicable, receipt of the patient's test results.
(5) All data Queries from SPONSOR/AXIS must be clarified completed and responded to AXIS/SPONSOR within a time frame mutually negotiated not more than 96 hours and/ or acceptable with AXIS.
(6) Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or study team will not be the liability of AXIS.

AXIS/ SPONSOR will provide Principal Investigator with a sufficient quantity of study supplies to conduct the study at investigational site as per the study requirement in timely manner. Site shall use study supplies only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Supplies,; and shall handle, store, and ship or dispose of Supplies in compliance with all applicable Local, State and Federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator will not charge any payment to Study patient or third-party to pay for any Supplies, or for Study procedures for which payment by AXIS has or will be made under this Agreement. All study supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of SPONSOR/AXIS, unless otherwise designated. The institution and principal investigator will be responsible for the return of excess, unused study supplies to the SPONSOR/ AXIS.

2. PAYMENT

In consideration for conducting the Study, AXIS shall pay Site as described in Exhibits A. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of AXIS's payment obligations are conditioned upon Site's compliance with standards identified in this Agreement. AXIS will not make payments, or, if payment has been made by AXIS, Site will repay to AXIS any payments, for study visits, procedures, or other work associated with a Study patient if AXIS determines that the patient's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

ATTESTED

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Payment will be released within 30 days from the date of receipt of two copies of original invoices duly signed and printed on letter head of the Institution with seal as per format provided by Axis Clinicals Ltd.

AXIS shall pay on a per patient basis for each Satisfactorily Completed Patient (as defined below) in accordance with Exhibits A. attached to this Agreement.

"Satisfactorily Completed patient" shall be one in which a patient is a Qualified Participant (as per inclusion/exclusion criteria), has completed the specified Study period, and has been evaluated in accordance with the Protocol. If a Patient is discontinued for reasons stipulated in the Protocol, the Site shall be paid a prorated rate for extent of participation.

Per Patient Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Exhibits A. The estimated total amount per patient listed in the Per Patient Budget is calculated for a patient that completes all the study visits. Screening Visits are paid for consented patients for whom all screening procedures are performed. All visit costs include institutional overhead, staff fees and applicable taxes.

A completed and evaluable patient defined as:

- All procedures must be performed and bound to be completed according to protocol
- A patient will only be included according to inclusion and exclusion criteria
- All data documented accurately and completely
- All data queries resolved completely in mutually agreed timely manner
- All source, eCRF and other study related documents completed as per good documentation practices / AXIS standard requirements. No document will be considered if AXIS requirements are not complied for completed and evaluable patient.

Per patient costs is a fixed fee which includes all costs and honoraria, including but not limited to:

- All study related activities such as conduct of visit assessment and eCRF completion
- Time and efforts of Principal Investigator/s and other Site personnel
- All manpower cost who are involved in the study conduct
- Housing or hospital stay for patients including meals
- patient reimbursement/ Compensation
- All over head costs of Institutions.
- Usage of Instruments/ equipments which during the study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Site infrastructure)

Screen Failures/ Drop-outs: A maximum of One (1) patient per Site will be allowed for screen failures. For drop-outs payment will be made on a prorated basis for the number of completed visits. This amount will be paid at the time of final payment.

Set-Up Fees: AXIS will pay to the PI an upfront initial advance amount of INR 100,000/- at least 15 days before initiation of the study after successfully obtaining the approval from Institution Ethics Committee & Drug controller General of India. This up-front advance payment would be deducted/ adjusted on pro-rata basis from further subsequent payments. In case the site is unable to enroll any patients, the PI will refund the site set up fees along with the TDS amount deducted (INR 90000/- [Original] + INR10000/- [TDS] to AXIS Clinicals Limited by cheque in the name of AXIS Clinicals Limited with a period of –days from the last date to enrollment or any other dates as mutually decided by the parties. AXIS Clinicals will also provide the confirmation in writing for the deduction of TDS if requested by the Site and will provide Form-16A at the end of current financial year.

Additional Testing, Treatment or Procedures: Reimbursement will not be made for any additional testing, treatment, or procedures not required by the Protocol, unless such additional testing, treatment or procedures are pre-approved by AXIS/ Sponsor in writing.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Patient Travel Reimbursement: Subject reimbursement will be done as per the details mentioned in Exhibits A. AXIS will release the funds to Site for each subject, i.e., **INR 15000/-** (fifteen thousand rupees only) on completion of 6 visits. However, it will be the obligation of Principal Investigator to pay the subject reimbursement on a pro rata basis **(INR 1250/-** per visit) at the end of study. A receipt will be provided by the Institution for amount paid to subject in a specified format supplied by AXIS/Sponsor on the letterhead of the Institution.

Hospitalization costs: Apart from study specific in-house, per actual, in the event of any Serious Adverse Event (SAE).

EC Fees: EC review fees will be reimbursed as per actual.

Payee name	Registrar, KLE Academy of Higher Education and research, Belagavi.
PAN Number	AABTK0881E
EC initial Review Fee (Excluding TDS)	82,500
EC Amendment Review Fee (Excluding TDS)	20000

Payments shall be directed as follows:

Investigator Fee/ Subject Reimbursement and Hospitalization:

Payee Name (Account name)	CMS Clinical Research Pvt. Ltd.
Account Number	50200007478582
Bank Name	HDFC Bank
Branch Name	Nacharam, Hyderabad
Swift/IFSC Code	HDFC0000368
PAN Number*	AAFCC8457M
Send to	CMS Clinical Research Pvt. Ltd., E-285, 1st Floor (M -Block Road) Greater Kailash Part-2, New Delhi -110048
#GST No.:	09AAFCC8457M1ZZ

* Payee should provide a copy of PAN Card.
TDS will be deducted as per Statutory norms.
In case of Govt. of India will implement any other Tax regimen, the same will be implemented in due course of time without amending the Clinical Trail Agreement (CTA).

KLE's Dr. Prabhakar Kore Hospital will raise Invoice as per the statutory requirement for each 1 patient completed according to actual work performed (Number of Days completed in the study site, eCRF completion, source data verification and eCRF review for completed visits). Advance paid will be adjusted against the subsequent payments.

In the event there is a refund due to AXIS at the time of premature termination by either party, the Principal Investigator agrees to remit the same to AXIS within fifteen (15) days of the date of effective termination. .

Tax deduction: All fees and amounts except patient reimbursement and otherwise specifically listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the institution for the study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year. Reimbursement of charges like CT scan,

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ECG, X-ray or any other tests / analysis charges if any will be reimbursed in actual in case they have been outsourced to the outside vendor by the study site.

In case the ECG, X-ray or any other tests/analysis charges will be carried out in **KLE's Dr. Prabhakar Kore Hospital** Itself, then TDS amount will be deducted as per the applicable requirement. All the payments will be done against the invoice/s that has been generated from sites in the name of AXIS Clinicals Limited.

3. ETHICS COMMITTEE APPROVAL

The Principal investigator shall be responsible for obtaining approval of the protocol, related study documents and study conduct at the Site before initiation of the study.

Site also represents and warrants that EC registration and re-registration with Central Drug Standard Control Organization (CDSCO) and they have obtained and will maintain the required authorization from the Ethics Committee and any other required forms fully complying with the applicable regulations.

4. PROPRIETARY INFORMATION AND CONFIDENTIALITY

Sponsor shall have sole ownership of intellectual property developed in the Study by Investigators supported through Study funds. The Site shall disclose to AXIS\Sponsor all inventions and other creative ideas and developments conceived or reduced to practice as a direct result of this Study. Such disclosure shall be made fully and promptly in writing to AXIS. All documents, data, know-how, formulas ("Data"), and unused drug provided to the Site for purposes of the Study are and will remain Sponsor's property and will be returned to Sponsor or their designate upon request.

SPONSOR/AXIS Confidential Information and all tangible expressions, in any media, of SPONSOR/AXIS Confidential Information are the sole property of SPONSOR/AXIS.

Institution agrees not to use SPONSOR/AXIS Confidential Information for any purposes other than to conduct the Study. Institution agrees not to disclose SPONSOR/AXIS Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard SPONSOR/AXIS Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

The obligation of non-disclosure and non-use shall not apply to the following.

(1) Information, which at the time of disclosure hereunder, is generally available to the public;
(2) Information, which after disclosure hereunder, becomes generally available to the public, except through breach of this Agreement;
(3) Information that the Institution can demonstrate was in its possession at the time of disclosure by Sponsor and that was not acquired, directly or indirectly, from Sponsor;
(4) Information that becomes available to the Institution from a third party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Sponsor; or
(5) Information that is required by law to be disclosed to representatives of a Governmental Agency and to which they are entitled when engaged in the proper performance of their duties.

The Investigator agrees to keep all aspects of the trial confidential. This includes the nature of the trial, the protocol and its attached forms as well as data generated by the trial.

The obligations of this Section shall survive till the termination of this Agreement.

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5. HANDLING INVESTIGATIONAL PRODUCTS

The Investigator agrees to exercise adequate care in the application and handling of Investigational products. The Investigator agrees to utilize test drug solely in accordance with
the protocol and to return to Axis/ Sponsor the unexpended test drug unless directed by AXIS/ Sponsor/ contracted third party vendor to do otherwise.

6. SERIOUS ADVERSE EVENT REPORTING

The Principal Investigator shall fully comply with adverse event assessment and reporting criteria as per the provisions of the Protocol. In the event of any omission of such provisions or in the event of the conflict of such provisions with the Regulations, then the Regulations shall apply in relation thereto.

The Principal Investigator shall also notify the IEC immediately of any Serious Adverse Events during the Study in accordance with the current existing regulations.

In the event of SAE injury, patients will be provided free Medical management as long as required by **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)**In the event of study related injury or death, **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)**, will provide complete medical care and financial compensation for injury or death as per current applicable regulatory requirements.

Investigator must report within 24 hours of learning of any AE that meets one of the criteria for an SAE, with pre printed SAE form provided by the AXIS as per Appendix XI of Schedule Y compliance notifying to SPONSOR/AXIS Clinicals, Licensing authority and ethics committee. SPONSOR/AXIS Clinicals with investigator shall send SAE report after due analysis to Licensing authority, ethics committee, expert committee of licensing authority (in case of death only) and head of the institute where trial is being conducted within 14 calendar days. Investigator shall ensure that ethics committee shall send SAE report and its opinion on financial compensation within 30 days after occurrence of SAE to the licensing authority. Sponsor shall pay compensation as per the orders by licensing authority within 30 days after receiving the opinion from DCGI regarding compensation of the SAE. A follow up report shall be sent to SPONSOR/AXIS Clinicals, Licensing authority, expert committee licensing authority and head of the institute where trial is conducted as per regulatory requirements, which shall include outcome and treatment provided. If, during follow-up, any non-serious AE worsens and eventually meets the criteria for an SAE, that AE should be recorded as a new SAE.

7. USE OF OTHER PARTIES' NAMES

The Site shall not use SPONSOR's or AXIS's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ AXIS.

8. INDEPENDENT CONTRACTORS

Site shall perform services under this Agreement only as an independent contractor, and nothing contained herein shall be construed to be inconsistent with that relationship or status. This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

9. INSURANCE AND INDEMNIFICATION

INSURANCE:

Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon AXIS's request, Institution shall have its insurance carrier (or shall cause the medical

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professional to have his or her insurance carrier) furnish the certificate to AXIS that all insurance required under this Agreement is in force.

INDEMNIFICATION:

SPONSOR shall indemnify the investigator and institution (including principal investigator's and institution's affiliates, contractors, agents, fellows, employees and servants collectively "Indemnity") for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against investigator or institution arising directly out of the performance of the study pursuant to the protocol; provided however,

- SPONSOR will not indemnify any Indemnity for Loss to the extent and the Loss arose out of an Indemnity's failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a patient's safety or well-being and which were communicated to and accepted by AXIS/Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;

- SPONSOR will not indemnify any Indemnity for Loss to the extent the Loss arising out of the negligence or wrongful acts or omissions of an Indemnities or any other person patient to an Indemnities control;

10. MONITORING; AUDIT; REGULATORY INSPECTIONS

The Site shall, permit authorized personnel of the SPONSOR/ SPONSOR designee, AXIS and any Regulatory Authority including Ethics Committee to inspect the facilities the Site proposes to use for the Study; before, during and after the Study. There will be AXIS and sponsor audits during the study apart from the monitoring visit as per the mutually agreed dates

The Site shall notify AXIS or Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, European or any other governmental or regulatory authority requests permission to or does inspect the Site's facilities or research records relating to this Study whenever and will provide in writing to AXIS copies of all materials, correspondence, statements, forms and records which the Site receives, obtains, or generates pursuant to any such inspection.

The Site will permit to Sponsor/Axis/USFDA/DCGI other regulatory authorities

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
b) Inspect and copy all data, documents and records related to such work and the study

The obligations of this Section shall survive termination of this Agreement.

11. TERM; WAIVER; SEVERABILITY

Unless earlier terminated in accordance with the provisions of this Agreement, the term of this agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date.

This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Agreement.

This Agreement may be terminated by either party upon giving at least a thirty (30) days notice to that effect to the other party. A reasonable adjustment will be made between the parties to ensure the Site is reimbursed for project costs incurred to the date of termination of this Agreement. Any funds paid by AXIS to the Institution in excess of project costs will be returned to the AXIS.
AXIS or SPONSOR may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by either AXIS or SPONSOR that the Study is terminated shall also constitute effective notice of termination of this Agreement.

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12. EFFECT OF TERMINATION

(1) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall cease enrolling patients into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(2) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which AXIS has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, AXIS has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, AXIS may deduct/adjust an equivalent amount from any payment then or later due from AXIS to Institution under this or any other arrangement between the parties.

(3) Upon termination of this Agreement, all unused Materials and all SPONSOR Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to SPONSOR at SPONSOR's expense, or, at SPONSOR's option, destroyed with the destruction must be certified in writing.

13. AMENDMENT

This agreement and protocol may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. The parties agree that this agreement constitutes the sole, full and complete agreement by and between the parties and supersedes all other written and oral agreements and representation between the parties with respective to the study. No amendments, changes, additions, deletions, or modifications to or of this agreement shall be valid unless reduced to writing and signed by the parties.

All changes and amendments to this agreement shall be agreed in writing between the parties.

14. RECORDKEEPING/ DOCUMENT ARCIVAL/ AND INVESTIGATIONAL PRODUCT RETENTION

Investigational Product/s will be retained either at Site or Third party archival facility after having a mutually agreed decision with Sponsor, AXIS and Sites. The Investigational product will be re-packed and sealed as per the requirements and retained at the site / Third party facility. In case if the IPs are retaining at third party facility, Site and Third party will have one agreement for the transfer of IP as per the required conditions. The payments towards the maintenance of retained samples at third party facility will be paid by AXIS on the receipt of Invoice from Third party. The Archival Charges for retaining the samples at the sites if any will be mentioned in the CTA and will be paid in due course of time. In case of retrieval requirement for the regulatory authority site will inform first to AXIS by mail requesting for the retrieval of IP, after obtaining the response from AXIS site will inform the Third party facility about the retrieval as per the procedure. Any charges related to retrieval of the IPs/ documents AXIS will reimburse the same to the Third party facility against proper Invoice. Under no other circumstances sites will be having any authority related to retrieval of retained IP/documents at any time.

Institution or investigator shall ensure the storage of data related to study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the applicable laws and regulations in INDIA or until at least 15 years after completion of all regular site close out activity, whichever period is longer, unless to the extent that AXIS/ SPONSOR require the return or destruction of this data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such data, sponsor/Axis written approval shall be obtained.

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Study documents will be maintained for Two years (2) at site after completing Site Close-out visit. Then the documents will be shipped to Third party or Axis Clinicals for archival for period of 15 years after having mutually agreed decision with sponsor and AXIS. Site will be not paid for the archival for these Two years.

15. DISCLAIMER

The Site acknowledges that the Sponsor has engaged AXIS to manage the Study. AXIS has performed no independent research or analysis regarding the safety or efficacy of the Investigational Product, materials or treatment procedures that are to be administered pursuant to the Study and therefore AXIS makes no warranties, expressed or implied concerning the Investigational Product, materials, treatment procedures, results to be obtained in administering the Investigational Product, or the Investigational Product's fitness for any particular purpose.

16. PUBLICATION

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the clinical study is the sole property of the sponsor. Therefore, Principal investigator agrees not to publish or present the results or any information derived from the study.

17. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by and interpreted in accordance with the laws of India, without conflict of laws or principles. Any dispute between the Parties as to construction, meaning or effect of the Agreement or any clause contained therein or the rights, duties, liabilities and obligations of either Party there under, shall be resolved mutually within thirty days, failing which, shall be referred to arbitration before a sole arbitrator appointed by the Parties. The arbitration proceedings shall be conducted in accordance with the Arbitration and Conciliation Act, 1996 and rules made thereof in Hyderabad. The arbitration proceedings shall be conducted in the English language. The arbitrators' decision shall be final and legally binding and judgment may be entered thereon before the courts of competent jurisdiction. The arbitrator shall also decide on the costs of the arbitration proceedings.

IN TESTIMONY WHEREOF, the parties hereto have caused this instrument to be executed, in duplicate, by their officers, thereunto duly authorized to sign on behalf of the party.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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1. Principal Investigator

Represented by (Name) ; Dr.Mahesh Kalloli

Title : Surgical oncologist

Signature and date : 20/8/18

2. AXIS Clinicals Ltd

Represented by (Name) : Mr. Phani Bushan Reddy

Title : Executive Director

Signature and date : 21/08/18

Witness

Represented by (Name) : Dr. Subhra Lahiri

Title : Associate Vice President

Signature and date : Subhra Lahiri 21/08/18

3. KLE's Dr. Prabhakar Kore Hospital

Represented by (Name) :

Title :

Signature and date : 27/8/2018

Witness

Represented by (Name) : Revanna S Devarinti

Title : Assistant Coordinator

Signature and date :

4. CMS Clinical Research

Represented by(Name) : Nidhi

Title : Head Clinical Operations

Signature and date : 20/8/18

Witness

Represented by (Name) : Shivaprakash

Title : CRC

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EXHIBIT A :

For each completed patient AXIS agrees to pay the site sum of INR **1, 30,040/- (One Lakh thirty thousand forty rupees Only)** to the payee name as mentioned above. . Hospitalization fees of **INR 30,000/-**(Thirty thousand rupees Only) perRs.**15000/-(Fifteen Thousand rupees Only) as patient reimbursement and travel allowance** In case of early withdrawal of Patients, the reimbursement can be provided on Pro-rata basis

Investigator Fees and Hospitalization charges confirmed are inclusive of applicable tax (TDS- Tax Deduction at Source). There will be no TDS deduction for the Subject reimbursement provided the voucher will be forwarded to Sponsor before claiming of the same.

For 1 to 5 patients

Description	Visit 1 (Screening)	Visit 2(day 0) Randomization	Visit 3(Day 11,12,13)	Visit 4 (Day 14 &15	Visit 6 (Day 25,26,27)	Visit 7 Day 28 &29)	Total
PI Cost	9000	3500	10000	12000	10000	10000	54500
Sub-I Cost	3000	2000	3000	3000	3000	3500	17500
Study Coordinator	2500	1000	2000	2000	2500	2000	12000
Phlebotomist	1200		1500	2500	2000	3000	10200
Study Nurse	500		500	500	500	500	2500
Hospitalization	0		9000	6000	9000	6000	30000
ECG	500		0	500	0	500	1500
Chest X-Ray	500		0	0	0	0	500
Overhead Charges (25%)	4050	1625	6500	6500	6750	6250	31675
Patient Compensation	1250	1250		5000		7500	15000
Total							1,75,375
From 6th to 10th Patients	Site will receive per Completed subject						2,00,000/-
From 11th to15th Patients	Site will receive Per Completed Subject						2,25,000/-

1. An Archival fee of Rs.15000/- will be paid during site closure only for 2 years archival of all the study documents in secure condition . Site should provide a declaration that the documents archived will be safe, traceable and will be retrieved any time during any Regulatory audit after informing the Sponsor – AXIS Clinicals only . In no other circumstances these documents will be withdrawn .
2. Investigator Fee includes the charges towards involvement of **Co-Investigator, Research Nurse, CRC & Phlebotomist** in the study
3. **GST will** be as per Govt. Norms (If applicable).

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भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

ONE HUNDRED RUPEES

₹. 100

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

తెలంగాణ तेलंगाना **TELANGANA**

M 552677

Sl.No. 3453 Date: 04/08/2018

SOLD TO : B. Anji Reddy S/o. Obulu Reddy, R/o Hyd

FOR WHOM : M/s. Axis Clinicals Limited, Miyapur, Hyd.

MOHD ABDUL RAWOOF
LICENCED STAMP VENDOR
LIC. No. 16-04-13/2016
H.No.8-4-369/748/B, NRR Puram Colony, Site-III, Borabanda, HYDERABAD-18. (SOUTH) DISTRICT. Phone No..9948287671

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into as of this day of _____ (the.**66 (Part) & 67 (P** "Effective Date"), by **AXIS Clinicals Ltd having registered office situated at 1-121/1, Sy. Nos art), Miyapur, Serilingampally , Hyderabad 500049,** [hereinafter referred as **"AXIS"**] acting as an independent contractor for **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)** a company with offices located Sy No: 550,551& 552, Kolthur (Village), Shameerpet (Mandal) R,R (District) Telangana (State)-5000078- India [hereinafter referred as **"Sponsor"**].

And

Dr.Mahesh Kalloli [hereinafter referred to as **"Principal Investigator"**] employee/ affiliate of **KLE's Dr. Prabhakar Kore Hospital** [hereinafter referred to as "Institution"] located at Nehru Nagar, Belagavi-590 010, Karnataka, India.

And

KLE's Dr. Prabhakar Kore Hospital whose principal place of business is, at Nehru Nagar, Belagavi-590 010, Karnataka, India .**(Hereinafter** referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administration, execution, assigns & successetion-in-interest).

Investigator and institute shall hereinafter be collectively referred to as the ***"Site"***.

ATTESTED

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WHEREAS, the Site has personnel and facilities for carrying out the Study Number: CR178-17 entitled "**A Multicentric, Open Label, Randomized, Two-Treatment, Two-sequence, Two-period, Cross-over, Multiple dose, Steady-state Clinical Bioequivalence Study of Everolimus 10 mg tablets of Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) (Test) with Afinitor® (Everolimus) 10 mg tablets of Novartis Pharmaceuticals Corporation, USA (Reference) in advanced renal cell carcinoma (RCC) patients under fasting conditions**" described in study protocol.

WHEREAS **Sponsor** is desirous of engaging the said Site for carrying out the Study through **AXIS**

NOW, THEREFORE, in consideration of the premises and the covenants and agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

DEFINITIONS

"**Study**" means the clinical study of the test for the SPONSOR conducted through and under control of AXIS and conducted at Site as specifically identified in this Agreement.

"**SPONSOR'S Confidential Information**" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of **SPONSOR or SPONSOR's** Affiliates that are: (1) provided to Sites in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigation, or Study Staff in connection with the Study (except for a Study patient's medical records); and (3) cumulative Study data, results, and reports generated from all sites conducting the Study.

"**Investigator/s**" means the individual(s) responsible for the conduct of the Study at Site and for direct supervision of Study Staff.

"**Study Staff**" mean the individuals providing services on behalf of Site with respect to the Study at Site, including without limitation sub-investigator, study coordinator, and other Site employees, agents, or subcontractor.

"**Invention**" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigator, or Study Staff: (1) in connection with the Study; or (2) which incorporate **SPONSOR** Confidential Information.

"**Study Timelines**" means the Enrollment date, End Date, the Visits Completed Date and the eCRF Target Date set out in Section 1 of this Agreement.

"**Study Supplies**" means Study drug(s) and related devices, equipment (if required), or other trial supplies provided by AXIS/Sponsor for the conduct of the Study.

"**Protocol**" means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

"**eCRF or Electronic Case Report Form**" means electronic document designed to record all of the protocol required information to be documented and reported on each patient.

"Test" means **A Multicentric, Open Label, Randomized, Two-Treatment, Two-sequence, Two-period, Cross-over, Multiple dose, Steady-state Clinical Bioequivalence Study of Everolimus 10 mg tablets of Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) (Test) with Afinitor® (Everolimus) 10 mg tablets of Novartis Pharmaceuticals Corporation, USA (Reference) in advanced renal cell carcinoma (RCC) patients under fasting conditions.**

ATTESTED

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"Data" shall mean all information, reports, records, and document provided and /or generated under this agreement excluding patient hospital medical records (case sheets). Data shall be the sole and exclusive property of **Sponsor.**

1. STATEMENT OF WORK

The Site has study staff, other personnel and facilities for carrying out the Study in strict compliance with any and all applicable Central, State, and Local laws, Regulations and Guidelines, Good Clinical Practices, all requirements of the host institution or facility, and any other relevant professional standards, and specifically to conduct the Study in accordance with the 'Undertaking by the Investigator' and Protocol, which Principal Investigator has read, gone through in detail, discussed with AXIS signed, and delivered to AXIS prior to the commencement of the Study at the Site.

The Principal Investigator shall use his or her best efforts to recruit only qualified participants as per Inclusion and Exclusion criteria and shall not knowingly enroll any participants, which in his or her best professional judgment do not adequately meet the criteria for qualified participants.

The following plan will apply to the Study:

(1) The maximum allowed enrollment at a site is 5 Patients with Advanced Renal Cell Carcinoma (as mutually agreed between Axis and Site) shall be completed on or before four (4) months from the date of site initiation. However, if the Site is unable to enroll patients for the study within one month of initiation, AXIS will be having the authority to determine the enrollment number in a unilateral manner.
(2) Institution or Investigator may enroll more study patients than Institution's allotted Enrollment number after having a written communication with AXIS. .
(3) All patient visits will be completed no later than Five (5) months from the date of site initiation. This condition may be relaxed in case of exceptional circumstances which may be the sole discretion of AXIS / Sponsor.
(4) Source Documents, Electronic Case Report Forms ("eCRF") and other information associated with a patient's visit must be satisfactorily completed. If applicable, receipt of the patient's test results.
(5) All data Queries from SPONSOR/AXIS must be clarified completed and responded to AXIS/SPONSOR within a time frame mutually negotiated not more than 96 hours and/ or acceptable with AXIS.
(6) Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or study team will not be the liability of AXIS.

AXIS/ SPONSOR will provide Principal Investigator with a sufficient quantity of study supplies to conduct the study at investigational site as per the study requirement in timely manner. Site shall use study supplies only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Supplies,; and shall handle, store, and ship or dispose of Supplies in compliance with all applicable Local, State and Federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator will not charge any payment to Study patient or third-party to pay for any Supplies, or for Study procedures for which payment by AXIS has or will be made under this Agreement. All study supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of SPONSOR/AXIS, unless otherwise designated. The institution and principal investigator will be responsible for the return of excess, unused study supplies to the SPONSOR/ AXIS.

2. PAYMENT

In consideration for conducting the Study, AXIS shall pay Site as described in Exhibits A. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of AXIS's payment obligations are conditioned upon Site's compliance with standards identified in this Agreement. AXIS will not make payments, or, if payment has been made by AXIS, Site will repay to AXIS any payments, for study visits, procedures, or other work associated with a Study patient if AXIS determines that the patient's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010,Karnataka

Payment will be released within 30 days from the date of receipt of two copies of original invoices duly signed and printed on letter head of the Institution with seal as per format provided by Axis Clinicals Ltd.

AXIS shall pay on a per patient basis for each Satisfactorily Completed Patient (as defined below) in accordance with Exhibits A. attached to this Agreement.

"Satisfactorily Completed patient" shall be one in which a patient is a Qualified Participant (as per inclusion/exclusion criteria), has completed the specified Study period, and has been evaluated in accordance with the Protocol. If a Patient is discontinued for reasons stipulated in the Protocol, the Site shall be paid a prorated rate for extent of participation.

Per Patient Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Exhibits A. The estimated total amount per patient listed in the Per Patient Budget is calculated for a patient that completes all the study visits. Screening Visits are paid for consented patients for whom all screening procedures are performed. All visit costs include institutional overhead, staff fees and applicable taxes.

A completed and evaluable patient defined as:

- All procedures must be performed and bound to be completed according to protocol
- A patient will only be included according to inclusion and exclusion criteria
- All data documented accurately and completely
- All data queries resolved completely in mutually agreed timely manner
- All source, eCRF and other study related documents completed as per good documentation practices / AXIS standard requirements. No document will be considered if AXIS requirements are not complied for completed and evaluable patient.

Per patient costs is a fixed fee which includes all costs and honoraria, including but not limited to:

- All study related activities such as conduct of visit assessment and eCRF completion
- Time and efforts of Principal Investigator/s and other Site personnel
- All manpower cost who are involved in the study conduct
- Housing or hospital stay for patients including meals
- patient reimbursement/ Compensation
- All over head costs of Institutions.
- Usage of Instruments/ equipments which during the study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Site infrastructure)

Screen Failures/ Drop-outs: A maximum of One (1) patient per Site will be allowed for screen failures. For drop-outs payment will be made on a prorated basis for the number of completed visits. This amount will be paid at the time of final payment.

Set-Up Fees: AXIS will pay to the PI an upfront initial advance amount of INR 100,000/- at least 15 days before initiation of the study after successfully obtaining the approval from Institution Ethics Committee & Drug controller General of India. This up-front advance payment would be deducted/ adjusted on pro-rata basis from further subsequent payments. In case the site is unable to enroll any patients, the PI will refund the site set up fees along with the TDS amount deducted (INR 90000/- [Original] + INR10000/- [TDS] to AXIS Clinicals Limited by cheque in the name of AXIS Clinicals Limited with a period of –days from the last date to enrollment or any other dates as mutually decided by the parties. AXIS Clinicals will also provide the confirmation in writing for the deduction of TDS if requested by the Site and will provide Form-16A at the end of current financial year.

Additional Testing, Treatment or Procedures: Reimbursement will not be made for any additional testing, treatment, or procedures not required by the Protocol, unless such additional testing, treatment or procedures are pre-approved by AXIS/ Sponsor in writing.

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Patient Travel Reimbursement: Subject reimbursement will be done as per the details mentioned in Exhibits A. AXIS will release the funds to Site for each subject, i.e., **INR 15000/-** (fifteen thousand rupees only) on completion of 6 visits. However, it will be the obligation of Principal Investigator to pay the subject reimbursement on a pro rata basis **(INR 1250/-** per visit) at the end of study. A receipt will be provided by the Institution for amount paid to subject in a specified format supplied by AXIS/Sponsor on the letterhead of the Institution.

Hospitalization costs: Apart from study specific in-house, per actual, in the event of any Serious Adverse Event (SAE).

EC Fees: EC review fees will be reimbursed as per actual.

Payee name	Registrar, KLE Academy of Higher Education and research, Belagavi.
PAN Number	AABTK0881E
EC initial Review Fee (Excluding TDS)	82,500
EC Amendment Review Fee (Excluding TDS)	20000

Payments shall be directed as follows:

Investigator Fee/ Subject Reimbursement and Hospitalization:

Payee Name (Account name)	CMS Clinical Research Pvt. Ltd.
Account Number	50200007478582
Bank Name	HDFC Bank
Branch Name	Nacharam, Hyderabad
Swift/IFSC Code	HDFC0000368
PAN Number*	AAFCC8457M
Send to	CMS Clinical Research Pvt. Ltd., E-285, 1st Floor (M -Block Road) Greater Kailash Part-2, New Delhi -110048
#GST No.:	09AAFCC8457M1ZZ

* Payee should provide a copy of PAN Card.
TDS will be deducted as per Statutory norms.
In case of Govt. of India will implement any other Tax regimen, the same will be implemented in due course of time without amending the Clinical Trail Agreement (CTA).

KLE's Dr. Prabhakar Kore Hospital will raise Invoice as per the statutory requirement for each 1 patient completed according to actual work performed (Number of Days completed in the study site, eCRF completion, source data verification and eCRF review for completed visits). Advance paid will be adjusted against the subsequent payments.

In the event there is a refund due to AXIS at the time of premature termination by either party, the Principal Investigator agrees to remit the same to AXIS within fifteen (15) days of the date of effective termination. .

Tax deduction: All fees and amounts except patient reimbursement and otherwise specifically listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the institution for the study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year. Reimbursement of charges like CT scan,

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ECG, X-ray or any other tests / analysis charges if any will be reimbursed in actual in case they have been outsourced to the outside vendor by the study site.

In case the ECG, X-ray or any other tests/analysis charges will be carried out in **KLE's Dr. Prabhakar Kore Hospital** Itself, then TDS amount will be deducted as per the applicable requirement. All the payments will be done against the invoice/s that has been generated from sites in the name of AXIS Clinicals Limited.

3. ETHICS COMMITTEE APPROVAL

The Principal investigator shall be responsible for obtaining approval of the protocol, related study documents and study conduct at the Site before initiation of the study.

Site also represents and warrants that EC registration and re-registration with Central Drug Standard Control Organization (CDSCO) and they have obtained and will maintain the required authorization from the Ethics Committee and any other required forms fully complying with the applicable regulations.

4. PROPRIETARY INFORMATION AND CONFIDENTIALITY

Sponsor shall have sole ownership of intellectual property developed in the Study by Investigators supported through Study funds. The Site shall disclose to AXIS\Sponsor all inventions and other creative ideas and developments conceived or reduced to practice as a direct result of this Study. Such disclosure shall be made fully and promptly in writing to AXIS. All documents, data, know-how, formulas ("Data"), and unused drug provided to the Site for purposes of the Study are and will remain Sponsor's property and will be returned to Sponsor or their designate upon request.

SPONSOR/AXIS Confidential Information and all tangible expressions, in any media, of SPONSOR/AXIS Confidential Information are the sole property of SPONSOR/AXIS.

Institution agrees not to use SPONSOR/AXIS Confidential Information for any purposes other than to conduct the Study. Institution agrees not to disclose SPONSOR/AXIS Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard SPONSOR/AXIS Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

The obligation of non-disclosure and non-use shall not apply to the following.

(1) Information, which at the time of disclosure hereunder, is generally available to the public;
(2) Information, which after disclosure hereunder, becomes generally available to the public, except through breach of this Agreement;
(3) Information that the Institution can demonstrate was in its possession at the time of disclosure by Sponsor and that was not acquired, directly or indirectly, from Sponsor;
(4) Information that becomes available to the Institution from a third party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Sponsor; or
(5) Information that is required by law to be disclosed to representatives of a Governmental Agency and to which they are entitled when engaged in the proper performance of their duties.

The Investigator agrees to keep all aspects of the trial confidential. This includes the nature of the trial, the protocol and its attached forms as well as data generated by the trial.

The obligations of this Section shall survive till the termination of this Agreement.

for

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Registrar
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5. HANDLING INVESTIGATIONAL PRODUCTS

The Investigator agrees to exercise adequate care in the application and handling of Investigational products. The Investigator agrees to utilize test drug solely in accordance with
the protocol and to return to Axis/ Sponsor the unexpended test drug unless directed by AXIS/ Sponsor/ contracted third party vendor to do otherwise.

6. SERIOUS ADVERSE EVENT REPORTING

The Principal Investigator shall fully comply with adverse event assessment and reporting criteria as per the provisions of the Protocol. In the event of any omission of such provisions or in the event of the conflict of such provisions with the Regulations, then the Regulations shall apply in relation thereto.

The Principal Investigator shall also notify the IEC immediately of any Serious Adverse Events during the Study in accordance with the current existing regulations.

In the event of SAE injury, patients will be provided free Medical management as long as required by **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)**In the event of study related injury or death, **Eugia Pharma Specialities Limited, India (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited)**, will provide complete medical care and financial compensation for injury or death as per current applicable regulatory requirements.

Investigator must report within 24 hours of learning of any AE that meets one of the criteria for an SAE, with pre printed SAE form provided by the AXIS as per Appendix XI of Schedule Y compliance notifying to SPONSOR/AXIS Clinicals, Licensing authority and ethics committee. SPONSOR/AXIS Clinicals with investigator shall send SAE report after due analysis to Licensing authority, ethics committee, expert committee of licensing authority (in case of death only) and head of the institute where trial is being conducted within 14 calendar days. Investigator shall ensure that ethics committee shall send SAE report and its opinion on financial compensation within 30 days after occurrence of SAE to the licensing authority. Sponsor shall pay compensation as per the orders by licensing authority within 30 days after receiving the opinion from DCGI regarding compensation of the SAE. A follow up report shall be sent to SPONSOR/AXIS Clinicals, Licensing authority, expert committee licensing authority and head of the institute where trial is conducted as per regulatory requirements, which shall include outcome and treatment provided. If, during follow-up, any non-serious AE worsens and eventually meets the criteria for an SAE, that AE should be recorded as a new SAE.

7. USE OF OTHER PARTIES' NAMES

The Site shall not use SPONSOR's or AXIS's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ AXIS.

8. INDEPENDENT CONTRACTORS

Site shall perform services under this Agreement only as an independent contractor, and nothing contained herein shall be construed to be inconsistent with that relationship or status. This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

9. INSURANCE AND INDEMNIFICATION

INSURANCE:

Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon AXIS's request, Institution shall have its insurance carrier (or shall cause the medical

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Dr. V.A.Kothiwale
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professional to have his or her insurance carrier) furnish the certificate to AXIS that all insurance required under this Agreement is in force.

INDEMNIFICATION:

SPONSOR shall indemnify the investigator and institution (including principal investigator's and institution's affiliates, contractors, agents, fellows, employees and servants collectively "Indemnity") for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against investigator or institution arising directly out of the performance of the study pursuant to the protocol; provided however,

- SPONSOR will not indemnify any Indemnity for Loss to the extent and the Loss arose out of an Indemnity's failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a patient's safety or well-being and which were communicated to and accepted by AXIS/Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;

- SPONSOR will not indemnify any Indemnity for Loss to the extent the Loss arising out of the negligence or wrongful acts or omissions of an Indemnities or any other person patient to an Indemnities control;

10. MONITORING; AUDIT; REGULATORY INSPECTIONS

The Site shall, permit authorized personnel of the SPONSOR/ SPONSOR designee, AXIS and any Regulatory Authority including Ethics Committee to inspect the facilities the Site proposes to use for the Study; before, during and after the Study. There will be AXIS and sponsor audits during the study apart from the monitoring visit as per the mutually agreed dates

The Site shall notify AXIS or Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, European or any other governmental or regulatory authority requests permission to or does inspect the Site's facilities or research records relating to this Study whenever and will provide in writing to AXIS copies of all materials, correspondence, statements, forms and records which the Site receives, obtains, or generates pursuant to any such inspection.

The Site will permit to Sponsor/Axis/USFDA/DCGI other regulatory authorities

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
b) Inspect and copy all data, documents and records related to such work and the study

The obligations of this Section shall survive termination of this Agreement.

11. TERM; WAIVER; SEVERABILITY

Unless earlier terminated in accordance with the provisions of this Agreement, the term of this agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date.

This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Agreement.

This Agreement may be terminated by either party upon giving at least a thirty (30) days notice to that effect to the other party. A reasonable adjustment will be made between the parties to ensure the Site is reimbursed for project costs incurred to the date of termination of this Agreement. Any funds paid by AXIS to the Institution in excess of project costs will be returned to the AXIS.
AXIS or SPONSOR may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by either AXIS or SPONSOR that the Study is terminated shall also constitute effective notice of termination of this Agreement.

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12. EFFECT OF TERMINATION

(1) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall cease enrolling patients into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(2) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which AXIS has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, AXIS has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, AXIS may deduct/adjust an equivalent amount from any payment then or later due from AXIS to Institution under this or any other arrangement between the parties.

(3) Upon termination of this Agreement, all unused Materials and all SPONSOR Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to SPONSOR at SPONSOR's expense, or, at SPONSOR's option, destroyed with the destruction must be certified in writing.

13. AMENDMENT

This agreement and protocol may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. The parties agree that this agreement constitutes the sole, full and complete agreement by and between the parties and supersedes all other written and oral agreements and representation between the parties with respective to the study. No amendments, changes, additions, deletions, or modifications to or of this agreement shall be valid unless reduced to writing and signed by the parties.

All changes and amendments to this agreement shall be agreed in writing between the parties.

14. RECORDKEEPING/ DOCUMENT ARCIVAL/ AND INVESTIGATIONAL PRODUCT RETENTION

Investigational Product/s will be retained either at Site or Third party archival facility after having a mutually agreed decision with Sponsor, AXIS and Sites. The Investigational product will be re-packed and sealed as per the requirements and retained at the site / Third party facility. In case if the IPs are retaining at third party facility, Site and Third party will have one agreement for the transfer of IP as per the required conditions. The payments towards the maintenance of retained samples at third party facility will be paid by AXIS on the receipt of Invoice from Third party. The Archival Charges for retaining the samples at the sites if any will be mentioned in the CTA and will be paid in due course of time. In case of retrieval requirement for the regulatory authority site will inform first to AXIS by mail requesting for the retrieval of IP, after obtaining the response from AXIS site will inform the Third party facility about the retrieval as per the procedure. Any charges related to retrieval of the IPs/ documents AXIS will reimburse the same to the Third party facility against proper Invoice. Under no other circumstances sites will be having any authority related to retrieval of retained IP/documents at any time.

Institution or investigator shall ensure the storage of data related to study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the applicable laws and regulations in INDIA or until at least 15 years after completion of all regular site close out activity, whichever period is longer, unless to the extent that AXIS/ SPONSOR require the return or destruction of this data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such data, sponsor/Axis written approval shall be obtained.

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Registrar
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Study documents will be maintained for Two years (2) at site after completing Site Close-out visit. Then the documents will be shipped to Third party or Axis Clinicals for archival for period of 15 years after having mutually agreed decision with sponsor and AXIS. Site will be not paid for the archival for these Two years.

15. DISCLAIMER

The Site acknowledges that the Sponsor has engaged AXIS to manage the Study. AXIS has performed no independent research or analysis regarding the safety or efficacy of the Investigational Product, materials or treatment procedures that are to be administered pursuant to the Study and therefore AXIS makes no warranties, expressed or implied concerning the Investigational Product, materials, treatment procedures, results to be obtained in administering the Investigational Product, or the Investigational Product's fitness for any particular purpose.

16. PUBLICATION

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the clinical study is the sole property of the sponsor. Therefore, Principal investigator agrees not to publish or present the results or any information derived from the study.

17. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by and interpreted in accordance with the laws of India, without conflict of laws or principles. Any dispute between the Parties as to construction, meaning or effect of the Agreement or any clause contained therein or the rights, duties, liabilities and obligations of either Party there under, shall be resolved mutually within thirty days, failing which, shall be referred to arbitration before a sole arbitrator appointed by the Parties. The arbitration proceedings shall be conducted in accordance with the Arbitration and Conciliation Act, 1996 and rules made thereof in Hyderabad. The arbitration proceedings shall be conducted in the English language. The arbitrators' decision shall be final and legally binding and judgment may be entered thereon before the courts of competent jurisdiction. The arbitrator shall also decide on the costs of the arbitration proceedings.

IN TESTIMONY WHEREOF, the parties hereto have caused this instrument to be executed, in duplicate, by their officers, thereunto duly authorized to sign on behalf of the party.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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1. Principal Investigator

Represented by (Name) : **Dr.Mahesh Kalloli**

Title : Surgical oncologist

Signature and date : 20/8/18

2. AXIS Clinicals Ltd

Represented by (Name) : Mr. Phani Bushan Reddy

Title : Executive Director

Signature and date : 21/08/18

Witness

Represented by (Name) : Dr. Subhra Lahiri

Title : Associate Vice President

Signature and date : Subhra Lahiri 21/08/18

3. KLE's Dr. Prabhakar Kore Hospital

Represented by (Name) :

Title :

Signature and date : 27/8/2018

Witness

Represented by (Name) : Revanna S Devarnavi

Title : Assistant Coordinator

Signature and date :

4. CMS Clinical Research

Represented by(Name) : Nidhi

Title : Head Clinical Operations

Signature and date : 20/8/18

Witness

Represented by (Name) : Shivaprakash

Title : CRC

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EXHIBIT A :

For each completed patient AXIS agrees to pay the site sum of INR **1, 30,040/- (One Lakh thirty thousand forty rupees Only)** to the payee name as mentioned above. . Hospitalization fees of **INR 30,000/-**(Thirty thousand rupees Only) perRs.**15000/-(Fifteen Thousand rupees Only) as patient reimbursement and travel allowance** In case of early withdrawal of Patients, the reimbursement can be provided on Pro-rata basis

Investigator Fees and Hospitalization charges confirmed are inclusive of applicable tax (TDS- Tax Deduction at Source). There will be no TDS deduction for the Subject reimbursement provided the voucher will be forwarded to Sponsor before claiming of the same.

For 1 to 5 patients

Description	Visit 1 (Screening)	Visit 2(day 0) Randomization	Visit 3(Day 11,12,13)	Visit 4 (Day 14 &15	Visit 6 (Day 25,26,27)	Visit 7 Day 28 &29)	Total
PI Cost	9000	3500	10000	12000	10000	10000	54500
Sub-I Cost	3000	2000	3000	3000	3000	3500	17500
Study Coordinator	2500	1000	2000	2000	2500	2000	12000
Phlebotomist	1200		1500	2500	2000	3000	10200
Study Nurse	500		500	500	500	500	2500
Hospitalization	0		9000	6000	9000	6000	30000
ECG	500		0	500	0	500	1500
Chest X-Ray	500		0	0	0	0	500
Overhead Charges (25%)	4050	1625	6500	6500	6750	6250	31675
Patient Compensation	1250	1250		5000		7500	15000
Total							1,75,375
From 6th to 10th Patients	Site will receive per Completed subject						2,00,000/-
From 11th to15th Patients	Site will receive Per Completed Subject						2,25,000/-

1. An Archival fee of Rs.15000/- will be paid during site closure only for 2 years archival of all the study documents in secure condition . Site should provide a declaration that the documents archived will be safe, traceable and will be retrieved any time during any Regulatory audit after informing the Sponsor – AXIS Clinicals only . In no other circumstances these documents will be withdrawn .
2. Investigator Fee includes the charges towards involvement of **Co-Investigator, Research Nurse, CRC & Phlebotomist** in the study
3. **GST will** be as per Govt. Norms (If applicable).

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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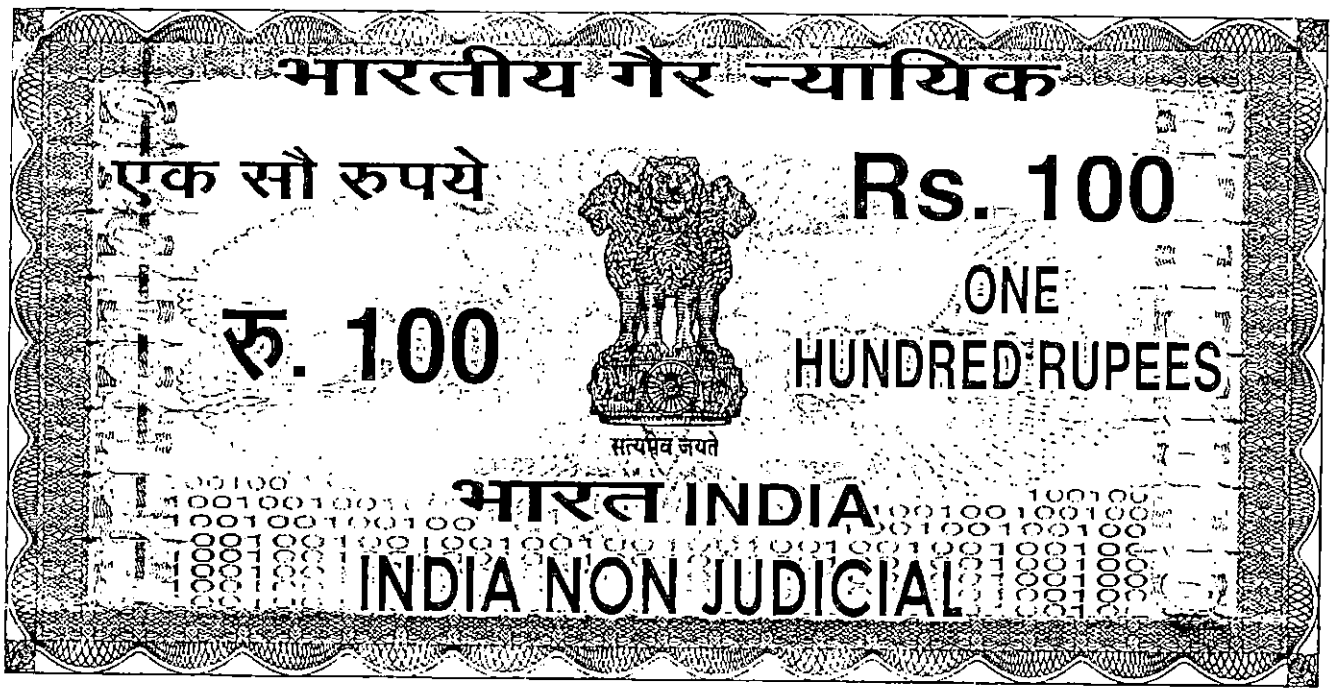

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તા. ૧૩ માહે ૭
નામ
સરનામુ
લા.નં.મેસ.બી.૧૬૪/૧૬૫/૮૮/૧૬
નિખીલ જીતેન્દ્રકુમાર શાહ
મિરઝાપુર કોર્ટના સર્વેદી અમદાવાદ
લેનારની સહી X .....

BL 284067

Cadila Pharmaceuticals Limited
"Cadila Corporate Campus"
Sarkhej-Dholka Road, Bhat,
Ahmedabad-382210.

Clinical Trial Investigation Agreement

Dated __/__/____

Between

Cadila Pharmaceuticals limited
And
Dr. Snehal Lunge
And
Dr. M. V. Jali
And
Mr. Kirti Kumar Patel

ATTESTED

Dr. V.A.Kothiwale
Registrar
(Deemed to be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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CLINICAL TRIAL INVESTIGATOR'S AGREEMENT

This CLINICAL TRIAL INVESTIGATOR'S AGREEMENT (**"Agreement"**) is made effective as on this _____2018 (the effective date);

Cadila Pharmaceuticals Ltd., a Company incorporated under the Companies Act 1956 & organized and existing under the laws of India, with its registered office at Village-"Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Dist. Ahmedabad (hereinafter referred to as "CPL") and it's CRO division (hereinafter referred to as "Cadila CRO" or "Sponsor") situated at, 1389, trasad road, Dholka-382225, Dist: Ahmedabad, Gujarat, India.

And

Dr. Snehal Lunge, as the Principal Investigator at the Institution, with offices at KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India (hereinafter the "Investigator")

And

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Dr. M. V. Jali, Director (Name & Designation) with its principal place of business at KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India (hereinafter the "Institution").

And

Mr. Kirti Kumar Patel, Chief Operating Officer with its principal place of business at KV Clinical Research Services, Office No. 615, Sixth Floor, Golden Trade Center, New Rajendra Nagar, Raipur – 492001, Chhattisgarh, India (hereinafter the "SMO")

Recitals

(A) WHEREAS, Cadila CRO on behalf of Cadila Pharmaceuticals Ltd., intends to conduct a multi-center clinical study of (A) WHEREAS, Cadila CRO on behalf of Cadila Pharmaceuticals Ltd., intends to conduct a A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.

(B) WHEREAS, the Institution has appropriate facilities and personnel and the Principal Investigator (as defined below) has the qualification, training, knowledge and experience necessary to conduct such a clinical study and laboratory test evaluations.

Agreement

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. Scope of Work.

1.1. Conduct of the Study:

As part of a multi-center clinical study entitled A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis. The Principal Investigator shall conduct the clinical study in accordance with this Agreement, Protocol Number (CRSC16004) incorporated by reference herein (the "**Protocol**") and the investigator's brochure for the Protocol (the "**Investigator's Brochure**"), as each may be amended, and all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, (collectively, "**Applicable Laws**"). For purposes of this Agreement, the term "Institution" shall include all employees, executives, officers, directors, faculty, staff and other authorized agents of the Institution.

The sponsor is conducting the clinical trial under Investigatiohnal New Drug (IND) applications filed with the Drugs Controller General of India (DCGI) te United States Food & Drug

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Administration (USFDA) and the European Medicines Evaluation Agency (EMEA). The SITE agrees to conduct the Study in strict accordance with the Protocol approved by the local Ethics Committee, and as amended from time to time. SITE will conduct the Study in strict accordance with the terms and conditions of this Agreement, the Protocol and any amendments thereto, and all applicable federal, state and local laws and regulations applicable to the territory in which the Study is being conducted including but not limited to (a) The revised and applicable versions of the Declaration of Helsinki Directive, as amended from time to time; (b) Schedule Y of the Drugs and Cosmetics Act, as revised from time to time; (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("ICH/GCP"); (c) all regulations and laws as applicable to clinical trials in India and USA (e) the Prevention of Corruption Act, 1988, (f) the U.S. Foreign Corrupt Practices Act, UK Bribery Act 2010, the federal anti-kickback laws (42 U.S.C. Section 1320a-7b(b)), (h) the Standards for Privacy of Individually Identifiable Health Information, and (i) the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 ("**Privacy Rule**") under the laws applicable for India and USA (collectively, "**Applicable Law**"). The Clinical Trial Annual report to be submitted to Ethics Committee every year.

2. **The Principal Investigator**.

For sake of clarity, the Principal Investigator is an employee of Institution and will be named in Appendix A. The Principal Investigator represents and certifies that he or she has read and understands the Investigator's Brochure. The Principal Investigator is not a party but must sign off read and acknowledge to the entire agreement. Prior to the commencement of the Study, the Principal Investigator shall deliver to CRO true, complete and correct copies of the Principal Investigator's investigator statement as mentioned in schedule Y and curriculum vitae, each of which shall be signed by the Principal Investigator. During the Study, the Institution shall immediately notify CRO in writing at such time as it becomes aware that the Principal Investigator plans to leave the Institution or shall be unable to complete the Study. If the Institution and CRO are unable to agree on an acceptable substitute investigator within fifteen (15) business days following such notice, CRO may terminate this Agreement pursuant to Section 17.

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3. Representations and Covenants.

The Institution and (to the extent that such representations and covenants relate to the Principal Investigator) the Principal Investigator each represents certifies and covenants to CRO, as follows:

3.1 The Principal Investigator is, and at all times during the course of the Study shall be, qualified by training and experience with appropriate expertise to conduct the Study;

3.2 The Institution and the Principal Investigator have, and at all times during the course of the Study shall have, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Study;

3.3 None of the Institution, the Principal Investigator, or any other person who assists in performing the Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Study or has entered into any contract with respect to the Study that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by the regulatory authority or that might create a conflict of interest;

3.4 The Institution and the Principal Investigator have been selected to conduct the Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any Sponsor product.

4 Facilities.

The Institution and the Principal Investigator shall conduct the Study at the facility first identified above, or such other facilities as CRO and the Institution may agree in writing, The Institution shall make available all personnel, facilities and resources necessary to efficiently and expeditiously accomplish its responsibilities under this Agreement.

5 Subject Enrollments and Informed Consent

5.1 Subject Enrollment: The Principal Investigator shall enroll subjects into the Study in accordance with appendix A, as described below, (each, a **"Subject"**). The Principal Investigator shall use all reasonable efforts to complete enrollment by any Subject Enrollment Closing Date set forth in Appendix A or otherwise notified in writing to the Principal Investigator by CRO. The Study period may be extended or shortened and the number of Subjects the Institution may enroll in the Study may be changed at CRO's sole discretion. The Institution acknowledges that the Study is part of the Multi-Center Study, and agrees that when the enrollment goal for the Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

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5.2 Informed Consent: The Principal Investigator shall obtain the informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Materials (as defined in Section 9.3) and in accordance with Applicable Laws. Each Subject shall complete an informed consent form that has been reviewed and approved in advance by CRO and by an institutional review board [IRB] approved by the Institution that complies with the requirements of Indian regulatory.

5.3 Adverse Events/ SITE shall report to CRO/Sponsor and Institutional Ethics Committee with a copy to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than 24 (twenty-four) hours of occurrence of such an event and shall be made in accordance with Schedule Y and the procedures outlined in the Protocol concerning the reporting of adverse events. In case, any adverse events are not reported to CRO within time limit prescribed under this clause by the SITE, then the insurance claim, if required to be made under clause 16, will be the responsibility of the SITE and the Insurance Policy of SITE shall be utilized.

6 **Compensation.** For the services to be rendered hereunder CRO on behalf sponsor shall pay the Institution in accordance with the budget, payment schedule and procedures set forth in Appendix A. The parties acknowledge that the amounts to be paid by CRO under this Agreement are reasonable compensation for the work performed and that neither the Institution nor the Principal Investigator has received any other compensation or other inducement in connection with this Agreement or its participation in the Study. Any amounts paid by CRO to the Institution for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly refunded to CRO upon the expiration or termination of this Agreement, or earlier at the written request of CRO. Except with respect to those expenses reimbursable under Sections 16 and 17.4, the Institution acknowledges and agrees that the payments made by CRO under this Section 6 represent CRO's total obligations under this Agreement, and fully cover the costs of conducting the Study. Accordingly, the Institution shall not submit claims to, or otherwise seek reimbursement from any other third party pay or, whether public or private, for any costs covered by payments made or goods or services provided by CRO under this Agreement or otherwise incurred for conducting the Study.

In the event SITE screens and/or enrolls very few patients, through no fault of the SPONSOR or CRO, CRO may close enrollment at the Institution without liability therefore. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Study patients, the Institution shall immediately inform the CRO in writing. In each such event, the Parties shall discuss the consequences of the delay and if reasonable, as determined by CRO, each Party shall undertake reasonable endeavors to agree on measures to overcome such a delay.

In rule 122-DAB DNC Act of the said rules:

In the case of an injury occurring to the subject during the clinical trial, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.";

7 **Ownership and Control of Study Drug.** All Study Drug supplied to the Institution shall remain the exclusive property of CRO until administered or dispensed to Subjects during the course of the Study. The Study Drug shall only be used as described in the Protocol and in compliance

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with Applicable Laws. Upon termination or completion of the Study, the Institution shall, at CRO's direction and expense, either return to CRO or dispose of any quantities of unused Study Drug, in accordance with CRO's written instructions. The Institution shall maintain complete and accurate records relating to the disposition of the Study Drug supplied to the Institution as set forth in Section 9.1.

Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, CT scans, MRI scans, PET scans, ultrasounds, subject files, and records kept at the pharmacy, at the laboratories involved in the Study in accordance with Applicable Law (collectively, **"Source Documents"**)however, Institution shall bound to provide the source documents to CRO as and when demanded by it for the purpose of evaluation and records of the study and its outcome, or any other reason.

8 Records; Reports; and Regulatory Assistance.

8.1 Study Documentation: The Institution and the Principal Investigator shall prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation in a manner acceptable for the collection of data for submission to, or review by regulatory or governmental authorities, and in full compliance with the Protocol and all Applicable Laws. [On a case-by-case basis, CRO may at its sole expense request, in writing, longer periods of retention times for Study Documentation.] For purposes of this Agreement, "Study Documentation" includes all records (related to the Study Drug or Protocol), accounts, notes, reports and data, collected, generated or used in connection with the Study, whether in written, electronic, video or other tangible form, including all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study. The Principal Investigator or designee will conduct data entry activities, which shall include entry of Subject data after Subject visit within 3 working days after a visit and SITE shall respond to all data queries within 7 (seven) days from the date of such request. The CRF instructions will also provide the Study site with data entry instructions. A duplicate copy of the CRF will be archived at the Study site for 15 years after the study completion.
The Sponsor / CRO will review the facilities at the Site to ensure adequate infrastructure for clinical trial at the site. SITE shall ensure that the facilities remain adequate for the duration of the Study (i.e. at a minimum, are safe, secure, hygienic, include adequately-maintained and calibrated equipment, and provide for secure and accessible storage of Study materials and records). Study Records will be retained by SITE for 2 (two) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until 3 (three) years after the study is complete and FDA / DCGI is notified, or any longer retention period mandated by Applicable Law.

The Principal Investigator agrees to limit access to the Investigational Product to only qualified and delegated Study staff and shall personally ensure, administer, instruct administration, or supervise the administration or instruction of administration of

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Investigational Product (whether active or placebo) to Study patients in accordance with the Protocol; shall not chemically, physically or otherwise modify Investigational Product,; and shall handle, store, and ship or dispose of Investigational Product with appropriate care and in compliance with manufacturer's instructions and all Applicable Laws, rules and regulations, including, but not limited to, those governing hazardous substances.

The Principal Investigator agrees to limit access to the Biological sample, specific marker sample, surrogate marker sample and or sample / test as per protocol to only qualified and delegated staff and shall personally ensure sample collection, processing, storage, transport, handling and or concercn activities in accordance with protocol and timeline.

8.2 Provisions of Data and Reports: The Institution shall provide to CRO original case report forms for each Subject participating in the Study and such other reports as and when required by the Protocol or Applicable Laws.

8.3 Institutional Review Board: The Institution shall provide to CRO documentation verifying review and approval by the IRB of the information to be provided to potential Subjects of the Study to secure their informed consent, including information about any compensation being provided to Subjects for participation in the Study (**"Informed Consent Materials"**), the Protocol, the Investigator's Brochure and amendments to any of the foregoing.

8.4 Regulatory Assistance: At the request and expense of CRO, the Principal Investigator or representative shall: (a) assist CRO in the preparation and submission of investigational new drug applications, new drug applications, any other premarket or marketing applications relating to the Study or the Study Drug, and any amendments or supplements; (b) attend meetings with regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such other reasonable assistance as CRO may request in connection with regulatory matters relating to the Study or the Study Drug.

8.5 CRO/Sponsor shall provide for the delivery to the SITE, the Investigational Product in sufficient quantities for use in the Study. Title to these materials provided by CRO/Sponsor shall remain solely and exclusively with SPONSOR, and the materials shall be used solely and exclusively by SITE for purposes of carrying out the Study.

9 **Audit and Review**. CRO or its authorized representatives shall have the right, upon advance written notice, at CRO's expense, and during regular business hours, to: (a) audit all Facilities used in performance of the Study; (b) monitor the conduct of the Study; (c) review, copy and audit all Study Documentation, any other books, records, data and Work Product (as defined below) relating to the Study or the IRB, and all required licenses, certificates and accreditation; and (d) interview the Principal Investigator and other persons who assisted in performing the Study. Subject's medical records are for review purposes only and it will be the property of CRO.

10 **Changes to the Protocol**. No change in the Protocol shall be made by the Institution or the Principal Investigator, subject to any Applicable Laws relating to the safety of Subjects that require a deviation from the Protocol, in which case the Institution shall promptly notify CRO and the IRB of the nature of the deviation and the facts necessitating such deviation as soon as the facts are known to the Institution. CRO may at any time make changes in the Protocol upon five (5) days'

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advance written notice to the Institution; provided, however, that, unless the changes are required by Applicable Laws, do not materially increase the cost of performance of the Study by the Institution or are otherwise agreed to by the Institution, the Institution may terminate this Agreement pursuant to **Section 17.**

11 **Regulatory Inspections**. If any governmental or regulatory authority (a) contacts the Institution or the Principal Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any Facility or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Institution, the IRB or the Principal Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Institution shall promptly notify CRO of such contact or notice. CRO shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Study. The Institution shall provide CRO with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. CRO shall have the right in advance to review and comment on any responses that pertain to the Study. No such response shall contain any false or misleading information with respect to the Study, the Study Drug or CRO.

12 **Confidential Information**

12.1 Definition. For purposes of this Agreement, **"Confidential Information"** means any information of CRO, whether of a technical, business or other nature, including information that relates to CRO's trade secrets, products, Study Drug, chemical structure, promotional material, developments, proprietary rights or business affairs, together with any Inventions, Work Product and all other written information, data and results collected, prepared, developed or generated by the Institution, the Principal Investigator and any other person pursuant to or in contemplation of this Agreement, including, subject to applicable laws and regulations, this Agreement. This Section 13 is subject to the Institution and the Principal Investigator's publication rights as set forth in Section 14. Confidential Information does not include any information that:

12.1.1 The Institution or the Principal Investigator can prove was known prior to the date of this Agreement and was not subject to any confidentiality restrictions;

12.1.2 The Institution or the Principal Investigator can prove was lawfully obtained from a third party without breach of any obligation of confidentiality;

12.1.3 is or becomes part of the public domain through no act or violation of any obligation of the Institution or the Principal Investigator; or (For the avoidance of doubt, when CRO lists or discloses any non-confidential information relating to the Study Drug or the Study in a clinical trial registry or clinical results database, any aspects or details of Confidential Information concerning the Study Drug or the Study that are not listed or disclosed in such registry or database shall not be deemed to be or become part of the public domain.)

12.1.4 Is independently developed by the Institution or the Principal Investigator.

12.2 Non-Disclosure. For a period of five (5) years after the expiration or termination of this Agreement, the Institution and the Principal Investigator shall not, without CRO prior written consent or as may be permitted by this Agreement, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. The Institution shall restrict the dissemination of Confidential Information to only those persons within the Institution who have a need to know, and shall ensure that they are aware of the obligation of

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confidentiality required by this Agreement. The Institution and the Principal Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its most sensitive confidential information. The Institution or the Principal Investigator, as applicable, shall notify CRO promptly upon the Institution or the Principal Investigator's discovery of any loss or compromise of the Confidential Information. Upon the termination or expiration of this Agreement or upon CRO earlier written request, the Institution or the Principal Investigator shall promptly return to CRO all Confidential Information at CRO reasonable expense, provided that the Institution shall have the right to retain, subject to the other provisions of this Section 13.2, the original copies of each Subject's primary medical records.

13 **Publication and presentations**

None of the Institution, the Principal Investigator, or any other person who assists in performing the Study shall not issue any press release or other publicity materials or make any presentation or announcement, private or public, which refers the name of CRO, Sponsor or the name of Test Product, without prior written consent of CRO & Sponsor. There shall be no publication based on Trial unless CRO & Sponsor shall have given its prior written approval. The Sponsor & CRO may require that Institution publish results jointly with them and others.

If any invention is described in a proposed publication which in the opinion of CRO should be made the subject of a patent application. CRO shall have four months after disclosure to CRO to file such patent application. Institution shall withhold publication respecting that invention until such application is so filed by CRO.

For multicentric studies it is mandatory that data be pooled and analyzed as stipulated in the protocol. Authorship will include representatives from each active trial site and from CRO. It is agreed that no presentations or publications will be authorized individually or by subgroups participating in the trial without the consent of all parties prior to publication of the pooled data, but in no event shall any institution involved in this study be restricted from publishing independently after the expiration of 24 months from completion of research.

14 **Use of name:**

Use of Name. Subject to Applicable Laws, none of the Institution, the Principal Investigator or CRO shall mention or otherwise use the name, trademark, trade name or logo of any other party in any publication, press release or promotional material with respect to the Study without the prior written approval of such other party; provided, however, that for non-commercial, internal purposes, CRO shall have the right to identify the Institution as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The Institution may use the name of CRO and the title of the Study for internal purposes, including, but not limited to, acknowledging the Principal Investigator's work.

Advertising. Neither the Institution nor the Principal Investigator shall issue to the public any information or statement through the press or any other media, including advertisements for the enrollment of Study Subjects, without the prior written permission of CRO and the review and approval of the IRB.

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15 Indemnification and insurance:

15.1 **Indemnification.** Except as set forth below, CRO shall defend, indemnify and hold harmless the Institution, System, their Regents, officers, agents, and employees, including the Principal Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare personnel providing services to the Institution in connection with its conduct of the Study (collectively, the **"Institutional Indemnified Parties"**) from and against any and all liability, claim, loss, damages and expense (including lawyers' fees and costs of suit) (collectively, **"Losses"**) incurred by them in connection with any and all suits, investigations, claims or demands by or on behalf of Subjects taking part in the Study (or their dependents) against any Institutional Indemnified Party for personal injury (including death) to Subjects to the extent arising out of or relating to: (a) the administration of the Study Drug in accordance with this Agreement, the Protocol and any other written instructions of CRO or (b) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, or the use by CRO of the results of the Study, provided that, in each case (a) or (b), the Institution and the Principal Investigator have (i) used reasonable medical judgment in the conduct of the Study (including the enrollment of Subjects for which participation in the Study is medically appropriate) and (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice.

15.2 **Reimbursement of Medical Expenses:** Notwithstanding Section 16, CRO shall reimburse the Institution for the direct, reasonable and necessary medical expenses incurred by the Institution for the treatment of any personal injury that is a direct result of (a) the administration of the Study Drug in accordance with this Agreement, the Protocol and any other written instructions of CRO or (b) any performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study if (i) the Institutional Indemnified Parties have complied with this Agreement, the Protocol and any written instructions of CRO concerning the Study and (ii) all the requirements of informed consent have been complied with in accordance with Section 5.2. CRO will not provide compensation for lost wages or for any other damages, expenses or losses, or for medical expenses that have been covered by a Subject's medical or other insurance, provided, however, CRO understands and agrees that Subject is not required to file an insurance claim.

15.3 Exceptions. Sections 15.1 and 15.2 shall not apply to any Loss:

15.3.1 arising out of or relating to the negligence, willful malfeasance or wrongful acts or omissions of any Institutional Indemnified Party, or by the negligent failure of any Institutional Indemnified Party to comply with the provisions of this Agreement, the Protocol or any written instructions of CRO concerning the Study;

15.3.2 to the extent that such Loss arises out of or relates to the Principal Investigator's or the Institution's negligent failure to promptly report to CRO any significant or alarming developments that may occur during the Study, including any Subject adverse experiences or Serious Adverse Events (as both such terms are defined in the Protocol); or

15.3.3 Effect of Termination or Expiration. Termination or expiration of this Agreement or the Study shall not affect CRO obligations to the Institutional Indemnified Parties with

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respect to any Loss or expense resulting from the conduct of the Study prior to the Institution's or the Principal Investigator's first receipt of notice of termination, to the extent that such Loss or expense would otherwise be covered by this Section 19, but CRO shall have no obligation under this Section 16 with respect to any activities performed by or on behalf of the Institution or the Principal Investigator after the receipt of such notice.

16 **Insurance**

The CRO will have insurance for Rs.2 crores adequate to cover the risks as specified under the aforementioned provisions of section 16. The CRO hereby also agrees that it will cover any claims above the insured amount however, it is understood and agreed that the maintenance of such insurance cover will not relieve either party of its obligations under this agreement. CRO and institution both shall maintain insurance policy. Policy will be used whose negligence / mistake is decided. The report decided mutually by the parties will be binding on the parties as to determine the negligence or mistake as specified under this clause.

17 **Termination:**

17.1 Right to Terminate or Suspend Study: The Study may be terminated or suspended by CRO immediately upon written notice to the other for safety concerns or as otherwise required by Applicable Laws. Further, CRO may terminate or suspend the Study if the Multi-Center Study is terminated or suspended.

17.2 Right to Terminate Agreement: CRO may terminate this Agreement, in its sole discretion, on ten (10) business days' advance written notice to the Institution. CRO or the Institution may terminate this Agreement in the event of material breach by the other of this Agreement, provided that the other is given written notice of the nature of the default and an opportunity to cure such default within a period of 15 business days after the giving of notice. CRO may terminate this Agreement, on written notice to the Institution, immediately upon suspension or termination of the Study. The Institution may terminate this Agreement, on written notice to CRO, if the Study is suspended or terminated and not recommenced within ninety (90) days. Further, the Institution may terminate this Agreement if CRO makes changes to the Study that are not required by Applicable Laws and not agreed to by the Institution or approved by the institutional review board [IRB] and such changes materially increase the cost of performance of the Study by the Institution

17.3 Transition upon Termination: Upon notice of termination of the Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into the Study and, at the election of CRO, shall: (a) terminate the Study with respect to the enrolled Subjects in an orderly and prompt manner, to the extent medically permissible, and pursuant to consultation with CRO's clinical monitor, including, without limitation, any required follow-up treatment with previously enrolled Subjects or (b) transfer the enrolled Subjects to another clinical site in accordance with CRO's instructions. CRO or its designee shall have the right to assume full control of the terminated Study and the Institution shall turn over all Study Documentation and materials in its possession associated with the Study, including all Work Product, Inventions and Materials, as expeditiously as possible, shall handle the Study Drug in accordance with Section 8 and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol. Upon notice of suspension of the Study, the Institution shall immediately cease

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enrollment of Subjects into the Study. CRO shall reimburse Institution for all expenses incurred from such transition except for such transitions required due to an uncured breach of this Agreement by Institution.

17.4 Payment Owed: Except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution, upon termination of the Study or this Agreement, CRO shall, upon receipt of applicable invoices and other supporting documentation satisfactory to CRO: (a) reimburse the Institution for its reasonable and verifiable Study costs and reasonable un-cancelable Study costs or expenses incurred in connection with transfer of Subjects pursuant to Section 17.3 and (b) with respect to Subjects who have not completed the Study at the date of the termination, make payments to the Institution in accordance with appendix A for work already performed in accordance with the Study.

17.5 Final Accounting: Within thirty (30) days after the termination of this Agreement, the Institution shall deliver to CRO a final accounting of all Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and all reasonable direct costs incurred in connection with any transfer of the Study. Within thirty (30) days of delivery or receipt of the final accounting, either the Institution shall refund to CRO any excess amounts paid by CRO or CRO shall pay any additional amounts owed to the Institution, as the case may be. CRO or its designee shall have the right for a period of two (2) years after the payment of any transfer costs to audit the Institution's books and records with respect to such accounting.

18 **Independent Contractor.** In undertaking to perform the respective services hereunder, the Institution and the Principal Investigator are doing so as independent contractors, and not as employees or agents of CRO. No party shall represent itself as an agent of any other party.

19 **Assignment**. No party shall assign this Agreement or any rights or obligations hereunder without the prior written consent of the other parties, except that CRO, without the consent of any other party hereto, may assign this Agreement and its rights and obligations hereunder (a) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, (b) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Drug or (c) to any direct or indirect affiliate of CRO.

20 **Severability**. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law and if the rights or obligations of any party will not be materially and adversely affected: (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the parties. To the fullest extent permitted by applicable law, the parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

21 **Notices**. Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, or by

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Belagavi-590 010,Karnataka

facsimile (with transmission confirmed), addressed to the parties at however, this agreement is subject to Ahmedabad Court jurisdiction:

If to Cadila CRO to: Dr. Manjul Joshipura
Address: 1389, Trasad Road, Dholka, and Dist: Ahmedabad- 382225, Gujarat, India

If to Principle Investigator to: Dr. Snehal Lunge,
Address: KLES Dr Prabhakar Kore Hospital & MRC,
Nehru Nagar, Belagavi 590010, Karnataka, India

22 **Business Communications.**

The Principal Investigator consent to receive communications sent by or on behalf of CRO via mail, e-mail and/or fax at the Principal Investigator mailing address, e-mail address and fax number set forth in this agreement.

23 **Entire Agreement**. This Agreement, together with the appendices hereto and that certain Confidentiality Agreement by and between the Principal Investigator and CRO in relation to the Study (the "**Confidentiality Agreement**") constitute[s] the entire agreement among the parties hereto with respect to the subject matter of this Agreement. This Agreement, together with the Confidentiality Agreement if applicable, supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is not relying on any representations, warranties or covenants of any other party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.
Period of Performance ;
The performance of this Agreement shall be from the Effective Date through termination of the Study by SPONSOR, unless earlier terminated in accordance with Section 17 of this Agreement.

24 **Amendment**. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each party.

25 **Waiver**. A party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

26 **Inconsistency**. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects (including Section 14), the terms of this Agreement shall prevail.

27 **Construction**. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, the word "or" has the inclusive meaning represented by the phrase "and/or" and the term "including" or "includes" means including, without limiting the generality of any description preceding such term. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope

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or intent of any provision contained in this Agreement. A reference in this Agreement to a Section or appendix is to the referenced Section or appendix of this Agreement. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied

28 **Counterparts.** This Agreement may be executed in two counterpart copies, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

29 Any dispute arising out of or in connection with this agreement, the same shall be solved amicably by the parties failing which the same shall be referred to Arbitration in accordance with Arbitration and Conciliation Act 1996, its amendments and rules and regulations thereof. The venue of arbitration shall be Ahmedabad, India. The Courts situated at Ahmedabad, shall have exclusive jurisdiction to this agreement

THIS AGREEMENT IS EXECUTED by the authorized representatives of CRO and the Institution as of the date first written above.

For: **CADILA PHARMACEUTICALS LTD.** Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	For: **PRINCIPAL INVESTIGATOR** Name: **Dr. Snehal Lunge** Designation: Principal Investigator Place: Belgavi Date: 29/08/2018
Dr. M. V. Jali MD & CE KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi. Name: Amitabha Banerjee Designation: Executive Director Name : Designation : Finance Controller	For **Institute name** **KLES Dr Prabhakar Kore Hospital & MRC** Place: Belgavi Medical Director & Chief Executive Date: KLES Dr. Prabhakar Kore Hospital & 29/08/2018 Medical Research Centre, BELAGAVI. Name : **Mr. Kirti Kumar Patel** Designation: SMO Place: Raipur 20 AUG 2018
Name : Vinod Jain Designation : Sr. VP-Finance Name: Hetal Hindocha Designation: DGM - Legal	

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APPENDIX -A

FINANCIAL AGREEMENT

Sponsor Study No. : **CRSC16004**

Protocol Title : A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.

Sponsor : Cadila Pharmaceuticals Ltd.

Cadila CRO on behalf of Sponsor offers to pay **Dr. Snehal Lunge,** (Principal Investigator), KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India **(Institution)** as follows for the study under taken. **Cadila CRO** will make a maximum payment of Rs. 38,000 per completed patient to on behalf of the Cadila Pharmaceutical. This per patient grant will take care of all the on-site expenses (administrative and clinical) and all the on-site Admissions and Investigations that are required by the Protocol as per the schedule mentioned therein.

Cadila CRO will make payment on monthly basis upon receiving bills or receipt for all the study procedures including payment to pateint for their trasportation.

Cadila CRO is expecting **Dr. Snehal Lunge,** to finish the enrollment of 20 to 25 subjects, before_____The enrollment is competitive had patient load will be redistrubuted to site where the recruitment is faster to achieve the largest sample size quickly.

In case the patient is not able to complete the study, the per patient grant will be paid to the PI depending upon the following parameters:

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Milestones:

1. Fixed Cost as PI fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 30,000/- per patient upon achieving the below milestones.

Milestone	Payment
Screening - Visit 1	6000
Visit 2	6000
Visit 3	6000
Visit 4	6000
Visit 5	6000

2. Rs. 8,000 will be paid to Observer physician as per the below milestones.

Milestone	Payment
Screening - Visit 1	Nil
Visit 2	2000
Visit 3	2000
Visit 4	2000
Visit 5	2000

Terms of Payment:

STUDY TITLE: A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.

1. Fixed Cost as PI fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 30000/- per completed Patient as per above table.
2. Maximum up to Rs. 8,000 will be paid to Observer physician as per above table.
3. Patient compensation will be provided Rs. 500/- per visit per study completed patient.
4. Study coordinator fees will be paid Rs. 13,000/- per month from SIV (Site initiation visit) to SCV (Site closeout visit). In case of no recruitment at the site, CRC fees will be given only for 3 months after SIV. In any case, CRC fees will not be paid for more than 9 months unless there is a written CRC term extension confirmed by Cadila management
5. Administrative cost (for stationary, courier, telephone, fax, internet) will be paid Rs. 10,000/- for entire study.
6. Study medications will be provided by sponsor. (As mentioned in protocol)
7. TDS will be deducted as per government policy.
8. As per new regulations, applicable GST will be paid over and above of total budget.
9. Screen failure charges will be paid Rs. 500/- with laboratory charges on actual basis not exceeding as per below table of laboratory charges, per screen failed patient up to a maximum of three subject.
10. Laboratory charges will be paid as per actual upon submission of original bills not exceeding as per the below milestones.

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Milestone	Payment
Screening - Visit 1	3300
Visit 3	2300
Visit 4	2300
Visit 5	2500

Note: Cost list has attached with this CTA.

11. Reimbursement of related Adverse Events/SAE medication management cost on actual as per DCGI Guidelines. In most situations where AE/SAE is prima facie unrelated, medical management cost will not be paid unless meeting all criteria of detailed DCGI guidelines.
12. Rs. ~~45,000/-~~ will be given for archiving the documents for 15 years
13. ~~10%~~ of PI Fees will be paid to Institutional Head
14. A minimum of 10 subject recruitment is mandatory prior to release of payment from Cadila. However payments directly linked with subject compention for participating in study will be reimbursed upon request.Payments other than PI charges has to be released once in two month as per expenses occurred

Investigator has to complete below information:

A. Payment Cheque required in favour of/payable to:

"KV CLINICAL RESEARCH SERVICES"
Account No.: 916020042282734
Bank Name: Axis Bank, Samta Colony, Raipur
IFSC Code: UTIB0001824 (5th,6th and 7th characters are zero)

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B. Address where payment Cheque would be sent:
Mr. Kirti Kumar Patel,
KV Clinical Research Services,
Office No. 615, Sixth Floor
Golden Trade Center, New Rajendra Nagar
Raipur – 492001, Chhattisgarh, India

C. PAN Number or TAN Number, if applicable: **AAPFK7058P**
Service Tax No.:
GST No.: **22AAPFK7058P1ZM**

By signing this FINANCIAL AGREEMENT, **Cadila CRO, Ahmedabad and the Principal Investigator** agree to adhere to the terms and conditions mentioned in the CLINICAL TRIAL INVESTIGATOR's AGREEMENT.

For: **CADILA PHARMACEUTICALS LTD.**	For: **PRINCIPAL INVESTIGATOR**
Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	Name: **Dr. Snehal Lunge** Designation: Principal Investigator Place: Belgavi Date: 29/08/2018
Name: Dr. M. V. Jali MD & CE, KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi. Name: Amitabha Banerjee Designation: Executive Director Name : Designation : Finance Controller	For **Institute name** Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. **KLES Dr Prabhakar Kore Hospital & MRC** Place: Belagavi Date: 29/08/2018 Name: **Mr. Kirti Kumar Patel** Designation: SMO Place: Raipur Date: 29 AUG 2018
Name : Vinod Jain Designation : Sr. VP-Finance Name: Hetal Hindocha Designation: DGM - Legal	

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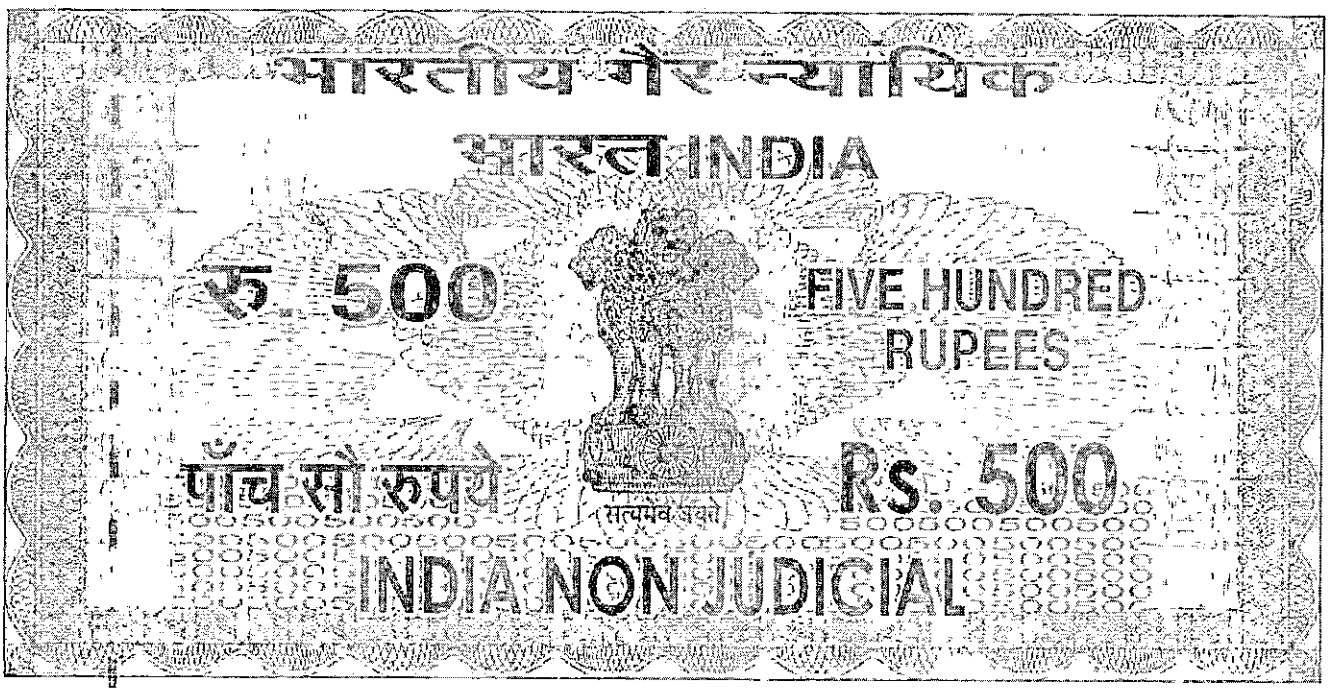

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ AM 066843

प्रधान मुद्रांक कार्यालय, मुंबई.
प.मु.वि.क्र. ८०००००९
24 AUG 2018
सक्षम अधिकारी

विजय म. निलावार

STATEMENT OF AGREEMENT

between

Dr. Mahesh Kumar Kalloli

(hereinafter referred to as the "Investigator")
and/or

KLES Dr Prabhakar Kore Hospital and Medical Research Centre
SMO office, Sharawati floor, Nehru nagar, Belagavi-590010,
Karnataka, India
(hereinafter referred to as the "Institution")

and
PPD Pharmaceutical Development India Private Limited
Office 101, A-Wing, Fulcrum, Hiranandani Business Park
Sahar Road, Andheri (East)
Mumbai-400099, Maharashtra INDIA
(hereinafter referred to as "PPD")

Protocol number: Celltrion Inc. CT-P16 3.1

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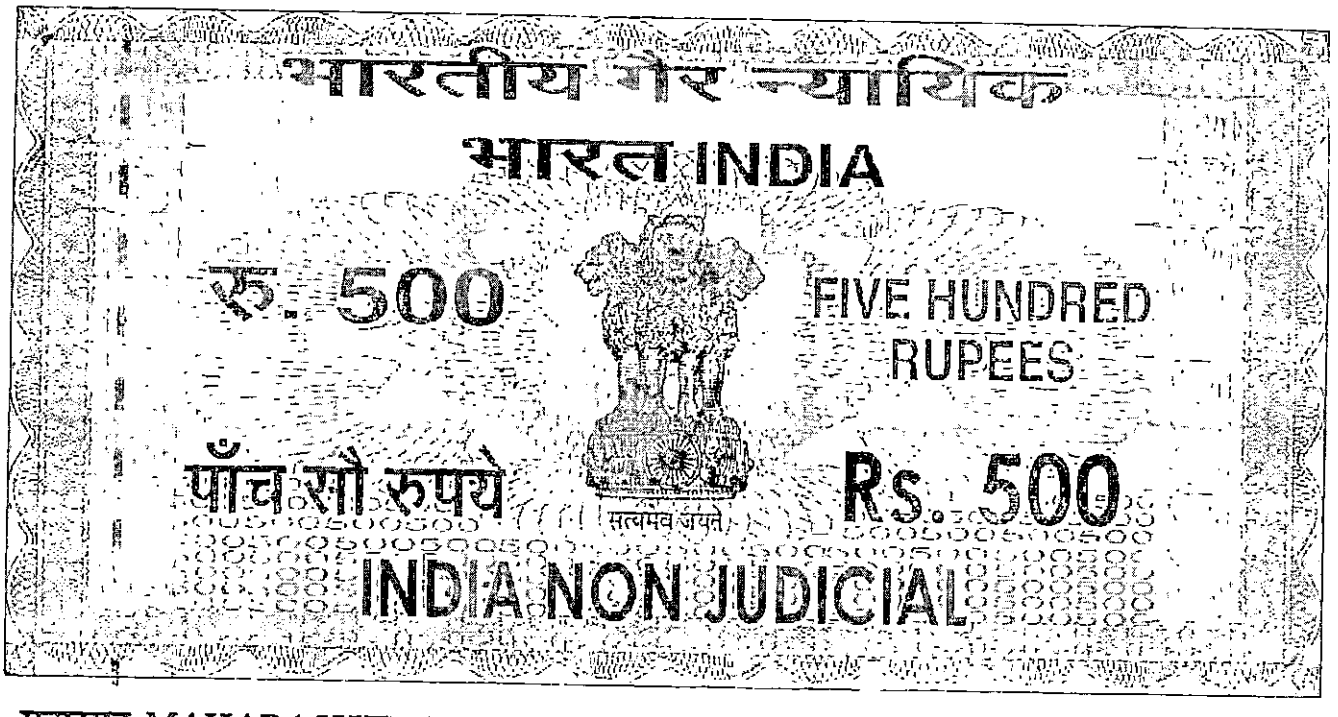

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ AM 066844

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००९
24 AUG 2018
सक्षम अधिकारी

1 Introduction

1.1 This CLINICAL TRIAL AGREEMENT ("Agreement") is effective as of the date of the last signature below ("Effective Date") by and between PPD, the Institution and the Investigator.

1.2 PPD, a clinical research organization, is pleased that our discussions have resulted in an agreement to participate in and conduct this collaborative clinical research study described below and sponsored by Celltrion, Inc. (the "Study" and the "Sponsor" respectively)

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1.3 In order to make this Study mutually rewarding, it is essential that the parties are in agreement with regard to the basic policies applicable to the Study. Accordingly, this agreement in conjunction with Sponsor's protocol no. **CT-P16 3.1** entitled "A Double-Blind, Randomized, Active-Controlled, Parallel-Group, Phase 3 Study to Compare Efficacy and Safety of CT-P16 and EU-Approved Avastin as First-Line Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer" (and any amendments thereto which maybe adopted from time to time) (the "Protocol"), which is incorporated by reference herein, will serve together as an Agreement, delineating the terms and applicable conditions (the "Agreement").

2 Study Conduct

2.1 The scope and nature of the Study and services to be performed at KLES Dr Prabhakar Kore Hospital and Medical Research Centre (the "Site") will be in accordance with the Protocol.

2.2 The Institution and Investigator each warrants to PPD that they have the education, experience, capabilities, adequate patient population, adequate personnel, equipment and other resources to conduct

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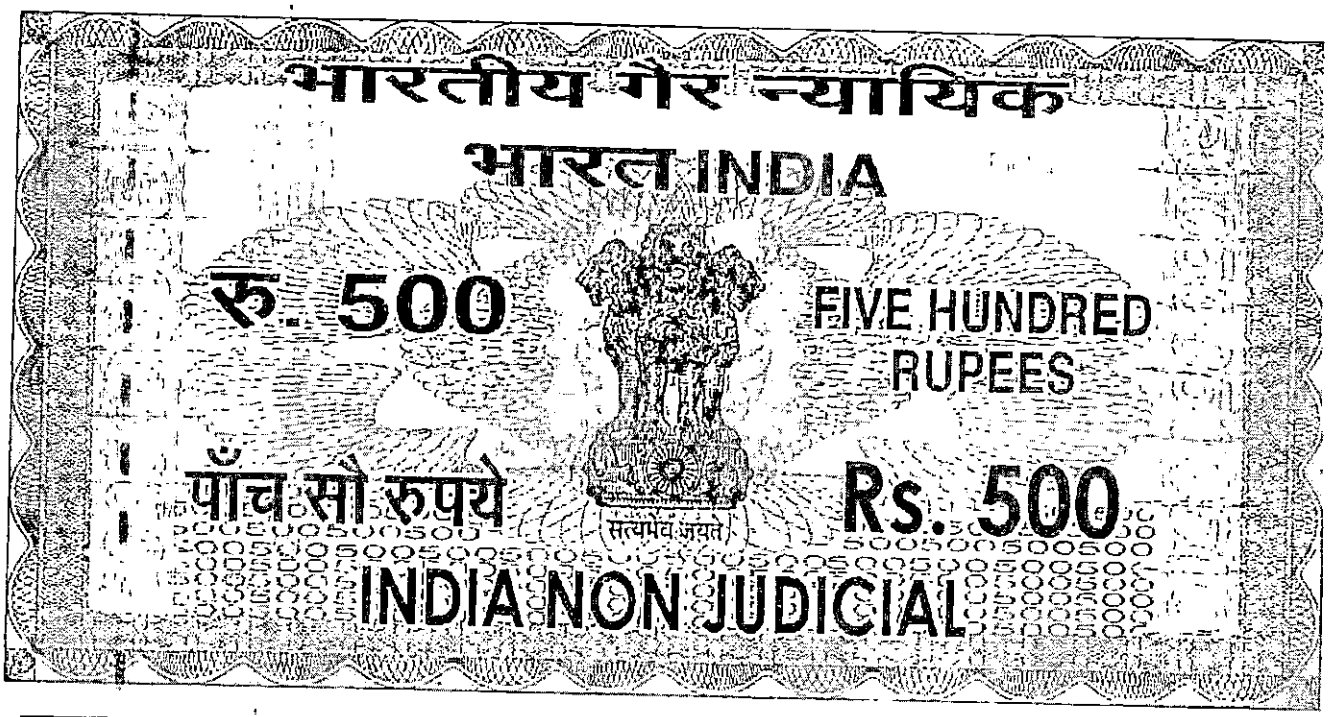

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ AM 066845

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क. ८०००००९
24 AUG 2018

the Study in a professional and competent manner, and that they are fully aware of and will comply with applicable regulations and legislation; furthermore, they agree that they will not participate in any other study that by its nature will prevent them from fulfilling their obligations in the Study hereunder.

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2.3 As it is essential that the Study is carried out exactly in accordance with the terms of the Protocol, the Institution and Investigator agree to study the Protocol, fully understand it and conduct the Study in the manner specified therein. Any change to the terms of this Agreement shall be valid only if the change is made by mutual written agreement of authorised representatives of all parties hereto. No changes or deviations to the Protocol should be implemented without agreement by the Sponsor and prior review and documented approval from the Ethics Committee ("EC"), unless to eliminate an immediate hazard to patients.

2.4 The Institution and Investigator will ensure that they are thoroughly familiar with the appropriate use of the investigational product(s), as described in the Protocol, the current Investigator's Brochure, the product information leaflet and all information provided to them in connection with the Study.

2.5 Accordingly the Institution and the Investigator each agree to carry out the Study in accordance with:

2.5.1 this Agreement;

2.5.2 the Protocol;

2.5.3 the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Investigator must at any time jeopardise the health or well-being of any patient by unwarranted continuation of the Study;

2.5.4 applicable national laws, regulations and guidelines including without limitation the Drug Act B.E. 2510 (1967) as amended, Psychotropic Substances Act. B.E. 2518(1975) as amended, Medical

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Device Act B.E. 2531 (1988) as amended, the National Policy on Clinical Studies, data protection laws and the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96); and

2.5.5 (if the Study is conducted under an Investigational New Drug (IND) the conditions specified in the Statement of Agreement and FDA Form 1572 which has been completed, signed, and returned to PPD for forwarding to the US FDA, and

2.5.6 the US Foreign Corrupt Practices Act and the UK Bribery Act.

3 Commencement and Duration

The Study will commence following signature of this Agreement as soon as the Institution and the Investigator have received EC approval and obtained a list of members and any national regulatory approval as appropriate has been obtained by Sponsor/PPD and/or Institution/Investigator. The recruitment of patients shall be performed on competitive basis. Institution and/or Investigator are free to enroll as many Patients as they can until the recruitment maximum at global level is achieved. Notwithstanding the foregoing sentence, Institution and Investigator shall stop the Patient recruitment immediately upon the request of Sponsor or PPD. Patient recruitment is scheduled to start on **December 2018**. The entire Study is scheduled to be completed by **December 2023.** If, at any time during the Study, it becomes apparent that either Institution or Investigator will be unable to complete the Study on schedule or enrol the number of patients specified, Institution or Investigator will notify PPD immediately to make appropriate alternative arrangements. Similarly, if Sponsor/PPD considers that recruitment at the Site is unduly slow then the Study terminated in accordance with section 15 below. Furthermore, if at any time during the course of the Study the overall target of the Study has been reached, Institution and Investigator will upon written request by Sponsor or PPD immediately stop recruitment.

4 Compensation

4.1 PPD will provide the financial support set out in the schedule attached to this Agreement ("Exhibit A") for the conduct of the Study in accordance with the terms of the Protocol.

4.2 Institution and Investigator hereby acknowledge and agree that payments due under this Agreement are pass-through payments from Sponsor and that PPD shall have no payment obligations hereunder until such time as said payments are received by PPD from Sponsor. PPD shall exercise reasonable efforts to ensure timely receipt of pass-through payments from Sponsor.

4.3 Sponsor, at its reasonable discretion, directly or through PPD, may provide equipment or reimburse Institution for procuring equipment needed for the Study. The Institution shall have responsibility to maintain and calibrate the equipment during Study and after the Study is completed. At the end of the Study, where permitted by applicable law and regulation, the equipment may become the property of the Institution or be returned to Sponsor or PPD according to Sponsor's decision. In the event of early termination of the Study at Institution, Sponsor shall have the right to decide whether the equipment is returned to Sponsor or not.

5 Confidentiality and Intellectual Property

5.1 Confidentiality

Neither the Institution nor the Investigator (nor any of their employees, directors, officers or agents) shall disclose to any third party or use for any purpose other than for the performance of the Study any data, records or other Information disclosed to Institution or Investigator by Sponsor or PPD or generated as a result of this Study (hereinafter, collectively "Information") without the prior written consent of Sponsor.

Such Information shall remain the confidential and proprietary property of Sponsor (or PPD as the case may be) and shall be disclosed only to Institution and Investigator or their employees or agents who "need to know" and who have agreed to terms of confidentiality substantially similar to those terms contained herein. The obligation of nondisclosure shall not apply to the following Information:

5.1.1 Information that is or becomes publicly available through no fault of Institution and Investigator;

5.1.2 Information that is disclosed to Institution and Investigator by a third party legally entitled to disclose such Information;

5.1.3 Information that is already known to Institution and Investigator as shown by their prior written records, provided they so advise PPD or Sponsor within twenty (20) days after disclosure of the Information to them by PPD or Sponsor; and

5.1.4 Information disclosed to a government authority or by order of a Court of competent jurisdiction, provided that a) such disclosure is subject to all applicable governmental or judicial protection available for like material; b) reasonable advance notice is given to Sponsor; and c) Institution and Investigator take reasonable steps to limit the scope of such disclosure.

All Information containing personal data shall be handled in accordance with all applicable laws, including without limitation data protection laws. In the event that Institution or Investigator should receive a request for Information, relating to this Agreement or the subject matter specified herein, in terms of the provisions of the Official Information Act B.E. 2540 (1997) as amended from a third party or an authorized governmental authority, Institution or Investigator will immediately notify and consult with PPD prior to making any disclosures.

5.2 Intellectual Property

5.2.1 Institution or Investigator agree any inventions, discoveries (whether patentable or not), innovations, suggestions, ideas, reports or other intellectual property made or developed by Institution or Investigator during the Term of this Agreement, alone or in conjunction with others, during or as a result of any deliverables provided by the Site, the Principal Investigator or PPD or conducting the Trial under this Agreement (collectively, the "Inventions") shall be promptly disclosed to Sponsor and shall become the sole and exclusive property of Sponsor. Upon Sponsor's request and at Sponsor's expense, Institution and Investigator shall take such actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name with respect to any of the foregoing.

5.2.2 Neither PPD nor Sponsor shall transfer to Institution and Investigator by operation of this Agreement or otherwise any patent right, copyright or other proprietary right of Sponsor.

Upon termination of the Study, all such materials, information and data in Institution and Investigator custody, except as required for archiving under ICH GCP and applicable national and local regulations, shall be promptly delivered to PPD.

6 Ethics Committee Approval

6.1 Written approval for the conduct of the Study, the terms of the Protocol and the informed consent form must be obtained from a properly constituted EC according to ICH GCP (section 3.0) prior to the commencement of the Study. A copy of such approval, clearly identifying the documents reviewed and

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approved (including version dates/numbers) along with other such documents required by the ICH GCPs must be obtained and copies provided to all parties before release of the Study drug will be permitted. Such approval must indicate the date approval was given and the name and signature of the Chairman/or authorised personnel. The names, occupations and institutional affiliations of the EC must also be submitted to PPD, along with a statement to the effect that they are organised and operate according to ICH GCP and the applicable laws and regulations.

6.2 Institution and Investigator agree to submit reports to the EC regularly and at least annually.

7 Adverse Event Reporting

7.1 An adverse event is any untoward medical occurrence in a patient administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. A serious adverse event is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect (an "SAE") (ICH GCP).

7.2 Within twenty-four (24) hours of first knowledge of any SAE, Institution and Investigator must notify PPD via telefax or telephone. This applies also for any event that could affect the safety of the Study participants or the conduct of the Study.

7.3 The relevant information should be completed on the "adverse event form for expedited reporting" that can be found in the Study binder. The form must be completed and forwarded immediately by fax to PPD responsible for receiving expedited reports, who will notify the Sponsor immediately.

8 Monitoring

8.1 The Study will be monitored by PPD's own clinical monitor. Institution and Investigator must allow a reasonable amount of time to be set aside at each monitoring visit for discussions and to make corrections to the case record forms (CRF). The monitor will give as much notice as possible when scheduling visits, and these will occur at a mutually convenient time. In accordance with ICH GCP, the Investigator and the Institution will provide **direct and prompt access** to source data and documents for Study related monitoring, audits, EC review, and regulatory inspection.

8.2 If any source data is kept on computer files only, for the purpose of source data verification, the Institution and the Investigator agree to make a print out of all patient data relevant to the Study. These print-outs will be dated and signed and retained as source documents. This includes relevant history information and all data obtained during the Study period.

8.3 Patient confidentiality will be respected by all the parties as required by local law, and neither the Institution nor the Investigator will remove (or permit to be removed) any documents bearing patient names from the Study Site. Patients will be identified by code numbers and initials.

9 Patient Consent

The Investigator must obtain written informed consent from each patient enrolling in the Study prior to commencement of any Study related procedures, including treatment. As part of the informed consent process, the Investigator shall inform patients that their medical records will be reviewed by representatives of PPD and Sponsor, EC and Regulatory authorities. The Investigator shall give a copy of the patient information sheet and the signed consent form to all patients for them to keep.

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Belagavi-590 010,Karnataka

10 Quality Assurance Audit

This Study may be audited by the Quality Assurance Department of PPD and/or by Sponsor, or inspected by governmental or regulatory bodies, in order to document the authenticity of recorded data and protocol adherence. Both the Institution and the Investigator agree, following written notification, to allow an independent audit of all Study documentation and processes at Site.

11 Record Retention

11.1 All documentation, records and correspondence relating to this Study, including that with the EC and PPD shall be retained by the Institution for at least fifteen (15) years or longer if required by applicable laws or policy. The period of retention starts with the termination of the Study at Institution. The Institution will i mmediately contact the Sponsor for authorisation prior to the destruction of any Study records or in the ev ent of accidental loss or destruction of any Study records.

11.2 Institution or Investigator shall be financially supported by sponsor for long term storage of records, if ne cessary. Payment shall be done by PPD on behalf of Sponsor

11.3 Sponsor must be informed in writing of any change of address or relocation of the Study files during this period

12 Publications

The findings of this Study are the exclusive property of Sponsor and shall not be published without prior written ap proval of Sponsor. The material for public dissemination will be submitted to the Sponsor for review and comment at least sixty (60) days prior to submission for publication, presentation, or any other ways which could lead expos ure of method and result of the Study.

If in the Sponsor's sole judgment, publication or presentation at a given time would hinder the Sponsor's develop ment of the investigational product, Investigator and/or Institution shall consider modifying the publication or pres entation schedules accordingly. All reasonable comments made by Sponsor in relation to a proposed publication by Investigator will be incorporated by Investigator/Institution into the publication.

As the Study is part of multi-centered clinical trial, Investigator nor Institution shall not make any publication or presentation based on the results obtained at Institution before the first multi-center publication.

The publication or presentation by Institution or Investigator shall make reference to the relevant multi-center publication(s).

The Sponsor shall also have the right to publish the results of the Study. In the event the Sponsor coordinates a multi-centre publication, the participation of Investigator/ as a named author shall be determined in accordance with the Sponsor's policy and generally accepted standards for authorship.

13 Independent Contractor

In their activities in connection with the Study, each of the Institution and the Investigator agree that they will act as an independent contractor, without the capacity to act on behalf of or legally bind PPD or Sponsor, and not as an agent, partner, joint venture or employee of Sponsor or PPD.

14 Insurance /Indemnity

14.1 Sponsor agrees to indemnify Institution and Investigator in accordance with the applicable laws governing pa

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tient injury compensation.

14.2 Sponsor shall defend, indemnify and hold harmless Institution and Investigator against any and all claims, actions, costs and expenses, (collectively hereafter: "Claim(s)"), arising out of Patients' claim that results from participation as a patient within the Study, inclusive of injury, death or effect related to any investigational drug, procedure or activity involved in the Study, provided, however, that Sponsor shall have no duty under this Agreement with respect to any Claim to the extent it arises from:

1) the gross negligence of, or reckless or intentional misconduct by Institution and Investigator or any of its or their employees, or from any material breach by Institution and Investigator or any of its or their material terms or conditions under this Agreement including without limitation a significant departure from the Protocol, malpractice and/or negligence of Investigator or Institution and Investigator's failure to deal adequately with an adverse reaction;
2) the failure of the medicinal product to have its intended effect or to provide any other benefit to the Patient
3) other licensed medicinal products or placebo administered to the Patient for the purpose of comparison with the product under Study; or
4) contributory negligence by the Patient.

14.3 PPD shall indemnify, defend and hold harmless Institution and Investigator from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Institution or Investigator as a result of PPD's negligence or willful misconduct, or breach of this Agreement.

14.4 Institution and Investigator shall indemnify, defend and hold harmless PPD and Sponsor from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or Sponsor as a result of the negligence or willful misconduct of, or breach of this Agreement by, Institution and/or Investigator.

14.5 Each of the Institution and the Investigator warrants that they will self-insure for any claims arising from their negligence, wilful misconduct or other actions or omissions.

14.6 Neither the Sponsor nor PPD will be liable for, or are a party to unauthorized representations or warranties made by the Institution or the Investigator or their agents relating to the product.

15 Termination

15.1 Sponsor through PPD, shall have the right to terminate this Agreement at any time upon thirty (30) days prior written notice to Institution without cause and without liability, or immediately upon written notification to Institution without liability, in case Sponsor, at its sole discretion, concludes that:

15.1.1 if available data indicate that it is, in their sole opinion, not safe to continue to administer the Study drug to patients;

15.1.2 if the Institution or the Investigator is in breach of any term of this Agreement (including but not limited to any warranty or undertaking);

15.1.3 if PPD's agreement with Sponsor is terminated or expires;

15.1.4 by agreement, in writing, between PPD and the Institution and the Investigator;

15.1.5 if the entry of valid patients in the Study is too slow to meet the agreed time scheduled;

15.1.6 if adherence to the Protocol is poor or data recording is materially inaccurate or incomplete; or

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15.1.7 if overall Study enrolment has been met even if enrolment in terms of this Agreement has not been c ompleted.

15.2 If Investigator is no longer able to act as Investigator and no replacement mutually acceptable to Insti tution and PPDcan be found.

15.3 Upon the termination of this Agreement, Institution shall cooperate with PPD and Sponsor to provide for an orderly wind-down of the Study conducted hereunder. In the event of early termination, if payment (whether for salaries or otherwise) has been made by Sponsor and/or PPD to Institution in advance for work not completed, such monies shall be refunded within forty five (45) days after the date of such termination.

15.4 Upon termination PPD will reimburse the Institution and the Investigator for actual and necessary expenses incurred or committed to the date of notice of termination. PPD will further cooperate with the Institution and the Investigator to ensure withdrawal of patients on a medically/ethically acceptable basis.

15.5 In the event of termination, the Institution and the Investigator will be obliged to notify the EC.

16 Debarment & Disqualification

16.1 Each of the Institution and the Investigator represents and warrants that neither they, their employees, offices, agents or affiliates, nor any other person retained by them to perform the Study pursuant to this Agreement: (i) is under investigation by the FDA for debarment action or is presently debarred pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. §301 et seq) or the applicable drug law in the relevant jurisdiction; or (ii) has a disqualification hearing pending or has been disqualified by the FDA pursuant to the applicable drug law in the relevant jurisdiction. In addition, each of the Institution and the Investigator represents and warrants that they have not engaged in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions. If during the term of this Agreement either the Institution or the Investigator or any person employed or retained by them to perform the Study (i) come under investigation by FDA for debarment action or disqualification; (ii) are debarred or disqualified; or (iii) engage in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions, said party shall immediately notify PPD of same.

16.2 For the purposes of this Agreement, reference to the FDA and the Generic Drug Enforcement Act shall also be deemed a reference to any other governmental or regulatory authorities having jurisdiction over the subject matter of the particular Study or any other laws and regulations applicable to the Study.

17 Publicity

17.1 PPD and Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Investigator consistent with applicable copyright laws, provided such use does not constitute an endorsement of any commercial product or service by the Institution or the Investigator. Neither the Institution nor the Investigator shall disclose the existence of this Agreement or its association with PPD or Sponsor, or use the name of Sponsor or PPD in any press release, article or other method of communication with the general public, without the express prior written approval of the party whose name is the subject of the potential disclosure.

17.2 Both PPD and Sponsor may use Institution and Investigator contact details and Study status in Study specific n ewsletters and on the World Wide Web for the purpose of conducting this Study. Newsletters (which may be distributed to all participating sites) and postings to the web are for the purpose of providing information to po tential patients regarding the Study, giving them the ability to contact participating sites.

17.3 Sponsor shall have the right to use, refer to and disseminate reprints of scientific, medical and other publis hed articles which disclose the name of Institution and/or Investigator consistent with U.S. or other applica

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ble copyright laws, provided such use does not constitute an endorsement of any commercial product or se rvice by Institution or Investigator.

18 Ethical Conduct

18.1 Institution/Investigator undertakes that Institution/Investigator shall not, directly or indirectly through any third party, give, offer or promise any payment, gift or other thing of value to any person in order to improperly influence them or otherwise assist Institution/Investigator, PPD or the Sponsor in obtaining an improper advantage.

18.2 Institution/Investigator undertakes that Institution/Investigator shall not, directly or indirectly through any third party, accept, agree or receive or request any payment, gift or other thing of value from any person offered or given as a reward for or with the intention of improperly influencing Institution/Investigator, PPD or the Sponsor.

19 Miscellaneous

19.1 This Agreement supersedes all prior written and oral agreements and representation between parties with respect to the subject matter hereof. All obligations contained herein as to which performance is required after termination shall survive termination. This Agreement may not be assigned or transferred by the Institution or the Investigator without the prior written consent of PPD. PPD may assign or transfer this Agreement upon written notice to Institution. In the event that PPD assigns or transfers this Agreement to a third party who will assume all obligations hereunder, the Institution and the Investigator shall each release and forever discharge PPD and its subsidiaries and affiliates from any and all liabilities and obligations of them arising under the Agreement from and after the effective date of such assignment.

19.2 The rights and obligations of the Parties under and pursuant to this Agreement shall be governed by and construed in accordance with the laws of India. Where the Indian Law is silent or does not address any particular issue, English law shall apply. Disputes regarding this Agreement which the parties fail to settle amicably will be settled in accordance with the laws of India in the Court of law having jurisdiction.

19.3 If any provision of this Agreement conflicts with the law under which this Agreement is to be construed, or if any such provision is held invalid by a court, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law and the remainder of this Agreement shall remain in full force and effect.

19.4 This Agreement shall be binding upon the parties, their heirs, successors, and permitted assigns.

19.5 Waiver or forbearance by either party with respect to a breach of any provision of this Agreement or any applicable law shall not be deemed to constitute a waiver with respect to any subsequent breach of any provision hereof.

19.6 Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified mail, return receipt requested postage prepaid, to the following address:

If to PPD:

PPD Pharmaceutical Development India Pvt.Ltd.
101-A Wing Fulcrum,Hiranandani Business Park
Sahar Road,Andheri East, Mumbai – 400 099
Telephone: 022 -6602 2900
Facsimile: 022-6602 2999
Attn.: Clinical Trial Manager

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If to Institution:

KLES Dr Prabhakar Kore Hospital and Medical Research Centre
SMO office, Sharawati floor, Nehru nagar, Belagavi-590010,
Karnataka, India
Telephone: 9945014996
Email ID: mahesh.kalloli@gmail.com
Attn.: Dr. Mahesh Kumar Kalloli

If to Investigator:

KLES Dr Prabhakar Kore Hospital and Medical Research Centre
SMO office, Sharawati floor, Nehru nagar, Belagavi-590010,
Karnataka, India
Telephone: 9945014996
Email ID: mahesh.kalloli@gmail.com
Attn.: Dr. Mahesh Kumar Kalloli

Any party may change its notice address and contact person by giving notice of same in the manner herein provided.

INSTITUTION AND INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, INVESTIGATOR OR ANY EMPLOYEES OR AGENTS OF INSTITUTION OF ANY PATIENT DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION AND INVESTIGATOR AND IN CIVIL LIABILITY TO PPD AND SPONSOR.

19.7 In case the Institution is a governmental organization, the Institution agrees that:

19.8.1 the execution, delivery and performance by it of this Agreement constitute private and commercial acts rather than public or governmental acts; and

19.8.2 should any proceedings be brought against it or its assets in any jurisdiction in relation to this Agreement, no immunity from such proceedings shall be claimed by or on its behalf or with respect to its assets which it now has or may acquire in the future.

20 Agreement

It is the Institution and Investigator's responsibility to ensure that the hospital Trust management or the equivalent is made aware of their participation in this Study and approval is obtained prior to commencing the Study.

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We hereby agree to the conditions in this Agreement:

Signed for and on behalf of Institution

KLES Dr Prabhakar Kore Hospital and Medical Research Centre

Signature:

Name: Dr. M.V. JALI

Title: MD & CE

Address: KLEs Dr. Prabhakar Kore Hospital & MRC, SMO office, Sharawati floor, Nehru nagar, Belagavi-590010, Karnataka, India

Date: 22 Nov 2018

Signed for and on behalf of PPD

Signature: Rashmi Chitgupi

Name: Associate Director - Clinical Management

Title: PPD Pharmaceutical Development India Pvt. Ltd. 101-A Wing, Fulcrum, Hiranandani Business Park Sahar Road, Andheri East Mumbai – 400 099, India.

Address: PPD Pharmaceutical Development India Pvt.Ltd,101-A Wing Fulcrum, Hiranandan Business Park, Sahar Road, Andheri East, Mumbai – 400 099

Date: 23/11/2018

Signed for and on behalf of Investigator

Dr. Mahesh Kumar Kalloli

Signature:

Name: Dr. Mahesh Kumar Kalloli

Title: Surgical Oncologist

Address: KLEs Dr. Prabhakar Kore Hospital & MRC, SMO office, Sharawati floor, Nehru nagar, Belagavi-590010, Karnataka, India.

Date: 22 Nov 2018

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Exhibit 1
Budget and Payment Schedule

Payments: Payment should be made to the following:s

Payee Name: Mahesh Kumar V K
Payee Address: Site management office, Sharawatis, 2ND floor, Belgaum, Karnataka, India 590010
Bank Name: State Bank of India
Account Number:30182299687
IFSC Code SBIN0012257

Invoices: Please send original, correct and itemized invoices to the following.

PPD Pharmaceutical Development India Private Limited
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Anderi East,Mumbai – 400 099
InvestigatorPayments@ppdi.com

The Study shall be payable as follows:

Cost Per Subject: Institution will be paid per completed and evaluable subject as defined below based on the rates set forth in the Budget, which is inclusive of 25% overhead. Payments will be made on a quarterly basis (or Bi-Monthly Basis, only if applicable) in INR and will be based on completed visits verified in the subject electronic case report forms (eCRFs). A complete and evaluable patient is defined as follows: (i) all procedures must be performed according to the protocol and ICH GCP guidelines, (ii) a patient will only be included according to the inclusion/exclusion criteria, and (iii) all data are documented accurately, completely. In the event that a patient does not complete all visits as specified in the Protocol, PPD shall only be obligated to make payment for such patient on a pro-rated, completed visit, and eCRF basis.

Pharmacy Fees: Institution will receive a non-refundable or refundable pharmacy fee in the amount of 32431.00 INR. Pharmacy fees are those costs incurred by the Institution for purposes of storing and distributing Study Drug. Payment for such pharmacy fees will be payable upon PPD's receipt of correct and itemized invoice from Institution

Ethics Committee: Ethics committee Fees will be submitted by the Institution and reimbursable directly to the Institution as per the site policy upon the receipt of correct and itemized invoices by PPD.

Central Laboratory Fees: Central Laboratory costs will be paid by the Sponsor.

Equipment Allocation: Sponsor, at its reasonable discretion, directly or through PPD, may provide equipment or reimburse Institution for procuring equipment needed for the Study. The Institution shall have responsibility to maintain and calibrate the equipment during Study and after the Study is completed. At the end of the Study, where permitted by applicable law and regulation, the equipment may become the property of the Institution or be returned to Sponsor or PPD according to Sponsor's decision. In the event of early termination of the Study at Institution, Sponsor shall have the right to decide whether the equipment is returned to Sponsor or not.

Screen Failures: The Institution will be paid for Screen Failures (as defined below). Institution will be reimbursed 80% of the Screening visit cost as stated in the Budget for all screen failed subjects. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the pre-screening and/or screening visit but does not enroll into the Study. Payment for Screen Failures will be payable to Institution based upon the receipt of correct and itemized invoices.

Patient Transportation Reimbursement: Transportation costs not to exceed 1000.00 INR (exclusive of OH) per enrolled patient per Protocol defined scheduled visit will be paid to Institution/Investigator for patient reimbursement upon receipt of invoice and supporting documentation. Any patient transportation reimbursement

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GST: All fees payable by PPD will be exclusive of GST, VAT, and similar indirect taxes as per the existing rules in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India.

Unscheduled Visits: An Unscheduled Visit means a Study subject visit which is not expressly set forth in the Protocol, but is otherwise required for the Study. Unscheduled visits will be reimbursed on a per procedure basis in accordance with the rates set forth in Budget upon Sponsor or PPD's receipt of invoice. Any invoiced item performed during an unscheduled visit will also be reimbursed the amount set forth in the budget upon Sponsor of PPD's receipt of invoice. Unscheduled visits for safety evaluation are allowed at any time. In the event a medically necessary procedure is not included in the Protocol, Institution must receive prior written approval before procedure is performed. The amount of compensation for a procedure not included in Protocol will be approved at the time written approval is provided.

Pre-medications: Sponsor, at its reasonable discretion, through PPD, may reimburse Institution for procuring Pre-medications for the Study. The Institution shall obtain written approval from PPD or Sponsor prior to any purchase of Pre-medications. Payment will be made upon receipt of an undisputed invoice and supporting documentation. However, for sites that request for providing pre-medications by sponsor, Sponsor or Sponsor's designated Vendor will supply pre-medications that are required for the conduct of the Study.

Concurrent-medications: Sponsor or Sponsor's designated Vendor will supply concurrent-medications that are required for the conduct of the Study.

Study Meeting: Sponsor shall reimburse actual and reasonable costs incurred by an investigator and other site staff to attend Study Meeting in conformity with applicable fair trade rules, local law and Sponsor's policies. Sponsor may provide food, accommodation, and beverage as necessary for a study meeting in conformity with applicable fair trade rules, local law and Sponsor's policies.

Final Payment: The final payment will be payable upon completion of the close-out visit and upon receipt of the following: (i) all Study documentation, (ii) the accountability of all unused Study Drug, (iii) all completed and correct eCRFs/queries and (iv) any clarification requests made by PPD or Sponsor regarding Study data or records. Institution will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

All amounts mentioned in this Agreement are exclusive of GST. GST shall be of applicable rate (18%).

No other additional funding requests will be considered without the prior written consent of Sponsor or PPD.

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CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); Dr. Ritesh Vernekar, KLES Dr Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Principal Investigator**"); and in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20150238 entitled "A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double-dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for

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Site #: 30016
Purchase Order #: India

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Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals

The Principal Investigator will direct and supervise the Study

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies Company will notify such personnel as required by applicable law

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 416 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will supply the Site with the Required Material(s). The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI),

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and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement

5. REQUIRED EQUIPMENT

5 1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop (1). Such Required Equipment will be lent by Company or its representative to Site for use in the Study

5 2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address KLES Dr Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5 3 Installation of Required Equipment Company or its representative shall provide for installation of the following equipment: Laptop (1)

5.4 Technical Support of Required Equipment Company or its representative shall provide for technical support and maintenance of the following equipment. Laptop (1).

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following.

Payments payable to:	Ritesh Ramesh Vernekar "**Payee**"
Tax ID	AHEPV4044Q

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Personal Data. This section is applicable only where the Principal Investigator is an individual. Principal Investigator understands and agrees that "**Personal Information**" (as defined herein) including the name, contact details, curriculum vitae, areas of specialization of Principal Investigator and, where applicable, financial disclosure information will be Processed by Company, its affiliates and contractual partners. Personal Information will be used for the purpose to comply with this Agreement, Company's obligations imposed by law, regulatory authorities and good clinical practice, and may be used for other purposes including contacting Principal Investigator about future research or organizing safety reporting.

Personal Information may, if necessary, be made available to regulatory authorities and ethics committees Principal Investigator understands and agrees that Company's use and disclosure of Personal Information may involve use and disclosure in countries other than that where Recipient is located.

Company is a multi-national company that maintains datacenters around the world, including in the European Union and the United States (global headquarters of Amgen Inc.). Principal Investigator understands and agrees that Personal Information may be transferred to other Company's entities or to contractual partners providing services to Company located in countries that may not require the same level of data protection as the country in which Principal Investigator is located; however, Personal Information will only be transferred after ensuring that adequate safeguards (Standard Contractual Clauses in a form approved by the EU Commission) are in place to protect it.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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Transfers of personal information among Company and its group entities follow applicable laws and Binding Corporate Rules (BCRs) More information on the BCRs, including the ability to file a complaint about any processing of personal information in violation of the BCRs can be found on http //www amgen com/bcr/

For any request to access, correct or delete personal information or to request portability of data, Principal Investigator can contact an Amgen Data Protection Officer at privacyoffice@amgen com or lodge a complaint to the local data protection authority.

Company may process Personal Information for the duration required to fulfil the purposes described above and in any event as long as required by applicable law

For the purposes of this Agreement, "Personal Information" shall mean information relating to Principal Investigator which is capable either directly or indirectly of identifying Principal Investigator, and "Process" and "Processed" shall mean any operation or set of operations performed on Personal Information, including the collection, use, modification, retrieval, transfer, storage, deletion, processing (both by computer and manually), and combination, of Personal Information.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s) derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the

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results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed, (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

ATTESTED

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

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IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 1st Aug '18

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: Dr. M. V. Jali

Title: MD & CEO

Date: 22 Aug 2018

DR. RITESH VERNEKAR

(signature)

By: Dr. Ritesh Vernekar
(print or type name)

Title: Consultant Nephrologist

Date: 13 Aug 2018

ATTESTED

Dr. V.A.Kothiwale
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Protocol Number	20150238
Site Number	30016
Investigator	Dr Ritesh Varnekar
Contract Number	
Maximum number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 3,48,743	10	Subject(s)	INR 34,87,430
SCREEN FAILURES	INR 9,193	1	per Subject	INR 91,930
ADMINISTRATIVE FEES				INR 1,30,000
MAXIMUM CONTRACT TOTAL*				**INR 37,09,360**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs. Amgen has provided thermohygrometer for temprature reading.*

SUBJECT FEES (Overheads 20%)

VISIT TABLE: STUDY	Schedule A
Screening	INR 9,193
Day 1	INR 15,190
Week 2	INR 12,160
Week 3	INR 11,700
Week 4	INR 12,620
Week 5	INR 12,300
Week 6	INR 12,160
Week 7	INR 11,700
Week 8	INR 12,160
Week 9	INR 12,300
Week 10	INR 12,160
Week 11	INR 11,700
Week 12	INR 12,550
Week 13	INR 12,300
Week 14	INR 12,160
Week 15	INR 11,700
Week 16	INR 12,160
Week 17	INR 12,300
Week 18	INR 12,160
Week 19	INR 11,700
Week 20	INR 12,160
Week 21	INR 12,300
Week 22	INR 12,160
Week 23	INR 11,700
Week 24	INR 12,160
Week 25	INR 12,300
Week 26	INR 12,160
Week 27	INR 11,730
Follow-Up	INR 9,700
Early Term	INR 11,170
SUBJECT VISIT TABLE SUBTOTAL(S)	**Schedule A**
Completers, Screening to Week 27, Safety Follow-Up	INR 3,48,743
Early Termination	INR 11,170
MAXIMUM PER SUBJECT FEE	**INR 3,48,743**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel reimbursement. Subject travel reimbursement is included at a rate of 900.00 INR per protocol required in-clinic visit

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VISIT TABLE SCREEN FAILURE	Schedule A
Screen Failure	INR 9,193
MAXIMUM SCREEN FAIL	INR 9,193

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
[1] Study Start-Up/Site Set-Up Fee	INR 30,000	1	per Site	INR 30,000
[2] Document storage/Archiving total	INR 50,000	1	per Site	INR 50,000
[3] Infrastructure Fee	INR 50,000	1	per Site	INR 50,000
SUBTOTAL, ADMINISTRATIVE FEES				INR 1,30,000

[1] This will be paid after site initiation visit. Site has to provide rationale and supportive to justify the payment

[2] This is payable at the end of the study to archive study related documents for 15 years after end of the study

[3] Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure

PAYMENT TERMS

Initial Payment	50,000.00 *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Ritesh Ramesh Vernekar' (Tax ID AHEPV4044Q)

The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made as per EC SOP in the favor of 'Registrar, KLE University, Belagavi'

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."

2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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CLINICAL TRIAL AGREEMENT

Study No: NCS-549-17-CS

GOVT OF KARNATAKA
DEPT. OF STAMP & REGISTRATION

14107 192333 SEP 05 2019 10:43
INDIA Rs.0000100 PB6936
STAMP DUTY KARNATAKA

Sub Registrar
Bommanahalli.

CLINICAL TRIAL AGREEMENT

Norwich Clinical Services Pvt. Ltd.,, a company incorporated under Companies Act, 1956 and having its registered office at No.147/F, 8th main, 3rd block, Koramangala, Bangalore-560034, (hereinafter referred to as **CRO**),which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns being of the One Part:

AND

Dr. Archana Uppin having a medical practice (Hereinafter referred to as "Principal Investigator" or "**P.I**"), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the Second Part:

AND

Ardent Clinical Research Services situated at KLE's Dr. Prabhakar Kore Hospital and MRC, NH Service Road, G+2 Nehru Nagar, Belagavi- 590010, and Karnataka. (Hereinafter referred to as "SMO") being of the third part

AND

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into **04 Sep 18** by and between KLE's Dr. Prabhakar Kore Hospital and MRC, NH Service Road, G+2 Nehru Nagar, Belagavi-590010, Karnataka. (Hereinafter referred to as "Hospital") being of the fourth part

PI, Hospital/Institute, SMO and Norwich Clinical hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS the purpose of this agreement is for conducting clinical study having Study Title:

An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting

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perform his/her obligations under this Agreement are appropriately trained and qualified.

4.5. Norwich Clinical will appoint a representative (hereinafter referred to as the "Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)") to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Norwich Clinical and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Norwich Clinical may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

4.6. All Communication between the PI, Hospital/Institute, SMO and Norwich Clinical Services will be addressed to or routed through the CRA. The CRO reserves the right to change the CRA during the course of the study and inform the PI accordingly.

4.7. The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Norwich Clinical Services.

4.8. The CRO has also represented that all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement will be obtained and that all such licenses, authorizations and permissions will be in full force and effect at the time of executing the services outlined in this agreement.

4.9. Whereas the CRO desires to enter into agreement with KLE's Dr. Prabhakar Kore Hospital and MRC, Ardent Clinical Research Services and Dr. Archana Uppin to conduct the study in their hospital.

4.10. The CRO has agreed to engage Dr. Archana Uppin who is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.

4.11. The CRO has agreed to engage KLE's Dr. Prabhakar Kore Hospital and MRC& the principal Investigator and SMO for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

4.12. Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the KLE's Dr. Prabhakar Kore Hospital and MRC & Principal Investigator and SMO to CRO under any subsequent individual agreement for specific services to be rendered.,

4.13. The Project shall be conducted as per the CRO's confidentiality requirements.

4.14. KLE's Dr. Prabhakar Kore Hospital and MRC, & the principal Investigator agree that the CRO shall have the right to enter their facility at reasonable times to inspect the facility, and the performance of the services hereunder. The CRO shall have the right to inspect and audit KLE's Dr. Prabhakar Kore Hospital and MRC & the principal Investigator records only as they relate to services performed by KLE's Dr. Prabhakar Kore Hospital and MRC Principal Investigator hereunder for which the CRO is making payment to Ardent Clinical Research Services,

4.15. Such rights shall, however, be only exercised by the CRO during KLE's Dr. Prabhakar Kore Hospital and MRC& the principal Investigator's normal business hours and only following reasonable prior notice (48 hours prior notice being presumptively reasonable).

4.16. During the term of this Agreement, KLE's Dr. Prabhakar Kore Hospital and MRC, & Principal Investigator agrees to diligently and conscientiously use its

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7.3. **Clinical trial:** "Clinical trial "means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug.

7.4. **Clinical trial related injury(defined as per DCGI) means:** Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury, or death and the subject or his/her nominee(s), as the case may be, are entitled for financial compensation for such injury or death:

7.4.1. Adverse effect of investigational product(s)

7.4.2. Violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator

7.4.3. Failure of investigational product to provide intended therapeutic effect

7.4.4. Use of placebo in a placebo-controlled trial.

7.4.5. Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;

7.4.6. For injury to a child in-utero because of the participation of parent in clinical trial;

7.4.7. Any clinical trial procedures involved in the study.

7.5. **Contract:** A written, dated and signed document describing the agreement between two or more parties involved in a biomedical study, namely Investigator, Sponsor, and Institution. Typically, a contract sets out delegation / distribution of responsibilities, financial arrangements and other pertinent terms. The "Protocol" may form the basis of "Contract".

7.6. **Essential Documents:** The Documents that permit evaluation of the conduct of a study and the quality of the data generated.

7.7. **Final Report:** A final report is a complete and comprehensive description of the study after its completion. It includes description of experimental and statistical methods and materials, presentation and evaluation of the results, statistical analyses and a critical ethical, statistical and clinical appraisal. The Investigator's declaration closing the study is a part of the Final Report.

7.8. **Good Clinical Practice GCP** : Shall mean a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of "clinical trial activities" that provides assurance, that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of patients volunteers are protected.

7.9. **Informed Consent:** Informed consent is Voluntary written assent of a subject's willingness to participate in a particular study and in its documentation. The confirmation is sought only after information about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available and of the subject's rights and responsibilities has been provided to the potential subject.

7.10. **Inspection:** An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the study. The inspection may be carried out at the site of the trial, at the sponsor's / or CRO's facilities in order to verify adherence to GCP as set out in these documents.

7.11. **Investigator:** A person responsible for the conduct of the clinical trial at a trial site.

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The conditions regulating the use and consultation of such documents must be honored as prescribed under Confidentiality.

7.22. **Volunteer:** Volunteer shall mean persons who consent to be participants in any Study and who fulfil the entire requisite regulatory, scientific, and ethical and other criteria for the purpose.

7.23. **Publications: The publication rights for the data generated from the study vests with the Sponsor:** The Hospital may however retain a copy of the Study data arising out of the performance of this Study, and retains the right to use such data or results for its own publication only upon getting written approval from Sponsor. The sponsor should be acknowledged in any publications that are using the data generated from this study.

8. **INTELLECTUAL PROPERTY:** All improvements, enhancements or modifications of, or new uses for the Sponsor's proprietary materials discovered under the Sponsor's protocol will be the sole property of the Sponsor (hereinafter referred to as "Sponsor Inventions"). Site personnel will cooperate with the Sponsor in obtaining whatever patent protection or other protection that may be available on the same, and will execute documents deemed necessary by the Sponsor for the purposes of securing such patent protection or other protection.

9. **PROPRIETARY MATERIAL & RETENTION OF RECORDs**

9.1. **Proprietary Material:** All information whether oral or written (including, but not limited to, documents, descriptions, data, results, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product and comparator products) provided to P.I. and Hospital by Sponsor/ CRO is the proprietary material of Sponsor shall be treated as confidential (and hereinafter referred to as "Confidential Information"). The Hospital and P.I. undertake to keep in strict confidence, and agree not to disclose and permit not to be disclosed to any third party such Confidential Information. The Hospital and P.I. are obliged to keep the Confidential Information confidential even after termination of the agreement and the Study.

9.2. All said Confidential Information with any proprietary material for use under the Study; such Sponsor proprietary materials will be used solely for the Study and not for any other purposes.

9.3. Hospital and Principal Investigator shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of proprietary materials of Sponsor/ CRO used for the Study.

9.4. **Retention of Records:** All raw data and transcribed data pertaining to this study will be stored at the site and/or CRO for a minimum period of 05 years from the date of regulatory approval of the application.

9.5. **Archival:** The investigator shall return to the CRO/Sponsor all reports/documents/data including but not limited to the leftover/remaining consignments of the investigational products

9.5.1. On Completion of the study.

9.5.2. Termination of the clinical trial agreement.

9.5.3. Termination of the study by the sponsor.

Or as and when required by CRO/Sponsor. However, one copy can be retained by the investigator site for archival/legal purposes as per the mandatory local regulatory requirements.

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11.2.1. Only upon getting written approval from Sponsor and

11.2.2. Only after the first publication of such data by the Sponsor.

12. **ASSIGNMENT:** Neither party may assign this Agreement or any part of it without the written consent of the other party.

13. **REPRESENTATIONS; INDEMNIFICATION**

The Investigator agrees to participate by allowing the study to be undertaken on his premises utilizing such facilities, personnel and equipment as the Investigator may reasonably need for the purpose of the study.

Sponsor/NCS shall indemnify the P.I / Hospital participating in the study with regard to any adverse event or claim arising directly as a consequence of the Study, design and/or the investigational drug. Notwithstanding the above, the sole and only liability of sponsor under this Agreement, on any account whatsoever and/or howsoever arising, shall be limited to reimbursement of reasonable costs which may arise directly as a consequence of the Study, design and/or the investigational drug.

The above indemnity by the Sponsor shall not apply to any such claim or proceeding:

13.1. To the extent that such personal injury (including death) to the study subjects is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the institution, its employees or agents.

13.2. To the extent that such personal injury (including death) to the study subjects is caused by the failure of the institution, its employees or agents to conduct the study in accordance with the protocol.

13.3. Unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Investigator shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the CRO to have full care and control or proceeding using legal representation of its own choosing.

13.4. Without prejudice to the provisions of paragraph above, the investigator will use her reasonable endeavours to inform the sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep the sponsor reasonably informed of development in relation to any such claim or proceeding even where the institution decides not to make a claim under this indemnity. Likewise, the sponsor shall use its reasonable endeavours to inform the investigator of any such circumstances and shall keep the investigator reasonably informed of developments in relation to any such claim or proceeding made or brought against the sponsor alone.

13.5. The investigator and sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of subjects (or their dependents)

13.6. This indemnity will include without limitation any nurse or other health professional providing services to the investigator under a contract for services or otherwise and any person carrying out work for the institution under such a contract connected with such of the investigator's facilities and equipment as are made available for the study under paragraph above.

13.7. This indemnity shall be governed by and construed in accordance with Indian law.

14. **GOVERNING LAW**

ATTESTED

Dr. Archana Uppin

CLINICAL SERVICES

Dr. V.A.Kothiwale
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reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

19. RECORD KEEPING

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

20. REVIEW OF WORK, AUDIT

The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor and/or Norwich Clinical Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Norwich Clinical.

21. MISCELLANEOUS

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

22. NOTICES & SERVICE OF DOCUMENTS

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Norwich Clinical shall be addressed to:

Norwich Clinical Services Pvt. Ltd.,
147/F, 8th main, 3rd block,
Koramangala, Bangalore-560034

ATTESTED

Dr. Archana Uppin
Dr. V.A.Kothiwale
Registrar
(Secretary of Higher Education and Research,
(University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Exhibit A
Responsibilities of Principal Investigator

Name of the PI	Dr. Archana Uppin
Study Title	An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions.

As a Principal Investigator, I confirm and I agree to adhere to the following:

1. I hereby confirm each member of the research team including myself is suitably qualified by education, training and experience.
2. I hereby confirm that I have resources, including, but not limited to, sufficient personnel and equipment to perform the study in a professional manner.
3. I have agreed to conduct the study as per the agreed terms and conditions, and all current Indian regulation and guidelines implemented by Indian law, including applicable Drugs and Cosmetics Rules and Schedule Y in particular and government authorities including the DCGI.
4. I will comply with undertaking in Appendix VII, Schedule Y (Undertaking by the Investigator) as amended from time to time.
5. I will ensure the study is conducted in accordance with the ICH – GCP and regulatory guidelines of the country or regulatory agency to which such clinical trial report shall be submitted.
6. The PI as listed on the FDA Form 1572 "Statement of Investigator" will personally conduct or supervise the conduct of the study in accordance with the Protocol, FDA Regulations, ICH Guidelines, GCP and this Agreement.
7. I will personally conduct, delegate appropriately and supervise the Study in accordance with the aforementioned protocol, this Agreement, and conditions of approval imposed by regulatory authority (DCGI) and the Ethics Committee, and will comply with all requirements regarding the obligations of Principal investigators and all pertinent requirements there under.
8. Ethics Committee approvals and reporting:
   - 8.1 I will ensure that the Ethics Committee approval is obtained for the clinical trial protocol prior to initiation of the study.

ATTESTED

Dr. V.A. Kothiwale Uppin
Registrar
KLE Academy of Higher Education and Research,
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

19. I agree to produce the report on the progress and outcome of work required by the CTA/Sponsor on time and in an acceptable standard.
20. I agree to provide periodical progress report to the EC as required by them
21. I agree to perform the clinical trial and prepare its report strictly in accordance with the regulatory guidelines of the country or regulatory agency to which such clinical trial report shall be submitted and as such specified in the data collection form or Protocol.
22. Adequate and accurate records will be maintained and made available for inspection and audits by Sponsor. Ethics Committee and applicable regulatory authority.
23. I will also ensure that all associates, colleagues, and employees of Name of the Hospital assisting in the conduct of the Study are informed about their obligations to Sponsor per this Agreement.
24. In the event if I am unable or unwilling to continue with the study, I will notify the Sponsor/CRO in writing and the parties will attempt to find a mutually acceptable substitute.
25. I will ensure that arrangements are in place for the management of financial and other resources provided for the study including the management of any intellectual property.
26. I will have sufficient time, adequate staff, and appropriate facilities to conduct and complete the clinical study. PI agrees to make these resources available for the duration of the study and agrees that other studies will not divert essential subjects or facilities away from this trial.
27. I will assure Norwich Clinical Services., that no other clinical study conducted by her shall give rise to a conflict of interest or interfere with the clinical trial.
28. I will endeavor to ensure an adequate recruitment rate during the clinical investigation.
29. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the study.
30. I will ensure that an independent pharmacist to be delegated as a QC for verifying the reconstitution procedure in the trial
31. I understand that he will have primary responsibility for the accuracy, legibility, and security of all study data, documents, and subject records both during and after the study. PI will be responsible for completion of the paper CRF and signature of the same.
32. I agree to abide by the following conditions governing in handling of the data associated with this study:
    32.1. To maintain adequate records regarding all investigational product received and used by him/her including batch numbers, dates, and quantities. If the study is

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Dr. V.A.Kothivale
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Belagavi-590 010,Karnataka

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34. The patient's identity shall not be released to third parties without the patient's and/ or impartial witness prior consent. Accordingly, the study patient's and/ or impartial witness consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.
35. Responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Norwich Clinical Services.
36. I shall not commence the study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the patient's and/ or impartial witness.
37. Provide the Institutional Ethics Committee or Institutional Review Board with all required information.
38. Investigational products for clinical investigation will be provided only to the patients under his personal supervision or under the supervision of the Co-investigator/ Sub-investigator (if any) responsible (duly delegated the specific responsibilities during the study conduct).
39. Investigational products will not be supplied by her to any investigator, or to any clinic, medical facility, or study site for use.
40. No procedure will be performed until all personnel have been properly trained.
41. Responsible for the personal safety and well-being of the subjects. To this end, PI agrees to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:
42. Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature:
    42.1. I ensure that patient and/ or impartial witness or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the patient's and/ or impartial witness.
    42.2. The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any

ATTESTED

Dr. Archana Uppin

CLINICAL SERVICES

Dr. V.A.Kothiwale
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- New information that may affect adversely the safety of the patients or the conduct of the study.

44.2. All staff in contact with the patient should be aware of their responsibility to note and report all adverse events reported by the patient's and/ or impartial witness.

44.3. The Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

44.4. All serious adverse events (SAEs) should be reported to Norwich Clinical within 24 hours except for those SAEs that the protocol or other document (e.g. Investigator's Brochure) identifies as not requiring immediate reporting.

44.5. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

44.6. The immediate and follow-up reports should identify patients by unique code numbers assigned to the study patients rather than by the patients' names. personal identification numbers and/or addresses.

44.7. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Norwich Clinical/Sponsor according to the reporting requirements and within the time periods specified by Norwich Clinical/Sponsor in the protocol.

44.8. I will personally be responsible for, or will appoint a Co-Investigator/Sub-investigator (who has signed an Investigator Agreement and has been added to the Institution's. Norwich Clinical

Services and the Study Monitor's (CRA's) Investigator List) to be responsible for all study related medical decisions.

45. I will report all deviations from the protocol to Norwich Clinical Services and the study monitor (CRA).

46. I will notify Norwich Clinical Services, immediately, but in no event in more than five working days. about withdrawal of approval by the reviewing Ethics Committee of his/her part of the clinical study.

47. I will comply with any request by Norwich Clinical Services to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. I understands that Norwich Clinical Services. is required by law to discontinue shipments of investigational product to him/her if he fails to comply with the study protocol or

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TASK MATRIX

SL No.	DESCRIPTION OF ACTIVITY	RESPONSIBILITIES		
		SPONSOR / NCS	Hospital OR Principal Investigator	SMO
ADMINISTRATIVE RESPONSIBILITIES				
1.	Preparation of Project Contract (Clinical Trial Agreement preparation)	X		
2.	Review & finalization of Clinical Trial Agreement	X	X	X
3.	Confidentiality Disclosure Agreement	X	X	
4.	Conduct of study as per study protocol		X	X
5.	Training the Investigator & site personnel	X	X	X
REGULATORY RESPONSIBILITIES				
6.	Preparation, submission of Regulatory dossiers & Obtaining regulatory Approval	X		
7.	Regulatory updates & reports	X		
8.	Communication with regulatory body	X	X	X
9.	Updating study updates in CTRI	X		
10.	Compliance to protocol, GLP and GCP requirements	X	X	
11.	Completion of Investigator undertaking, 1572, 3455		X	X
12.	CTRI Registration	X		
DOCUMENTS –PROTOCOL, INFORMED CONSENT DOCUMENTS, SOURCE DOCUMENTATION & CRF				
13.	Protocol design and Sample size justification	X		
14.	Protocol Preparation	X		
15.	Protocol review and approval	X	X	
16.	Preparation of Informed consent document (ICD)	X		
17.	Review/approval of the ICD	X		
18.	Translation of ICD (In local language)	X		
19.	Source documentation and Maintenance		X	X
20.	Design of Case Report Form (CRF)	X		
21.	CRF review/approval	X		

ATTESTED

Dr. V.A.Kothiwale
Registrar
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Sl. No.	DESCRIPTION OF ACTIVITY	RESPONSIBILITIES		
		SPONSOR /NCS	Hospital OR Principal Investigator	SMO
INSPECTION/ MONITORING / AUDIT				
42.	Monitoring of the study	X		
43.	Quality assurance audit	X		
44.	Data query Resolution		X	X
45.	Documents availability for Ethics committee Audits during study conduct		X	
46.	Documents availability for Sponsor's Audit		X	X
47.	Documents availability for Regulatory Inspection	X	X	X
48.	Reporting of protocol deviation	X	X	
PK SAMPLE COLLECTION, TRANSFER and STORAGE ACTIVITES				
49.	PK sample collection and storage		X	
50.	PK sample shipment to Bioanalytical facility	X	X	
AE/SAE MANAGEMENT, REPORTING, COMPENSATION & INSURANCE				
51.	Documentation and follow-up of AEs and SAEs		X	X
52.	Providing of SAE template as per regulatory requirement	X		X
53.	Notification of any SAE to all stake holders as per current and applicable regulatory guidelines	X	X	X
54.	Safety Information update to other Investigator sites	X		
55.	Compensation for the trial related Injury	X		
56.	Clinical Trial Insurance	X		
57.	SAE Immediate reporting		X	X
58.	Detailed report of SAE	X	X	X
STATISTICAL REPORTING				
59.	Randomization development	X		

ATTESTED

Dr. Archana Uppin

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

EXHIBIT B: PROPOSAL (BUDGET)
BUDGET AND PAYMENT TERMS

Study Title: An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions..

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and comply to the protocol requirement including any amendments
2. The below payments will be made to the Ardent Clinical Research Services only after the completion of respective monitoring visit, retrieval of CRF & relevant data/Forms and Logs/resolution of queries after each stage by the CRA/designee.

Sl. No.	Payment particulars	Milestone	*Amount Paid
1.	Investigator Fee	TOTAL INVESTIGATOR FEE	Rs. 70,000 per patient as per the details below
		i. On completion of Period 1 including CRF completion	Rs. 20,000 per patient of the total investigator fees
		ii. On completion of period 2 and including CRF completion.	Rs. 20,000 per patient of the total investigator fees
		iii. Upon retrieval of completed CRFs by CRO	Rs. 10,000 per patient of the total investigator fees
		iv. Upon completion of study and resolution of all queries by site.	Rs. 10,000 per patient of the total investigator fees
		v. On completion of site close out visit.	Rs. 10,000 per patient of the total investigator fees
2.	Patient Compensation	After completion of each period	Rs. 3, 000 (Rs. 1500 per period)
3.	Lab Investigations Screening)	On completion of screening	As per actuals
	Period 1,2 and end of study	On completion of end of study	As per actuals
	Additional Safety Analysis if performed	On receipt of safety sample report	As per actuals
4.	Site Coordinator	Upon receipt of completed CRFs	Rs.10,000 per month till the study closeout

ATTESTED

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Belagavi-590 010,Karnataka

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Signatories For

Norwich Clinical Services Pvt Ltd	Principal Investigator	KLE's Dr. Prabhakar Kore Hospital and MRC	Ardent Clinical Research Services
Dr. Saral Thangam Chief Executive Officer.	Dr. Archana Uppin Principal Investigator		
Seal: NORWICH CLINICAL SERVICES PVT LTD BANGALORE	Seal: Dr. ARCHANA M UPPIN Consultant Physician and Rheumatologist KMC Reg. No. 84197 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.	Seal: Dr. Prabhakar Kore Hospital & MRC KLES Belagavi-10	Seal: Ardent Clinical Res... Pune
Witness	Witness	Witness	Witness
Witness name: Dr. Raja Designation: Head medical affairs.	Witness name: Amey Designation: CRC	Witness name: Rwan Designation: Asst-coordinator	Witness name: Pranjal Designation: Project Manager

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010,Karnataka

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Government of National Capital Territory of Delhi

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Certificate No.	:	IN-DL81475484029434Q
Certificate Issued Date	:	22-Sep-2018 02:04 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210367445644829066Q
Purchased by	:	Panacea Biotec Limited
Description of Document	:	Article Others
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Panacea Biotec Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	Panacea Biotec Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "**Agreement**") is made on 22nd day of October, 2018 ("Effective Date") by and between **Panacea Biotec Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at Ambala - Chandigarh Highway, Lalru-140501, Punjab, India and head office located at B-1 Extn./G-3 Mohan Co-op. Industrial Estate, Mathura Road, New Delhi–110044, India ("**Sponsor**"), of the First Part; and **Dr. Madhav Prabhu**, a registered medical practitioner holding MCI registration number 69158, currently working as Associate Professor in Department of Medicine, , KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum 590010

Panacea Biotec

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Exhibit B

Financial Details

Details of the payment to be made to Institution for completing the Study on subjects will be as follows:

Cohort 1(Adult):

Details	INR
P I and trial staff fee (for completed subject)	Rs.2,500* /- subject for visit 1
P I and trial staff fee (for completed subject	Rs.2,500*/- subject for visit 2
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 3
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 4
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 5
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 6
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 7
P I and trial staff fee (for completed subject)	Rs.2,000*/- subject for visit 8
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 270
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 360
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 450
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 540
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 630
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 720
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 810
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 900
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 990
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 1080
Total	**Rs. 22000*/- per completed subject**
Total Institutional Fees (25% of PI fees)	**Rs. 5500*/- per completed subject**
Subject Travel expense (Rs.500/visit X 8 visit)	**Rs. 4000**
Total Grant Per Subject	**Rs. 31500/-**

Cohort 2 (Children):

Details	INR
P I and trial staff fee (for completed subject)	Rs.2,500* /- subject for visit 1
P I and trial staff fee (for completed subject	Rs.2,500*/- subject for visit 2
P I and trial staff fee (for completed subject)	Rs.1,800*/- subject for visit 3
P I and trial staff fee (for completed subject)	Rs.1,800*/- subject for visit 5
P I and trial staff fee (for completed subject)	Rs.1,800*/- subject for visit 6
P I and trial staff fee (for completed subject)	Rs.1,800*/- subject for visit 7
P I and trial staff fee (for completed subject)	Rs.1,800*/- subject for visit 8
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 270
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 360
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 450

Panacea Biotec Ltd.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 540
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 630
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 720
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 810
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 900
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 990
P I and trial staff fee (for telephonic follow up)	Rs.500*/- subject for day 1080
Total	**Rs. 19,000 */- per completed subject**
Total Institutional Fees (25% of PI fees)	**Rs. 4750*/- per completed subject**
Subject Travel expense (Rs.500/visit X 7 visit)	**Rs. 3500**
Total Grant Per Subject	**Rs. 27250/-**

*The price mentioned above is excluding the applicable taxes.

Study startup cost (Advance/ pre-payment) INR. 50,000/- (Fifty Thousand) will be paid.
The advance payment (pre-payment) provided to the PI will be adjusted against first invoice raised by PI as per the PI grant & in case of no subject enrollment advance payment would be refundable

Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF for a properly qualified subject after each monitoring visit.
Tax deduction at source for all payment of fee will applicable unless a valid tax exemption certificate is provided by the Investigator/Institute.

Payee Details:

CMS Clinical Research Pvt. Ltd.
Account details: HDFC Bank
Bank Branch: Nacharam, Hyderabad
Account No: 50200007478582
ISFC: HDFC0000368
PAN Number: AAFCC8457M
GST Number: 09AAFCC8457M1ZZ

Note:

Payment set forth above will exclude the following expenses:

1. Laboratory investigations for screening, enrollment and follow up visits as per protocol (in case of local lab) and Ethics Committee fee which will be paid additionally on actual basis (as evidenced by supporting documents);
2. Subject ward stay as per protocol will be reimbursed as per the actuals;
3. Expense towards medical management of adverse events will be made as per actuals.
4. Courier Charges which will be paid on actual basis;
5. Subject travel expense will be paid for actual visit conducted by the subject.

Panacea Biotec Ltd

ATTESTED

Dr. V.A.Kothiwale
Registrar
351
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Sponsor. Sponsor will generally provide Cryovials, Cryoboxes, Thermometers, scales required for the Study. However, in the event Sponsor requires Principal Investigator to procure the aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection therewith.

for Panacea Biotec Limited	For Dr. Madhav Prabhu	For KLES Dr Prabhakar Kore Hospital & Medical Research Centre	For CMS Clinical Research Pvt. Ltd
Signature:	Signature:	Signature:	Signature: .....
Name: Rastogi	Name: Dr. Madhav Prabhu	Name: Dr. M.V Jali	Name: Dr. Ashish Gupta
Title: Head Global Sourcing	Title: Associate Professor	Title: Medical Director & Chief Executive	Title: Manager
Witness:	Witness:	Witness:	Witness:
Signature:	Signature:	Signature:	Signature: .....
Name: Dr. Lalitendu Mohanty	Name:	Name: Revanna Sdevarinti	Name: Shivaprakash
Title: Sr. GM - CRD	Title:	Title: Assistant coordinator	Title: project coordinator

Dr. Madhav Prabhu
Consultant Physician
Dept. of Medicine
KMC Reg. No. 69158
KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

CMS CLINICAL RESEARCH Date

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be University u/s 3 of the UGC Act,1956)
Belagavi-590010,Karnataka

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Binding & confidential

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Certificate No.	:	IN-KA76646089248364Q
Certificate Issued Date	:	02-Nov-2018 12:31 PM
Account Reference	:	NONACC (FI)/ kasfinc01/ BANGALORE/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKASFINC0190529206312299Q
Purchased by	:	LOTUS LAB PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	LOTUS LAB PVT LTD
Second Party	:	DR MAHESH KUMAR KALLOLI
Stamp Duty Paid By	:	LOTUS LAB PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" ("Agreement") is made and entered into this __day of ..... 2018 by and among Dr. Mahesh Kumar Veeranna Kalloli, working in KLEs Dr. Prabhakar Kore Hospital & MRC Hospital, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India (Hereinafter referred to as the "Principal Investigator" or "PI")

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

AND

KLEs Dr. Prabhakar Kore Hospital & MRC Hospital, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India herein after called the "**Institution**" (which expression shall wherever the context so admits include its successor and assignees) of the second part

AND

Lotus Labs Pvt. Ltd, a company incorporated under the Companies Act, 1956 of India having its registered Office at T-341, 4th Floor, International Technology Centre, CBD Belapur Railway Station Complex, Navi Mumbai - 400614, Maharashtra, INDIA and its Head office at No. 7, Jasma Bhavan Road, Millers Tank Bed Area, Opp. Gurunanak Bhavan, Vasanthnagar, Bangalore – 560 052, India and include its successors and assignees (hereinafter referred to as "**Lotus**") representing the interests of Sponsor Teva Pharmaceuticals USA,400 Interpace Parkway,Parsippany, NJ 07054 (hereinafter referred to as "**Sponsor**") in connection with conduct of clinical trial 'A Randomized, Open Label, Multi Center, Two Treatment, Two Period, Two Sequence, Single Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial manufactured by Teva Pharmachemie, The Netherlands, for Teva Pharmaceuticals USA, and Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound), 100 mg/vial manufactured by Abraxis BioScience LLC, USA for Celgene Corporation, USA in Patients with Metastatic Breast Cancer". ("**Study**") bearing the protocol/study number: CT/PAC/1701 **(v.1.0) (India)** ("**Protocol**") attached hereto as Exhibit A.

PI, Institution and Lotus hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company and had engaged the services of Lotus for execution of a clinical trial in **India.**
2. Lotus is in the business of providing contract research services and has necessary infrastructure and facilities to provide such services for the clinical trial and in turn desires to engage the services of the Institution to conduct/assist in such a trial;
3. Institution represents that it has qualified personnel and adequate facilities and equipment to competently conduct the Study and is desirous of rendering such services upon such terms and conditions as envisaged below.

1. Provision of Services

1.1 Scope of Work.

The Study to be performed under this Agreement shall be performed in accordance with the terms of the final Protocol, including as it may be amended in accordance with the terms of this Agreement, for the Study. Institution and Principal Investigator agree that all aspects of the Study will be conducted in conformity with all applicable laws and regulations, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: Consolidated Guideline ("ICH Guideline,) and applicable requirements of the *United States Food and Drug Administration ("FDA")*. Institution and Principal Investigator further agree not to conduct any research activities with the Study Drug

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Belagavi-590 010,Karnataka

(as such term is defined below), which are contrary to the provisions of the Protocol or outside the scope of the Protocol.

Institution shall use best efforts to enrol 10 study participants capable of being evaluated and having analyzable data in the treatment portion of the Study, within six months of receipt of investigational supplies. The enrolment period may be extended or shortened at the sole discretion of Sponsor at any time.

1.2 **Principal Investigator.**

Institution shall appoint **Dr. Mahesh Kumar Veeranna Kalloli** as Principal Investigator having the requisite education, experience and expertise to competently perform the Study according to the terms and conditions as hereafter set forth, and that said Principal Investigator shall act as representative of the Institution for medical and scientific matters arising under this Agreement. Principal Investigator will be responsible for the direction and supervision of all Study efforts in accordance with applicable Institution policies, the Protocol and this Agreement. Principal Investigator and Institution will ensure that any sub-investigators and any other staff comply with the terms of this Agreement and the Protocol. In the event that Principal Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of such departure by Principal Investigator, provide written notice of such event to Lotus and Sponsor. Any successor to Principal Investigator must be approved, in writing, by Lotus and Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with the terms and conditions of the Protocol and this Agreement).

Institution and Principal Investigator represent and warrant that they will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to any applicable laws or regulations, including debarments under the United States Federal Food, Drugs and Cosmetics Act, or exclusion from a United States federal healthcare program or Drugs and Cosmetics Act 1940.

Institution and Principal Investigator agree to immediately inform Lotus and Sponsor in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of their knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and Principal Investigator agrees to immediately inform Lotus and Sponsor in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Principal Investigator's debarment.

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Details of Principal Investigator's responsibilities are set forth in the Protocol and on Exhibit A attached hereto.

1.3 Lotus will provide the PI with all the information, documents, and materials which, in Lotus' reasonable opinion, are required in order to carry out activities in a clinical trial.

1.4 Lotus transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.5 Records and Reports.

Principal Investigator and Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data relating to the Study under this Agreement; and

(ii) preparation and submission to Lotus and Sponsor (in a periodic and timely manner during the term of this Agreement) of all raw data and other material called for in the Protocol in the form of properly completed patient case report forms ("Case Report Forms") or into an electronic database (i.e., remote data entry) supplied by Sponsor for each patient as provided in the Protocol. Case Report Forms and the electronic database shall be the exclusive property of Sponsor.

Principal Investigator and Institution agree to notify Sponsor and Lotus within one day after learning of any serious and/or unexpected adverse drug reaction affecting any patient in the Study. Principal Investigator and Institution further agree to follow up such notification of adverse drug reaction with appropriate reports in compliance with the Protocol and all applicable legal and regulatory requirements. In the event Principal Investigator and Institution become aware of any quality complaints associated with the Study Drug provided under this Agreement, they agree to notify Sponsor in compliance with the Protocol.

Principal Investigator and Institution further agree to conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA that are provided to Principal Investigator, local regulations, applicable GCP and per the directions of Lotus. Principal Investigator and Institution further agree to permit Sponsor or Sponsor's representatives to examine and audit all records and reports, with prior written notification from Sponsor and during normal business hours (subject to applicable patient confidentiality considerations). Principal Investigator and Institution agree to take any action necessary, as reasonably requested by Lotus and Sponsor, to properly

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correct or address any deficiencies noted during any audit and agree to cooperate with Lotus and Sponsor with respect to any action taken to address any such deficiencies.

Principal Investigator or Institution agree to notify Sponsor within twenty-four (24) hours in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Principal Investigator and Institution will forward to Lotus and Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to allow Lotus and Sponsor to assist in responding to any citations. Such responses shall be made within two (2) weeks of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Principal Investigator and Institution shall also provide to Lotus and Sponsor copies of any documents provided to any inspector or auditor. In the event the FDA or other regulatory authority requests or requires any action to be taken to address any citations, Principal Investigator and Institution agree, after consultation with Lotus and Sponsor, to take such action as necessary to address such citations, and agree to cooperate with Lotus and Sponsor with respect to any such citation and/or action taken with respect thereto.

1.6 **Project Monitor and Inspection Rights.** It is agreed that the project monitor(s) and others designated by Lotus and/or Sponsor may, at mutually agreeable times during the Study and for a reasonable time after completion or early termination of the Study, arrange with Principal Investigator or his/her designee:

(i) to examine and inspect, at regular business hours, Institution facilities required for performance of the Study; and

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Study conducted under this Agreement and to inspect and make copies of all data necessary for Lotus and Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable FDA requirements that Lotus and/or Sponsor has provided in writing.

Institution agrees to assist Lotus and Sponsor in order to facilitate the Lotus and Sponsor representatives' examination, inspection, auditing and copying of materials relating to the Study and in order to enforce the rights granted to Sponsor as per ICH Guidelines.

Institution further agrees that institution shall share all the details and findings of the regulatory inspections occurred for third party studies conducted at its sites upon Lotus /Sponsor's request.

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1.7 **Clinical Trial Approvals.**

Institution and Principal Investigator shall be responsible for obtaining the following:

(i) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrolment of subjects in the Study by the appropriate Ethics Committee ("EC") prior to beginning any Study on human subjects; and

(ii) an informed consent which complies with all applicable laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study. Additionally, Institution and Principal Investigator shall also obtain an audio-visual recording of the informed consent process of each Study subject while maintaining principles of confidentiality.

In the event the EC requires changes in the Protocol or informed consent, Lotus and Sponsor shall be advised in advance and all modifications to the Protocol and informed consent must be approved in advance by Sponsor. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the EC without the prior written approval of Sponsor.

2. **Payment**

2.1 The total fees and expenses payable by Lotus to the Institution for the services set forth herein shall not exceed the Budget as per **Exhibit B**. The payments set forth in the budget are acknowledged by the Parties hereto to be adequate consideration for the work taken hereunder.

2.2 Lotus shall pay the Institution for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

2.3 Payment shall be made by account payee cheque/ DD /NEFT only.

2.4 Institution agrees that, in the event of a dispute regarding Sponsor and Lotus' approval of documentation supporting costs incurred under this Agreement, data and information resulting from the Study cannot be withheld by Institution or Principal Investigator prior to the resolution of the dispute because such withholding of data may cause irreparable harm to Sponsor. The Institution further agrees to use reasonable efforts to resolve any disputes of this type in a timely manner.

3. **Term**

This Agreement shall commence on the date of execution and shall continue until the date of payment of the last sum due hereunder or until the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

Termination and Consequences of Termination

Termination:

Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

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4.2 Either Party may terminate this Agreement by written notice of sixty (60) days to the other Party without assigning any reason thereof and **with no penalty on either side.**

4.3 Either Party may terminate this Agreement for cause upon thirty (30) days prior written notice, provided the Party receiving such notice has neither remedied nor sufficiently explained the breach within the period specified in the notice. Notices shall be deemed delivered upon receipt by the recipient designated for each party. "Cause" shall be defined to include a material breach of this Agreement, a material violation of the Protocol, or a lack of enrolment of the stated study participant population, as described in Section 1.1.

4.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 4.3 above.

4.5 If there is any change in the constitution/ownership of Institution for whatever reason;

Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

4.6 Unless terminated pursuant to Section 4.3 above, upon the expiry or termination of this Agreement, Lotus shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Lotus to the PI under this Agreement exceed the project costs as set forth in the Study Budget.

4.7 If there is any change in the constitution/ownership of Institution for whatever reason;

4.8 Upon expiry ,termination or party otherwise ceases to carry on business under this Agreement, the Institution and PI shall, at Lotus' option, either immediately transfer to Lotus or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4.9 The expiry, termination, or party otherwise ceases to carry on business under this Agreement shall not relieve any Party of its obligation to the other with respect to:

(i) retaining in confidence all Confidential Information;
(ii) complying with record keeping and reporting obligations;
(iii) complying with any publication obligations and obtaining any written approval and consents for any publicity and promotional purposes;
(iv) complying with obligations relating to clinical supplies;
(v) indemnification and insurance obligations;
(vi) inspection rights; and

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(vii) the obligation to assist in obtaining patent protection

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

5. **Intellectual Property Ownership, Invention & Discoveries and Publication**

5.1 **Inventions and Patents.** The sole and exclusive right to any inventions, discoveries or innovations, whether patentable or not, arising from the performance of the Protocol and Study under this Agreement, and using Study funds or otherwise arising out of use, misuse or modification of the Study Drug provided under this Agreement (the "**Inventions**"), shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor in writing of any such Inventions, and at Sponsor's request and expense Institution and Principal Investigator will cause to be assigned to Sponsor all right, title and interest in and to any such Inventions and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other documents.

5.2 **Data Ownership.** All case report forms and other data (including, without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Institution and the PI in the course of conducting the Study (the "**Data**") and results shall be the exclusive property of Sponsor, and Sponsor reserves the right to use the Data and results for any corporate purpose

5.3 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor and/or Lotus which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor and/or Lotus.

5.4 **Publication.**

As this is a multi-center study, publications derived from this Study must include input from one or more investigators, their colleagues, Lotus and Sponsor personnel. Such input shall be reflected in publication authorship, and agreement regarding order of authors shall be established before writing a manuscript. Unless specifically approved by Sponsor, results from a single center in a multi-center study will not be submitted for publication separately before results of the multi-center study are published, unless (1) more than eighteen (18) months have elapsed since completion of the Study, and (2) the Institution provides Sponsor with a proposed manuscript for review and comment prior to publication. Sponsor shall complete review within sixty (60) days of receipt of a manuscript, during which time Institution shall not permit publication or presentation. Sponsor shall notify Institution of any comments, deletions or modifications requested in the proposed manuscript to protect its proprietary rights, and Institution shall make any such changes reasonably requested by Sponsor.

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In the event Sponsor, pursuant to this Section elects to file one or more patent applications relating to any invention made in the course of the Study, any publications and presentations will be delayed for an additional ninety (90) days to permit the preparation and filing of such patent applications.

Subject to the publication restrictions in this Agreement, Institution shall have the right to use the results of the Study provided by Institution under this Agreement, including, but not limited to the results of tests and any raw data and statistical data generated therefrom, for its own internal teaching and research purposes.

6. Representations.

6.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

(i) The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

(ii) All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

7. Indemnification.

7.1 Sponsor shall indemnify, defend and hold harmless Institution, its trustees, officers, agents, employees and Principal Investigator, (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments ("**Claims**") which may be made or instituted against any of them by reason of personal injury (including death) to any person, or damage to property, arising out of or connected with the performance of the activities to be carried out pursuant to the Protocol.

Notwithstanding the foregoing, Sponsor shall have no indemnification obligation or liability and Institution and Principal Investigator shall indemnify, defend and hold harmless Sponsor, its parent corporation, subsidiaries, affiliates, officers, directors, agents, and employees for loss or damage resulting from:

(i) failure of Institution or Principal Investigator to adhere to the terms and provisions of the Protocol or agreed amendments thereto or Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Study, including, but not limited to, the Study Drug, any comparative drug and any placebo;

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(ii) failure of Institution or Principal Investigator to comply with any applicable FDA or other governmental or state requirements, law, rules, ICH Guidelines or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of Institution or Principal Investigator to render professional service or to conduct the Study in a normal, prudent manner; or

(iv) negligent act or omission or willful misconduct by Principal Investigator, Institution, its trustees, officers, agents or employees related to the performance of services under this Agreement.

7.2 Institution agrees to indemnify and hold Sponsor and Lotus harmless from liability for any claim, demand or lawsuit arising out of (i) the willful, reckless or negligent act or failure to act of Institution (including failure to comply with the terms of the Study Protocol), or (ii) the breach of any of the Institution's or PI's covenants or representations contained in this Agreement.

7.3 Institution and/or Principal Investigator shall secure and maintain in full force and effect through the performance of the Study (and following termination or early termination of the Study to cover any claims arising from the Study) insurance coverage in amounts as required by applicable legal requirements and appropriate to the conduct of Institution's and Principal Investigator's activities and the services contemplated by the Study. Upon request of Lotus or Sponsor, copies of certificates evidencing such insurance coverage will be made available to Sponsor. Institution and/or Principal Investigator shall provide thirty (30) days' prior written notice to Lotus and Sponsor in the event of cancellation or any material change in such insurance.

7.4 These indemnification obligations of the Parties shall only apply provided that in regards to the Claim (i) the indemnified party promptly notifies the indemnifying party of such Claim; (ii) the indemnified party allows the indemnifying party and/or its insurers the right to assume direction and control of the defense (including settlement) of any such claim, demand or lawsuit (the indemnifying party shall not admit fault on any one or all of the indemnified party's behalf without the indemnified party's advance written permission); (iii) the indemnified party cooperates fully with the indemnifying party and/or its insurers in the defense of such claim, demand or lawsuit; and (iv) the indemnified party agrees not to settle or compromise any claim, demand or lawsuit without prior written authorization of the indemnifying party.

8. Confidentiality

8.1 Upon execution of this Agreement a confidential relationship shall exist between Lotus, Sponsor, Institution and Principal Investigator, whereby Institution and Principal Investigator agree to hold in confidence confidential information disclosed by Lotus and/or Sponsor, in connection with the Study. As used in this Agreement

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"Confidential Information" shall be understood to include information disclosed by Lotus and/or Sponsor which is not in the public domain, including but not limited to: technical, scientific, market and marketing information, know-how, data, formulae, processes, plans, assessments and methods for Study Drug and/or its uses or modes of action, as well as similar information relating to any other Sponsor compound. Confidential Information shall also include all test articles and proprietary data and/or information generated pursuant to the Study, including, but not limited to the Protocol, the investigator's brochure, interim results and any other information or material disclosed under secrecy agreements preciously entered into by the Parties. For purposes of this Agreement, Confidential Information supplied by Lotus and/or Sponsor to Institution shall be deemed to be in the public domain or in the possession of Institution only if the Confidential Information as a whole is in the public domain or in the prior possession of Institution.

8.2 Confidential Information shall not be deemed to include information which: (i) is in or enters the public domain through no act or omission of Institution; (ii) is lawfully in Institution's or Principal Investigator's possession prior to disclosure, which possession can be documented through business records maintained in the ordinary course of Institution's business; (iii) is obtained by Institution or Principal Investigator from a third party having an apparent lawful right to provide such information and having no known obligation of confidentiality to Lotus or Sponsor; (iv) is independently developed by Institution personnel not privy to Lotus or Sponsor Confidential Information, as applicable, disclosed under this Agreement; or (v) is required by law to be disclosed.

8.3 Institution and Principal Investigator shall limit disclosure of Confidential Information received hereunder to only those of its (i) representatives, agents and officers bound by a written agreement with terms equivalent to or more stringent than this Agreement, and (ii) employees (collectively, "**Agents**") who are directly involved with the Study and only on a need to know basis. Institution and Principal Investigator shall advise its Agents upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized use or disclosure by such Agents. Institution and Principal Investigator shall be responsible for any breach of these confidentiality provisions by its Agents.

8.4 Institution and Principal Investigator acknowledge and expressly agree that any disclosure of Confidential Information in violation of this Agreement would be detrimental to Sponsor's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, Sponsor shall be entitled to seek equitable relief by way of injunction or otherwise.

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8.5 The disclosure of Confidential Information to Institution and Principal Investigator shall not be construed in any way as a license or transfer of other rights.

9. Change of control/management:

If the party intends to undergoes Merger, Amalgamation, Change of Control /Change of Management or party otherwise ceases to carry on business under, the party undergoing such change shall provide a prior advance written notice of the nature of proposed change to the other party and seek written consent of Lotus prior to undergoing such Merger, Amalgamation, Change of Control / Change of Management or Winding up, as the case may be. Providing consent to the proposed Merger, Amalgamation, Change of Control or Change of Management shall be at the discretion of Lotus, which consent shall not be unreasonably withheld. In the event, the consent is granted by Lotus, Lotus shall be at liberty to suggest modifications to the original terms of this Agreement, the acceptance of such modifications shall be upon mutual discussion which will be recorded in writing. In the event, the consent is not granted by Lotus, this Agreement shall stand Terminated, pursuant to (clause-Termination) above, all the Consequences of Terminations pursuant to in clause-(Consequences) shall immediately come into effect.

10. Return of Equipment

In the event that equipment is made available, by Lotus to the PI or its Personnel for the purpose of rendering the Services, at the end of the assignment of PI or such Personnel and/or the rendering of Services by such PI or Personnel the said equipment shall be returned to Lotus in a functional and usable state. In the event that any equipment is not returned in such state, PI or such Personnel shall be liable to Lotus for the cost of replacing such equipment and without derogating from any additional claim by Lotus under this Agreement Lotus shall have the right to set off such cost against the amount owed by Lotus to the PI or such Personnel. In the event that any equipment is not returned as set out above, Lotus shall notify the PI or such Personnel of this fact and afford the PI or such Personnel an opportunity to approach and settle the return of the equipment. The said set off by Lotus shall be made only after thirty (30) days following Lotus 's notice to the Service Provider, and only in case the equipment has not been returned in a functional state at the end of such period.

11. Miscellaneous

11.1 Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

11.2. Arbitration

Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

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11.3 **Force Majeure (Act of God)**

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

11.4 **Record Keeping**

During the term of this Agreement or as applicable by law, PI shall maintain all materials, records and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

11.5 **Headings.**

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

11.6 **Publicity.**

Except as required by applicable law, neither Institution nor PI shall use, or authorize others to use, the name, symbols, or marks of Sponsor in any advertising or publicity material or make any form of representation or statement in relation to the Study, which would constitute an express or implied endorsement by Sponsor of any commercial product or service without prior written approval from Sponsor.

11.7 **Independent Contractors.**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of Sponsor. Institution represents that Principal Investigator is an employee of the Institution. Investigator acknowledges and agrees that Principal Investigator's sole recourse for compensation for his or her services, as well as the services of Principal Investigator's staff affiliated with the Study, shall be from Institution and not Watson.

11.8 **Assignment.**

This Agreement is, not assignable by Institution or Principal Investigator and any attempted assignment or delegation in violation hereof shall be void. Sponsor may assign this Agreement to an affiliated company without the prior consent of Institution or Principal Investigator. Notwithstanding such assignment, Sponsor shall remain liable for all of its obligations under this Agreement.

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11.9 **No Modifications.**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by the Parties.

11.10 **Severability.**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a Party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

11.11 **No Waiver.**

Failure on the part of a Party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

11.12. **Notices & Service of documents**

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Lotus shall be addressed to:

Lotus Labs Pvt. Ltd.
No. 7, Jasma Bhavan Road,
Millers Tank Bed Area,
Opp. Gurunanak Bhavan,
Vasanthnagar, Bangalore – 560 052
Phone No. 080-42708400/080-22370912
Fax No. 080-2237091

All the correspondence/ notices to be sent by Lotus to PI shall be addressed to:

Dr. Mahesh Kumar Veeranna Kalloli
KLEs Dr. Prabhakar Kore Hospital & MRC Hospital,
NH 4, Nehru Nagar,
Belagavi, Karnataka 590010., India.

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For LOTUS LABS PVT LTD

Dr.Radha Shekar **Senior Director**	**Dr. M.V. Jali** **Head of Institute**	**Dr. Mahesh Kumar** **Veeranna Kalloli** **Surgical Oncologist** **Principal Investigator**
Date: 19/Nov/2018	**Date:** 14/NOV/2018	**Date:** 14th NOV 2018
Seal: LOTUS LABS PVT. LTD. BANGALORE	**Seal:** KLES Dr. Prabhakar Kore Hospital & MRC Belagavi-10	**Seal:** Dr. MAHESH KALLOLI M.S.,Mch (Surgical Oncology) Consultant Surgical Oncologist KMC Reg No. 71566 KLES DR Prabhakar Kore Hospital & MRC, Belagavi - 10.
Witness	**Witness**	**Witness**
Date: 19/Nov/18	**Date:** 14-11-18	**Date:** 14/11/18
Name: P. Baskaranan **Designation:** Sr. Manager.	**Name:** Revanna Soevarini **Designation:** Assistant Coordinator	**Name:** Shivaprakash **Designation:** CRC

ATTESTED

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[illegible] 590 010,Karnataka

Exhibit A

Responsibilities of PI for

'A Randomized, Open Label, Multi Center, Two Treatment, Two Period, Two Sequence, Single Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial manufactured by Teva Pharmachemie, The Netherlands, for Teva Pharmaceuticals USA, and Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound), 100 mg/vial manufactured by Abraxis BioScience LLC, USA for Celgene Corporation, USA in Patients with Metastatic Breast Cancer" bearing the protocol / study number: CT/PAC/1701 (v.1.0) (India)

1. PI has sufficient time, adequate staff, and appropriate facilities to conduct and complete the clinical study. PI agrees to make these resources available for the duration of the study and agrees that other studies will not divert essential subjects or facilities away from this trial.

   PI assures Lotus Labs Pvt. Ltd., that no other clinical study conducted by him shall give rise to a conflict of interest or interfere with the clinical trial.

   PI will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Lotus Labs Pvt. Ltd. will furnish PI with copies of the Investigator's Brochure, the Study Plan and Protocol and agrees:

   a. To become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and
   b. To become well acquainted with the Study Plan before signing it.

3. PI agrees to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the study.

4. PI understands that along with the Institution, he will have primary responsibility for the accuracy, legibility, and security of all study data, documents, and subject records both during and after the study. PI will be responsible for electronic signature of the Electronic Case Report Forms (e-CRF).

   PI agrees to abide by the following conditions governing his/her handling of the data associated with this study.

   a. PI is required to maintain adequate records regarding all investigational product received and used by him/her including batch numbers, dates, and quantities. If the study is terminated, suspended, discontinued, or completed, PI shall return to Lotus Labs Pvt. Ltd., any unused supplies other than retention samples unless other arrangements are made by Lotus Labs Pvt. Ltd.

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b. PI is required to prepare and maintain adequate and accurate patient case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the clinical study.

c. PI understands to furnish records of the study to Lotus Labs Pvt. Ltd./Sponsor.

d. PI will maintain records of the disposition of the investigational product and other records for the longer of the following periods:
   I. the period defined by national or local law and rules
   II. Five years after the study is terminated or completed, or
   III. Five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
   IV. To avoid any possible errors PI will contact Lotus Labs Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. PI, along with Institution, agrees to provide accurate information to the Ethics Committee upon request. PI, along with Institution, also agrees to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and ethical obligations, as set forth below:

   I. The patient's identity will not be released except under the following limited circumstances
      i. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, PI will make records related to the clinical study available for inspection and copying

   II. Where data verification procedures demand inspection of patient's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person

   III. The patient's identity shall not be released to third parties without the patient's and/ or impartial witness prior consent. Accordingly, the study patient's and/ or impartial witness consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. PI agrees to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Lotus Labs Pvt. Ltd.

PI shall not commence the study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject

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recruitment procedures, and any written material to be provided to the patient's and/ or impartial witness.

PI shall provide the Institutional Ethics Committee or Institutional Review Board with all required information.

6. PI certifies that the investigational products for clinical investigation will be provided only to patient under his personal supervision or under the supervision of the Co-investigator/ Sub-investigator (if any) responsible to him.

   PI further certifies that the investigational products will not be supplied by him to any investigator, other than those listed above as Co-Investigator/ Sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. PI shall be responsible for completing and signing the FDA 1572.[Applies only US Studies]

9. PI agrees to be responsible for the personal safety and well-being of the subjects. To this end, PI agrees to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

   Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature:

   a. PI ensures that patient and/ or impartial witness or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the patient's and/ or impartial witness. Additionally, as required by Indian law, Principal Investigator shall also obtain an audio-visual recording of the informed consent process for each Study subject. Such process shall be undertaken while maintaining principles of confidentiality.

      The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

   b. PI will ensure that the patient and/ or impartial witness are given the opportunity to inquire about the details of the clinical study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the clinical study at any time without any sanction. PI will make an effort to ascertain the reasons for any

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withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

c. PI will ensure that the patient and/ or impartial witness are provided adequate time to decide whether or not they wish to participate/ wish their ward to participate in this clinical investigation.

10. PI will discuss with Lotus Labs Pvt. Ltd. any question of modification of the study plan and obtain Lotus Labs Pvt. Ltd./ Sponsor written agreement and also approval from the ethics committee prior to implementation of any modification. PI will not proceed with a non-emergency deviation from the Clinical Protocol without approval from Lotus Labs Pvt. Ltd. and as needed the Ethics Committee. It is PI's responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Lotus Labs Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. PI will report all adverse events/ serious adverse events to Lotus Labs Pvt. Ltd./ Sponsor.

a. PI will report within one day:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study patients.
   - Changes increasing the risk to patients and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) those are both serious and unexpected.
   - New information that may affect adversely the safety of the patients or the conduct of the study.

b. All staff in contact with the patient should be aware of their responsibility to note and report all adverse events reported by the patient's and/ or impartial witness

c. The Principal Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Lotus within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify patients by unique code numbers assigned to the study patients rather than by the patients' names, personal identification numbers and/or addresses.

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g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Lotus/Sponsor according to the reporting requirements and within the time periods specified by Lotus/Sponsor in the protocol.

h. **Dr. Mahesh Kumar Veeranna Kalloli** will personally be responsible for, or will appoint a Co-Investigator/ Sub-investigator (who has signed an Investigator Agreement and has been added to the Institution's, Lotus Labs Pvt. Ltd. and the Study Monitor's (CRA's) Investigator List) to be responsible for all study related medical decisions.

12. PI will be responsible to ensure that the data generated at the site is ALCOA (Attributable, Legible, Contemporaneous, Original & Accurate) and will report all the deviations from protocol to Lotus Labs Pvt. Ltd. All the information should be documented in the correct time frame (before starting the next activity) along with the flow of the events, by appropriate person.

13. PI will notify Lotus Labs Pvt. Ltd., immediately, but in no event in more than five working days, about withdrawal of approval by the reviewing Ethics Committee of his/her part of the clinical study.

14. PI will comply with any request by Lotus Labs Pvt. Ltd. to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. PI understands that Lotus Labs Pvt. Ltd. is required by law to discontinue shipments of investigational product to him/her if he/she fails to comply with the study protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

15. PI agrees to permit personnel from Lotus Labs Pvt. Ltd. (study monitors/auditors) to visit the study site whenever required with a notice of as short as 24 hours. PI further agrees to make records related to the clinical study available for inspection and copying.

16. PI agrees to submit and sign a Final Report of the clinical study within three months after termination or completion of the clinical study or of his/her part in the clinical study to the Ethics Committee.

PI agrees to abide by this Investigator Agreement.

Investigator Signature: _____

Date Signed: 15th NOV 2018

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Exhibit B: Proposal (Budget)
Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. A total of Rs. 1,40,000 /- (One lakh Forty thousand only) per subjects will be paid to the PI in the name of Dr. **Mahesh Kumar Veeranna Kalloli and Pan no: BAYPM5101M** according to the payment schedule provided below. This investigator payment includes institutional overhead charges of Rs. 16,800/-. Thus the total grant will be paid as below:

INVESTIGATOR GRANT - PER PATIENT

Part 1: STUDY TEAM CHARGES

Particulars		PI grant	Co-I grant	CRC grant	Admin charges	Sub Total
Visit 1 Screening		6000	1500	1000	500	9000
Visit 2: Period I	Day 0	2500	1500	1000	500	5500
	Day 01	6000	1500	1000	500	9000
	Day 02	2500	1500	1000	500	5500
	Day 03	2500	1500	1000	500	5500
	Day 04	3000	1500	1000	500	6000
Visit 3 (Day 14)		3000	1500	1000	500	6000
Visit 4: Period II	Day 0	2500	1500	1000	500	5500
	Day 01	6000	1500	1000	500	9000
	Day 02	2500	1500	1000	500	5500
	Day 03	2500	1500	1000	500	5500
	Day 04	3000	1500	1000	500	6000
Visit 5 (End of study)		3000	1500	1000	500	6000
Sub Total						84000
Institutional Over head Charges(25%)						16800
Grand Total						100800

Part 2 : PATIENT TRAVEL REIMBURSEMENT

Visit No	Amount
1	1000
2	1000
3	1000
4	1000
5	1000
Grand Total	5000

Part 3: HOSPITALIZATION AND LAB CHARGES

Particulars		12 Lead ECG	2 D ECHO	Chest X-ray	CBC(ANC, Platelet and Hemoglobin) and Serum Albumin)	Hospitalizatli on charges	Sub Total
Visit 1 Screening		750	3000	600			4350
Visit 2: Period I	Day 0				1500		1500
	Day 01					3000	3000
	Day 02					3000	3000
	Day 03					3000	3000
	Day 04					3000	3000
Visit 3 (Day 08)					1500		1500
Visit 4: Period II	Day 0				1500		1500
	Day 01					3000	3000
	Day 02					3000	3000
	Day 03					3000	3000
	Day 04					3000	3000
Visit 5 (End of study)		750		600			1350
Sub Total							34200

Investigator - per patient grant	
Part 1: Study team charges	100800
Part 2: Patient travel reimbursement	5000
Part 3: Hospitalization and Lab charges	34200
Grand Total	140000

Notes:

1. For any Unschedule visit, a sum of INR 5000(five thousand only) will be paid to the study team
2. GST charges of 18 %, if applicable.

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Note:

The following deductions will be made, if applicable:

- Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
- Goods &Service Tax (GST) as applicable on all payments of fee. The GST Number along with the certificate shall be provided by Institution / Investigator as applicable.
- Any Capital expenses for the site incurred by Lotus on behalf of PI will be deducted from the fee payable to PI.
- Phlebotomist's charges will be paid upon no of collection in each period. i.e 100/ sample maximum of Rs 1700 per period.
- Expenses related to lab investigations, Hospitalization and patient travel re-imbursement will be paid will be on actual upon producing the bills/ invoices otherwise TDS will be deducted.
- Archival fee of INR 50,000 is applicable towards archiving the study documents for period 15 Years at the site after completion/termination of study which will be paid only on or prior to the site close out visit only.
- If GCSF administered to the patients, then on case to case basis the reimbursement claim would be considered against actual bills.
- Any additional expense related to the study (SAE management /Additional lab test) will be paid on actuals upon submission of original bills post confirmation of activities by Lotus PM/ study monitor.

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Dr.Radha Shekar **Senior Director**	**Dr. M.V. Jali** **Head of Institute**	**Dr. Mahesh Kumar** **Veeranna Kalloli** **Surgical Oncologist** **Principal Investigator**
Date: 19/Nov/2018	**Date:** 14/NOV/2018	**Date:** 14th Nov 2018
Seal: LOTUS LABS PVT. LTD. BANGALORE	**Seal:** KLES Dr. Prabhakar Kore Hospital & MRC Belagavi-10	**Seal:** Dr. MAHESH KALLOLI M.S.,Mch (Surgical Oncology) Consultant Surgical Oncologist KMC Reg No. 71566 KLES DR Prabhakar Kore Hospital & MRC, Belagavi - 10.
Witness	**Witness**	**Witness**
Date: 19/Nov/18	**Date:** 14-11-18	**Date:** 14/11/2018
Name: P. Narayanan **Designation:** Dr. Manager	**Name:** Revanna SDoranis **Designation:** Asst Coordinator	**Name:** Shivaprakash S **Designation:** CRC

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CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

- SHANTHA BIOTECHNICS PRIVATE LIMITED a company organized and existing under the laws of India, having its registered office at 3rd and 4th Floors, Vasantha Chambers, H. No. 5-10-173, Fateh Maidan Road, Basheerbagh, Hyderabad – 500 004, Telangana - India;

  (hereinafter referred to as the "**Sponsor**")

  On the first part,

AND:

- KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, an institution incorporated under the laws of, having its registered head office at Belagavi, Karnataka 590010

  (hereinafter referred to as the "**Institution**")

- and -

- Dr. S.M.Dhaded, practicing at Department of Pediatrics as Professor, KLE University's J.N.Medical College, Belagavi, Karnataka, India- 590010.

  (hereinafter referred to as the "**Principal Investigator**")

  On the second part,

With each of the parties collectively or individually referred to as "Party" or "Parties"

THIS AGREEMENT RELATES TO THE FOLLOWING CLINICAL TRIAL:

Phase III Safety and Immunogenicity of an Investigational *versus* the Licensed Formulation of the Pentavalent Vaccine (DTwP-HepB-Hib) SHAN 5® when administered as Three Dose Primary Series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants and Safety and Immunogenicity of the Investigational SHAN 5® Formulation when administered as a Single Booster Dose at 12-24 Months of Age. Code: SH504.

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PREAMBLE

WHEREAS, Shantha Biotechnics Private Limited is the Sponsor, as defined in the ICH GCP guidelines, of the above mentioned Clinical Trial and therefore wishes to perform this Clinical Trial;

WHEREAS, the Institution and the Principal Investigator have capable personnel and the necessary expertise to organize and perform clinical trials in the field of vaccines;

WHEREAS, the Institution and the Principal Investigator are willing to organize, conduct and perform this Clinical Trial on behalf of the Sponsor;

WHEREAS, the Principal Investigator is responsible for the scientific supervision and direction of the Clinical Trial and will conduct the Clinical Trial in the facilities of the Institution;

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE 1 – DEFINITIONS

For the purposes of this Agreement the following words and phrases shall have the following meanings:

- "**Additional Personnel**" means any co-investigator and/or any of Institution's contractors, employees, post-doctoral fellows, residents, demonstrators, students and/or technical staff, who may be involved in the Clinical Trial (as hereinafter defined), other than the Principal Investigator.

- "**Affiliate**" means, with respect to Shantha Biotechnics Private Limited, (i) any Person of which the securities or other ownership interests representing fifty per cent (50%) or more of the equity or fifty per cent (50%) or more of the ordinary voting power or fifty per cent (50%) or more of the general partnership interest are, at the time such determination is being made, owned, Controlled or held, directly or indirectly, by Shantha Biotechnics Private Limited, or (ii) any other Person which, at the time such determination is being made, is Controlling or under common Control with Shantha Biotechnics Private Limited.

- "**Agreement**" means this Clinical Trial Agreement, all amendments and supplements to this Agreement and all schedules to this Agreement.

- "**Case Report Form**" means the form to be completed and returned to the Sponsor for each Subject participating in the Clinical Trial. This form will be an electronic form accessible through a web link which shall be communicated by the Sponsor to the Principal Investigator.

If the electronic data capture is used for the purpose of the Clinical Trial, then "Case Book" shall have the same meaning.

- "**Clinical Trial**" means the clinical trial above-mentioned in the Preamble of the Agreement

- *OR*

- "**Concomitant Product**": There is no Concomitant Product in the Agreement.

- "**Confidential Information**" means any and all information relating to the Sponsor or its Affiliates which is of a confidential and proprietary nature, including but not limited to preclinical, clinical or formulation data, investigator's brochures, case reports, source documentation, study protocols and SOPs (as defined hereafter) as amended from time to time.

- "**Control**" means, whether used as a noun or verb, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

- "**Control Product**" means the Shan5® (with imported pertussis and Shantha HBsAg) manufactured by Shantha Biotechnics private Limited to be used in the Clinical Trial in accordance with the Protocol.

- "**Enrollment Cap**" means that the Sponsor reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to the Institution and the Principal Investigator to cease further enrollment of Subjects in the Clinical Trial.

- "**GCP**" means:

  (i) the set of regulations established by Health Authority(ies) for conducting clinical studies including without limitation the set of regulations established by the CDSCO.
  (ii) the current international ethical and scientific quality standards for designing, conducting, recording and reporting clinical studies known as ICH Guidelines for Good Clinical Practice.

- "**Health Authorities**" means applicable health authorities, either governmental, regulatory or otherwise, including but not limited to the Drug Controller General of India (DCGI), United States Food and Drug Administration ("FDA"), the European Medicines Evaluation Agency ("EMEA"), the French *"Agence Natinale de Sécurité des Médicaments et des produits de santé"* ("ANSM") and Health Canada.

- "**ICH**" means the International Conference of Harmonization.

- "**IEC**" means the t Institutional Ethics Committee responsible for review and approval of the Protocol.

- "**IND**" means an investigational new drug.

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- "**Indemnitee**" means collectively the Institution, its trustees, officers, directors, agents, Additional Personnel and the Principal Investigator.

- "**Inventions**" means any inventions, discoveries, or innovations, products, processes, data, reports, results, formulations, technologies and compounds, whether patentable or not, arising directly or indirectly, in the performance of the Clinical Trial under this Agreement or using Clinical Trial funds or otherwise arising out of use of the Product.

- "**Investigational Product**" means Shan5 (with Shantha pertussis and imported HBsAg) Pentavalent vaccine (DTwP-HepB-Hib) manufactured by Shantha Biotechnics private Limited to be used in the Clinical Trial in accordance with the Protocol

- "**Person**" means an individual, partnership, joint venture, trustee, trust, corporation, unincorporated organization or other entity or a government, state or agency, or political subdivision thereof.

- "**Personal Data**" means any and all data concerning an individual participating in the Clinical Trial whether as a Subject or as an investigator.

- "**Principal Investigator**" means the person who is named on the head of the Agreement and corresponds to the person who is named *"Investigator"* or *"Principal Investigator"* in the Protocol for either the entire study or a study site.

- "**Privacy Rules**" means any national and international standards of practice, establishing a category of information regarding the patients or Subjects, which may be used or disclosed to others in certain circumstances or under certain conditions.

- "**Processing**" means, in accordance with applicable rules and regulations, any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

- "**Protocol**" means the last approved version of the protocol including any and all amendments, which will be considered as attached hereto upon completion, and is incorporated herein by reference.

It is agreed that this Agreement shall be governed by the most recent version of the Protocol, and should this Agreement be executed prior to complete finalization of the Protocol, the last-dated version thereof will be considered to be incorporated by reference in place of any prior versions. In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern with respect to contract terms and conditions but the Protocol will govern with respect to the conduct of the Clinical Trial and with respect to serving the best interests of patient welfare.

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- "**Public Presentation**" means, collectively or individually, drafts of abstracts and/or manuscripts for publication (including slides and texts of oral or other public presentations).

- "**Recipient**" means, collectively and individually, the Institution and/or the Principal Investigator.

- "**Related Person(s)**" means any Person(s) having a relationship with a Party whether as an employee, Additional Personnel, Affiliate, agent or representative.

- "**Subject**" means an individual who is selected in accordance with the terms of the Protocol to participate in the Clinical Trial.

- "**SOPs**" means the Sponsor's Standard Operating Procedures as amended from time to time to be used for the purpose of the Clinical Trial

- "**Trial Product**" means collectively the Investigational Product, the Control Product and the Concomitant Product.

- "**Trial Site**" means the location(s) where the Clinical Trial activities are conducted by the Institution and/or the Principal Investigator.

ARTICLE 2 – SCOPE OF WORK

The Institution and the Principal Investigator shall conduct the Clinical Trial relating to the Product in accordance with the Protocol. Creation and modification of the Protocol shall be the sole responsibility of the Sponsor.

ARTICLE 3 - CLINICAL TRIAL APPROVALS

3.1 The Principal Investigator is responsible for ensuring that the Ethics Committee is registered before starting the Clinical Trial. The Investigator is responsible to follow up and ensure updating of serious adverse events causality opinion by the Ethics Committee to Appropriate Authority and Sponsor.

3.2 The Principal Investigator shall be responsible for having the Clinical Trial documents (such as Protocol, Sponsor informed consent form and / or site inform consent form, any advertisement(s) pertaining to the recruitment of Subjects in the Clinical Trial) approved by the IEC prior to the beginning of the Clinical Trial.

3.2 In the event the IEC requests that changes be made to the Protocol such as the informed consent form template, the Institution shall immediately inform Sponsor of the IEC request in detail. Any modifications to the Protocol including the informed consent form template

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must be approved by the Sponsor and/or appropriate regulatory authority, if applicable, before being implemented by Institution.

3.3 The Institution and the Principal Investigator shall not modify the Protocol without the prior written approval of the Sponsor.

3.4 The Sponsor shall be responsible for the submission of any IND application, if applicable resulting from the Clinical Trial, and the Parties agree to fully cooperate as necessary with the Sponsor and at Sponsor's expense, in the completion and filing of the IND.

ARTICLE 4 – ORGANIZATION OF THE CLINICAL TRIAL

4.1 The **estimated** time schedule of the Clinical Trial described in detail in the Protocol may be summarized as follows:

- Planned starting of the Subjects' recruiting process: [Dec 2018]
- Planned final report: [Oct 2020]

It is understood that the effective beginning of the Clinical Trial is dependent upon timely approval of key Clinical Trial documents and/or performance of preparatory activities by Sponsor and/or third parties (e.g. IEC/IRB or Health Authority) and/or availability of the Trial Product. Thus, any delay in this approval and/or the performance of those preparatory activities and/or availability of the Trial Product may have a cascade effect on the Clinical Trial initiation. The Principal Investigator and the Institution agree that any such delay shall not entitle them to any compensation or remedy.

4.2 It is estimated that the Principal Investigator participating in this Clinical Trial will enroll a target number of Subjects of 70 (Seventy) subjects in study at KLEs JNMC Belagavi, Karnataka, in approximately 90 days respectively starting from the first Subject recruited in the Clinical Trial. This target of recruitment can be increased only upon written agreement of the Sponsor.

If not achieved, the Sponsor might decide to reallocate the Subjects enrollment to another site and in this case, the rules set forth in section 4.2.1 of the Agreement will be applied.

For a multi-center Clinical Trial, the Sponsor may amend the number of Subjects to be recruited by the Principal Investigator and in this case the rules set forth in sections 4.2.1 and/or 4.2.2 of the Agreement will be applied.

4.2.1 if in the reasonable opinion of the Sponsor, recruitment of Subjects is proceeding at the Trial Site at a rate below that required to enable the relevant timeline to be met, the Sponsor may by notice to the Institution require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment in the Clinical Trial at the date of such notice; or

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4.2.2 if recruitment of Subjects is proceeding at the Trial Site a rate above that required to meet the relevant timeline the Sponsor may with the agreement of the Institution increase the number of Subjects to be recruited by the Principal Investigator.

For a multi-center Clinical Trial having a competitive enrollment, the Sponsor reserves the right to request the Principal Investigator to limit recruitment of further Subjects or cease the recruitment, notably if the global recruitment target for the Clinical Trial has been reached. In such event, the Sponsor will inform the Principal Investigator on interrupting the recruitment of any Subject who has not yet signed the informed consent form.

The Principal Investigator shall upon receipt of a notice for stopping recruitment, stop immediately further recruitment of Subjects. Payment shall only be made according to the number of Subjects recruited up to the date of receipt of the said notice of stopping. The Sponsor will neither take any responsibility, nor make any payment for the Subjects recruited after this date.

The Institution acknowledges that it is able to perform a competitive enrollment and has a capacity of recruitment of 100 (Hundred) subjects in the study within a period of approximately 90 days.

4.3 It is agreed among the Parties that the Principal Investigator and the Additional Personnel shall attend the mandatory training session(s) organized in relation with the Clinical Trial.

The Parties agree to inform each other of the Clinical Trial performance and therefore agree to organize and to participate in meetings related thereto.

The Principal Investigator agrees to take the necessary time to meet with any person duly appointed by the Sponsor for monitoring the Clinical Trial.

4.4 If, at any time, Institution or Principal Investigator have reason to believe that the Clinical Trial will not be initiated or completed as per the schedule initially anticipated and agreed upon by the Parties, Sponsor will be advised immediately, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor as provided in Article 14 hereafter.

ARTICLE 5 - OBLIGATIONS OF THE INSTITUTION AND/OR THE PRINCIPAL INVESTIGATOR

5.1 The Institution shall apply its best efforts to retain the services of the Principal Investigator.

In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his tasks as Principal Investigator, the Institution shall so inform the Sponsor by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, which replacement shall have a similar background and also knowledge of the Clinical Trial.

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Any successor to the Principal Investigator must be approved, in writing, by the Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

The Institution agrees to immediately inform the Sponsor in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

5.2 The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

(a) the Protocol and all other terms of this Agreement;

(b) all laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration as amended in Edinburgh, Scotland (October 2000), including, but not limited to the Public Health Service Act, the Food, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities and the Code of Federal Regulations of the United States if the Clinical Trial is performed in the USA;

(c) any and all Sponsor's requirements, directions or instructions, including but not limited to the SOPs;

(d) those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

(e) all applicable laws and regulations.

5.3 The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

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Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

5.4 The Institution and the Principal Investigator shall have the following record keeping and reporting obligations:

(i) To prepare and maintain complete and accurate written records, accounts, notes, reports and data relating to the Clinical Trial under this Agreement.

(ii) To prepare and submit to the Sponsor (in a periodic and timely manner during the term of this Agreement) all raw data and other material called for in the Protocol, in the form of properly completed Case Report Forms or into an electronic database (i.e., remote data entry) supplied by the Sponsor, for each Subject. All Case Report Forms and the information and data stored in any electronic database shall be the exclusive property of the Sponsor.

(iii) To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial during Twenty Five (25) years. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor.

5.5 The Principal Investigator shall report any adverse experiences and adverse events observed in the Clinical Trial to the Sponsor. All adverse experience/event reports shall be prepared and collected by the Principal Investigator according to the procedures outlined in the Protocol.

5.6 The Institution and the Principal Investigator shall use their best efforts to complete expeditiously the Clinical Trial in accordance with the time-schedule provided for in the Protocol.

5.7 The Institution shall, on or before the signing date of this Agreement, supply the Sponsor with a complete list of its additional personnel who it anticipates will be involved in carrying out Institution's obligations under this Agreement, specifying the role each individual will play in carrying out these obligations. The Institution agrees to inform the Sponsor of any changes to such list and train new Additional Personnel to the specificities of the Clinical Trial.

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5.8 The Institution and the Principal Investigator agree to inform the Sponsor of any cooperation or collaboration they would like to undertake regarding a therapeutic/ prophylactic concept similar to the one studied according to the Protocol if such a project would compete with the Clinical Trial. The Sponsor will be entitled to terminate this Agreement if such a cooperation or collaboration is deemed by the Sponsor to be incompatible with its interests.

5.9 To comply with applicable Health Authorities' regulations, as well as the Sponsor's conflict of interest policies that require investigators conducting clinical trials to provide the Sponsor with information regarding certain types of relevant financial or business relationships between the Sponsor and the Principal Investigator, his spouse and dependent children, the Sponsor will provide the Institution with a form, which the Institution shall ensure is completed and updated from time to time by the Principal Investigator. Completion of this form is a material condition which must be satisfied before the beginning of the Clinical Trial. The Principal Investigator hereby consents to the use by the Sponsor of such information (including disclosure to Health Authorities, if necessary). The Institution understands that similar obligations exist for sub-investigator(s) and agrees to provide the Sponsor with similar disclosures from each sub-investigator before permitting them to participate in the Clinical Trial.

5.10 The Sponsor registers all its clinical trial protocols on the web site http://ctri.nic.in. If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor shall support them by providing the required information.

5.11 If electronic data capture will be used for the purpose of the Clinical Trial, it is hereby understood that the Principal Investigator and/or the Additional Personnel shall strictly adhere and respect the provisions of Shantha Biotechnics Private Limited procedure entitled "Information Systems Usage Charter" attached to the Agreement as Schedule C.

ARTICLE 6 – TRIAL PRODUCT, EQUIPMENT AND DOCUMENT

6.1 The Trial Product, as well as the documents and the material necessary to conduct the Clinical Trial, as described in the Protocol, shall be supplied free of charge to the Institution by the Sponsor. In certain circumstances, the Sponsor might instruct the Institution to purchase the Control Product and/or the Concomitant Product and/or equipment. In such a case, the Sponsor will reimburse these expenses to the Institution at invoice value (all invoices are requested by the Sponsor prior to reimbursement).

The Institution shall inform the Sponsor on or before the signing date of this Agreement of the name and complete address to which the Product shall be shipped by the Sponsor.

6.2 All the Trial Product, the document, the equipment and the material supplied pursuant to this Agreement shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to the Agreement. It is understood that the Trial Product is provided by the Sponsor for the sole purpose of conducting the Clinical Trial.

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THE SPONSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE TRIAL PRODUCT OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OTHER THAN FOR ITS USE IN THIS CLINICAL TRIAL.

All unused doses of Trial Product shall be promptly returned to the Sponsor upon the completion of the Clinical Trial as directed by the Sponsor, or upon earlier termination of this Agreement, unless written authorization to destroy the Trial Product is given by Sponsor. If authorization to destroy unused Trial Product is previously given in writing, the Institution shall provide the Sponsor with documentation as to the method of destruction. The Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals during any destruction of unused quantities of the Product. Upon delivery, the Institution and the Principal Investigator shall be responsible for any improper administration, storage or handling of the Trial Product and for its use beyond its applicable expiration date.

6.3 If some products among the Investigational Product and/or Control Product and/or Concomitant Product were to be recalled, the Principal Investigator and the Institution commit to implement the Sponsor's instructions immediately and to quarantine the product(s) at stake.

ARTICLE 7 - AUDITS

7.1 During the Clinical Trial and for such additional period of time that records are required to be retained by law or otherwise, it is agreed that representatives of the Sponsor may arrange with the Principal Investigator or his designee, after having duly informed the Institution respecting at least seven (7) days prior notice:

(i) to examine and audit, at regular business hours, the locations where the Clinical Trial is performed;

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Clinical Trial conducted under this Agreement and to inspect and make copies of all data necessary for the Sponsor to confirm that the Clinical Trial is being conducted in conformance with the Protocol and in compliance with all applicable legal and/or regulatory requirements of any and all Health Authorities; and

(iii) to meet with any person involved in the Clinical Trial's performance.

7.2 The Institution agrees to assist the Sponsor, to the extent deemed reasonable by the Sponsor, in facilitating the Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Clinical Trial and in order to enforce the rights granted to the Sponsor in this Article 7.

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The Principal Investigator and the Institution agree to take any action, as reasonably requested by the Sponsor, to properly correct or address any deficiencies noted during any audit and agree to cooperate with the Sponsor with respect to any action taken to address any such deficiencies.

7.3 If the need arises (or if the need be), the Institution agrees to notify Sponsor within twenty-four (24) hours in the event that an Health Authority notifies the Institution of a pending inspection/audit. In addition, the Institution will forward to Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to accept Sponsor's assistance in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing Health Authority. The Institution shall also provide the Sponsor with copies of any documents provided to any inspector or auditor. In the event any applicable Health Authority requests or requires any action to be taken to address any citations, the Principal Investigator and the Institution agree, after consultation with the Sponsor, to take such action as necessary to address such citations, and agree to cooperate with the Sponsor with respect to any such citation and/or action taken with respect thereto.

ARTICLE 8 - FINANCIAL PROVISIONS

The financial provisions applicable to the Agreement in consideration of the performance of the Clinical Trial are provided for in Schedule A and depicted in Schedule B attached hereto.

ARTICLE 9 - CONFIDENTIALITY

9.1 Before and during the course of the Clinical Trial, the Recipient may obtain, or have access to Confidential Information.

Except as expressly set forth in this Article, the Recipient shall each cause its Related Person(s) to keep the Confidential Information confidential, and the Recipient shall not disclose directly or indirectly, and shall cause its Related Persons not to disclose directly or indirectly, any Confidential Information to anyone, except that the foregoing restriction shall not apply to any information disclosed hereunder if such Confidential Information, as reasonably demonstrated by the Recipient:

(i) is generally available to the trade or public or becomes after the time of receipt by the Recipient part of the public domain, other than by reason of any breach or default by the Recipient or any of its Related Persons of a confidentiality obligation under this Agreement;

(ii) was already known to the Recipient at the time of disclosure by the Sponsor;

(iii) is disclosed to the Recipient or any of its Related Persons by a Third Party who has the right to disclose such information; or

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(iv) based on such person's good faith judgment with the advice of counsel, is otherwise required to be disclosed in compliance with applicable legal requirements to a Health Authority.

Whenever the Recipient becomes aware of any state of facts which would or might result in disclosure of Confidential Information pursuant to subparagraph (iv) above, it shall, if possible, promptly notify the Sponsor prior to any such disclosure so that the Sponsor may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement.

In any event, if the Recipient is unable to promptly notify the Sponsor or if such protective order or other remedy is not obtained, or if the Sponsor waives compliance with the provisions of this Agreement, the Recipient will furnish only that portion of the information which its counsel directs is legally required and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded the Confidential Information.

The Sponsor shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security except as required by the relevant laws, enjoining or restraining the Recipient and any of its Related Persons from any violation or threatened violation of this Article.

9.2 The Recipient agrees that no Confidential Information shall:

(i) be used in its own business except as necessary to the fulfillment of the rights and obligations of the Recipient under this Agreement;

(ii) be disclosed, assigned, licensed, sublicensed, marketed, transferred or loaned, directly or indirectly to any third party other than to an Affiliate or a representative of the Recipient in accordance with the provisions of this Agreement, except as necessary to the fulfillment of the rights and obligations of the Parties under this Agreement;

(iii) be used or exploited by the Recipient or any of its Related Persons for its or their respective benefit or the benefit of any other relationships with customers of such Party and its Related Persons.

(iv) be used by the Recipient or its Affiliates for obtaining intellectual property rights.

Without limiting the generality of the foregoing, the Recipient agrees that, it shall not (and shall not permit any of its Related Persons) at any time use any Confidential Information in the conduct of its business without the prior written consent of the Sponsor.

The obligations set forth in this Article shall extend to copies, if any, of Confidential Information made by the Recipient and/or its Related Persons and to documents prepared by such persons which embody or contain Confidential Information.

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9.3 The Recipient shall deal with Confidential Information so as to protect it from disclosure with a degree of care not less than that used by it in dealing with its own information intended to remain exclusively within its knowledge and shall take reasonable steps to minimize the risk of disclosure of Confidential Information which shall include, without limitation, ensuring that only their respective Related Persons who have a *bona fide* "need to know" such Confidential Information for purposes permitted or contemplated by this Agreement shall have access thereto.

The Recipient shall notify all of its Related Persons who have access to Confidential Information of its confidentiality and the care therefore required, and shall obtain from any such Related Person an agreement of confidentiality incorporating the restrictions set forth herein.

9.4 The obligations set forth in the present article shall survive the termination of this Agreement for a period of Fifteen (15) years.

9.5 Except as otherwise agreed to by the Parties in writing, the Recipient shall (and shall cause its Related Persons to), within thirty (30) days after the termination of this Agreement, return to the Sponsor or destroy all documents and tangible items then in its possession which it has received from the Sponsor or its Related Persons pertaining, referring or relating to the Sponsor's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Related Persons has made from the documents or tangible items received from the Sponsor or Related Person; provided, however, that the Recipient may retain one copy of each document in its legal files solely to permit the Recipient to continue to comply with its obligations hereunder and, in addition, may upon notice to the Sponsor, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

ARTICLE 10 – INVENTIONS AND PATENTS

The sole and exclusive right to any Inventions shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor in writing of any such Inventions, and at Sponsor's request, and expense, Institution and Principal Investigator will cause to be assigned to Sponsor all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents.

ARTICLE 11 – DATA, PUBLICATIONS, OTHER RIGHTS

In recognition of the importance of disseminating information relating to any novel or important observations or results that may arise from the Clinical Trial, and understanding that such need must be balanced with the Sponsor's obligations to maintain control over Confidential Information as well as to comply with all appropriate Health Authorities' rules and regulations, the Parties hereby agree to the following:

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11.1 The Institution and the Principal Investigator agree that all research data and results generated during the course of or as a result of the Clinical Trial shall be the property of the Sponsor. The Principal Investigator and the Institution further agree to execute any documents or undertake any further actions requested by the Sponsor to evidence transfer of title to such data.

11.2 Subject to the terms and conditions of this Agreement, the Institution and the Principal Investigator have the right to publish or publicly present their results of the Clinical Trial. The Principal Investigator and the Institution agree not to publish or publicly present any interim results of the Clinical Trial without prior review by the Sponsor, as provided below. The Principal Investigator and the Institution further agree to provide ninety (90) days written notice to the Sponsor, including a complete copy of the intended Public Presentation, prior to submission for publication or presentation to permit the Sponsor to review a Public Presentation which reports any results arising out of the Clinical Trial. The Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the data analysis and presentation to ensure that:

(i) Confidential Information is protected by the provisions contained in Article 11.4 below;
(ii) the information contained in the Public Presentation are accurate; and
(iii) the Public Presentation is fairly balanced and in compliance with applicable Health Authorities' regulations.

If the Parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, the Institution agrees to meet with Sponsor's representatives, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

In the event that the Parties cannot resolve their dispute within a period of ninety (90) days, they may refer the matter to an independent adjudicator having expertise in the field of the Clinical Trial selected jointly by them who shall decide the matter. The Parties agree to abide by the adjudicator's decision. The Principal Investigator and Institution agree not to release a Public Presentation until such time as a resolution has been reached, whether by the Parties on their own, or by the adjudicator.

11.3 To the extent that the Institution's participation in the Protocol is a part of a multi-center clinical trial, the Institution and the Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from the Sponsor for Public Presentation of separate results. The Sponsor shall advise as to the implications of timing of any Public Presentation in the event the Clinical Trial is still in progress at sites other than the Principal Investigator's one and any institution or investigator participating in a multi-center clinical trial shall follow the Public Presentation review procedures set forth in Article 11.2 above.

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11.4 No Public Presentation shall contain any Confidential Information. Public Presentation shall be confined to new discoveries and interpretations of scientific fact. At the Sponsor's request, the Sponsor shall be acknowledged as one of many or as the sole financial Sponsor, as the case may be, of the Clinical Trial reported in the Public Presentation.

11.5 The Institution and the Principal Investigator shall be aware that a publication or presentation of patentable subject matter prior to filing respective patent application will jeopardize such patent rights. Therefore, if the Sponsor believes there is a patentable subject matter contained in any Public Presentation submitted for review, the Sponsor shall promptly identify such subject matter to the Institution. If the Sponsor requests and at the Sponsor's expense, the Institution and the Principal Investigator shall use their best efforts to assist the Sponsor in filing a patent application covering such subject matter prior to any publication.

Furthermore, in the event that the review of the proposed publications or other public disclosure results in a determination that potentially patentable subject matter would be disclosed, and that such disclosure would be prejudicial to perfecting Sponsor's intellectual property rights, the Principal Investigator or Institution shall delay the publication or public disclosure for an additional ninety (90) days, at Sponsor's request, to allow for filing the necessary patent applications.

ARTICLE 12 – LIABILITY, INDEMNIFICATION AND INSURANCE

12.1

1. In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required;

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b)violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the

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INVESTIGATOR. Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect;
(d) use of placebo in a placebo-controlled trial;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

6. The Sponsor shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled for compensation.

7. The Sponsor in case of injury or death occurring to the clinical trial subject, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII.

8. However, the Sponsor is liable to pay the medical management fee or compensation, only for those clinical trial related injury or death which happened by or before 28th day from the day of administering the vaccine/product to the subject.

9 The Sponsor shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

Therefore, the Sponsor shall maintain, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section 12 and shall also provide product liability and clinical trials liability coverage. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor's liability with respect to its indemnification under this section 12. The Sponsor shall maintain the aforementioned insurance during the Clinical Trial. This obligation to maintain insurance shall survive the termination of this Agreement. The Sponsor shall provide the Institution with written evidence of such insurance upon the written request of the Indemnitee.

12.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or

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the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor and shall assist the Sponsor and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

12.3 Notwithstanding the foregoing, the Sponsor shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, its Affiliates, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol)), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

(iv) any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

12.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) general liability (including coverage for the Clinical Trial site); and
(iii) worker's compensation coverage,

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in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor and the Institution shall provide thirty (30) days' prior written notice to the Sponsor in the event of cancellation or any material change in such insurance.

ARTICLE 13 - TERM

This Agreement shall become effective from the day of last signature and shall remain in full force and effect until completion of the final report of the Clinical Trial, Trial which for reference only is expected by October 2020.

ARTICLE 14 – TERMINATION AND ENROLLMENT CAP

14.1 The Sponsor may terminate this Agreement at any time by giving thirty (30) days written notice to the Institution. In the event thirty (30) days is determined by the Institution to be insufficient notice based upon evaluation of risks to enrolled Subject(s) then receiving the Product, the Parties will cooperate to safely withdraw Subjects from the Clinical Trial over a mutually agreeable period of time but in no event shall the Sponsor's obligation to supply the Product hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event the Sponsor believes that immediate termination is necessary due to its evaluation of risks to enrolled Subject(s), the Sponsor may terminate this Agreement immediately.

The Sponsor reserves the right not to perform the Clinical Trial. In such a case, the Agreement shall be considered as automatically terminated upon the Sponsor's formal notice to both the Institution and the Principal Investigator.

14.2 Notwithstanding any other provision hereof, the Sponsor shall be entitled to terminate this Agreement for any Material Breach, which shall be defined as:

(i) The Institution and/or the Principal Investigator's failure to comply with their obligations, responsibilities and the terms and conditions of this Agreement including the Protocol;

(ii) The Institution and/or the Principal Investigator's failure to comply with: (a) their obligations for keeping the Sponsor informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Clinical Trial; or (c) the work to be performed under this Agreement; or

(iii) A breach by the Institution, the Principal Investigator, or their Related Persons of the confidentiality provisions of this Agreement.

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Dr. V.A.Kothiwale 394
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KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

14.3 Upon termination, for any reason:

(i) the Institution shall return to the Sponsor all unused materials, including but not limited to, the Product and any clinical supplies (unless written authorization to destroy them is given by the Sponsor, in which case the Institution shall comply with the applicable provisions of Article 6 hereof);

(ii) except in the event of termination because of a Material Breach by the Institution, and unless otherwise specified in writing between the Parties, the total sums payable by the Sponsor pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by the Sponsor to the Institution being refunded to the Sponsor;

(iii) in the event of termination as a result of a Material Breach, the Parties agree to make a good faith effort to reach agreement to compensate the Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) the Principal Investigator shall return to Sponsor all Confidential Information (as defined in Article 9 hereof) owned or controlled by the Sponsor and in the possession of the Institution or its Related Persons;

(v) the Principal Investigator must submit to the Sponsor the Case Report Forms for all the work in progress as of the effective date of termination.

14.4 The termination of this Agreement shall not relieve either Party of its obligations set out in Sections 5.3, 5.4, 5.5 and Articles 6, 7, 9, 10, 11 and 12 of this Agreement

14.5 Upon receipt of notice of Enrollment Cap, the Institution and the Principal Investigator agree to enroll no further Subjects in the Clinical Trial, and the funds payable pursuant to this Agreement shall be adjusted to reflect only the number of Subjects actually enrolled and the number of visits and technical procedures actually performed prior to receipt of such notice. The Institution and the Principal Investigator, as the case may be, shall refund to Sponsor any funds received in advance from Sponsor that are in excess of the adjusted funding.

ARTICLE 15 – DATA PROTECTION

15.1 It is understood among the Parties that Personal Data will be collected during the course of the Clinical Trial.

The Institution, the Principal Investigator and the Sponsor agree to comply with all applicable Privacy Rules relating to such Personal Data including, if necessary, notification of their Processing activities under this Agreement to the supervisory authority.

The Principal Investigator and the Institution shall take any other steps requested by the Sponsor in order to enable the Sponsor to comply with any notification or other obligations applicable to it or its Affiliates under such laws.

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Sponsor represents and affirms to the Institution and the Principal Investigator that it has complied with, and will continue to comply with its obligations under the Privacy Rules applicable to the Clinical Trial.

15.2 The Principal Investigator and the Institution shall:

(a) Ensure that Personal Data collected for the purpose of the Clinical Trial will be processed only in accordance with this Agreement or as otherwise instructed in writing from time to time by the Sponsor.

(b) Ensure that Personal Data are not disclosed or transferred to any Third Party without the prior written consent of the Sponsor, except:

(i) as specifically stated in this Agreement, or

(ii) where such disclosure or transfer is required by any applicable law, regulation or supervisory authority, in which case the Institution and Principal Investigator shall, wherever possible, notify promptly in writing (and in any event within five days of receipt) the Sponsor prior to complying with any such request for disclosure or transfer and shall comply with all reasonable directions of the Sponsor with respect to such disclosure or transfer.

(c) Ensure that Personal Data are accurate and, where necessary, kept updated and use best efforts to ensure that any Personal Data which are inaccurate or incomplete are erased or rectified where appropriate.

(d) Ensure that all appropriate technical and organizational measures are taken to protect Personal Data against accidental or unlawful destruction or accidental loss or alteration, or unauthorized disclosure or access and against all other unlawful forms of Processing.

(e) Notify the Sponsor in a timely manner of any accidental, unlawful or unauthorized uses or disclosures of Personal Data; ensure that it refers any communication received from a Subject relating to the Subject's rights to access, modify or correct its Personal Data to the Sponsor and to comply with all instructions of the Sponsor before responding to such communications; comply with the provisions of this Agreement and the reasonable instructions of the Sponsor to return, store or destroy the Personal Data.

15.3 According to Privacy Rules, the Principal Investigator may request access to his Personal Data or to have his Personal Data rectified, blocked, erased or destroyed. In such case, the Principal Investigator shall send a written notice to:

Shantha Biotechnics Private Limited
Clinical R&D,
4th Floor, Vasantha Chambers,
Fateh Maidan Road, Basheerbagh, Hyderabad – 500 004

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010,Karnataka

ARTICLE 16 – NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and may be effectively given if delivered personally or if sent by prepaid registered mail, or by facsimile addressed in the case of the Sponsor to:

Shantha Biotechnics Pri/vate Limited
Clinical R&D,
4th Floor, Vasantha Chambers,
Fateh Maidan Road, Basheerbagh, Hyderabad – 500 004

with a copy to:

Attention: Dr. Badri Narayan Patnaik, Head Clinical R&D
facsimile: +91 40 23234133

or in the case of the Institution to:

- Attention: Dr. M.V.Jali, Medical Director & CEO, KLE Dr. Prabhakar Kore Hospital & MRC, Belgavi-590010, Karnataka. Fax :+91-(0)831-2493099.

For the Principal Investigator

- Dr. S.M.Dhaded, Professor, Department of Pediatrics, KLEs J.N Medical College, Belagavi. -590010 India. Facsimile: +91-(0)831-2470759.

Any such notice shall be deemed to have been given and received when actually received. Either Party may change its address for service from time to time by notice given in accordance with the foregoing.

ARTICLE 17 - REPRESENTATION

17.1 Representations and Warranties by the Sponsor: The Sponsor represents and warrants to the Institution and the Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Institution and the Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) the Sponsor is an institution duly organized and validly existing under the laws of France; and

(b) the Sponsor has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of their obligations under this Agreement;

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(c) the Sponsor has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Sponsor;

(d) this Agreement has been duly authorized, executed and delivered by the Sponsor and constitutes a legal, valid and binding obligation of the Sponsor enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) the Sponsor shall hold harmless the Principal Investigator, the Institution, its employees and representatives against any and all liability arising out of any misrepresentation from its part.

17.2 Representations and Warranties by the Institution: The Institution represents and warrants to the Sponsor and Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Sponsor and Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) the Institution is a corporation duly incorporated and validly existing under the laws of Hyderabad, Telangana State / Lucknow, Uttar Pradesh, India.

(b) the Institution has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of its obligations under this Agreement;

(c) the Institution has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Institution ;

(d) this Agreement has been duly authorized, executed and delivered by the Institution and constitutes a legal, valid and binding obligation of the Institution enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) the Principal Investigator is an employee of the Institution.

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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

17.3 Representations by the Principal Investigator: The Principal Investigator represents to the Sponsor and the Institution, as of the signing date of the Agreement, and acknowledges that the Sponsor and the Institution are relying on such representations in entering into this Agreement, that Principal Investigator has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of his obligations under this Agreement.

ARTICLE 18 – ETHICAL CONDUCT

The Parties will conduct themselves and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business.

In particular, the Parties will not offer, promise or give any improper pecuniary or other advantage, whether directly or through intermediaries to a public official, for the benefit of that official or of a third party, for the purpose of influencing decision or actions with respect to the subject matter of this Agreement.

Failure to comply with the provisions of this Article 18 will be deemed a material breach of a material provision of this Agreement.

ARTICLE 19 - BENEFIT, ASSIGNMENT & TRANSFER

This Agreement shall benefit and be binding upon all of the Parties hereto, and their respective successors and assigns. This Agreement is concluded by the Sponsor intuitu personae. Hence the Agreement may not be assigned or transferred, whether directly or indirectly, by any Party without the prior written consent of the other Party, which consent may be reasonably withheld. However, the Sponsor shall be entitled to assign and transfer to one or more of its Affiliates this Agreement, without the prior written consent of the other Party, with notice thereafter to the other Party.

The Institution and the Principal Investigator shall not be allowed to subcontract totally or partially the obligations the Sponsor charged them with, without the prior written consent of the Sponsor. In this latter case, the Principal Investigator and the Institution shall be fully responsible for the part of the obligations so subcontracted and warrants to the Sponsor that such part of the obligations shall be rendered under conditions consistent in all respect with the terms and conditions set forth herein. For sake of clarity, such consent from the Sponsor will not relieve the Institution and the Principal Investigator from any liability or obligation under this Agreement and Institution and Principal Investigator will remain liable *vis-à-vis* the Sponsor for the acts, omissions, defaults or negligence of its sub-contractors.

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ARTICLE 20 - LAW

This Agreement shall be governed by and construed in accordance with the laws of the Republic of India, exclusive of its conflicts of laws principles. All and any dispute arising in connection with the interpretation or execution of this Agreement shall be settled by the competent courts of Hyderabad - India.

ARTICLE 21 - PUBLICITY

No Party shall use the name of any other Party (or the name of any of the Sponsor's divisions or Affiliates) for promotional purposes without the prior written consent of the Party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Clinical Trial, shall be made by the Institution or the Principal Investigator without the prior written approval of the Sponsor.

ARTICLE 22 - INDEPENDENT CONTRACTOR

Each Party acknowledges that it is an independent contractor. For greater certainty, the relationship between Sponsor, on the one hand, and Institution and Principal Investigator, on the other hand, shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party to do so.

ARTICLE 23 – COUNTERPARTS

This Agreement may be executed in one or more counterparts which, together, shall constitute one and the same Agreement.

ARTICLE 24 - AGREEMENT MODIFICATIONS

The provisions of this Agreement, may not be altered, amended or modified except by written agreement signed by both Parties.

The Parties acknowledge and agree that the schedule of the present clinical trial agreement may be subject to amendments and/or update and in such a case, the last-dated version approved in written by a representative of all Parties will be considered to be incorporated therein by reference in place of any prior versions.

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Dr. V.A.Kothiwale
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ARTICLE 25 - SEVERABILITY

If any term or condition of this Agreement (the deletion of which would not adversely affect the receipt of any material benefit by either Party hereunder) shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

ARTICLE 26 - NO WAIVER

Failure on the part of the Sponsor to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

ARTICLE 27 - FORCE MAJEURE

Noncompliance by any Party with the obligations of this Agreement due to force majeure, (laws or regulations of local government, war and/or civil commotion in the country of Clinical Trial's performance, destruction of facilities and materials necessary for the Clinical Trial's performance, fire and/or flood and/or earthquake and/or storm and/or shortage of materials and/or failure of public utilities or common carriers directly impacting the Clinical Trial's performance) shall not constitute breach of this Agreement and such Party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other Party in writing of such prevention and that it uses its best efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

ARTICLE 28 - CONSENT

Whenever a Party's consent or permission is required under this Agreement, such consent or permission shall not be unreasonably withheld, except as provided for in Article 19.

ARTICLE 29 - SUPERIORITY

In the event of any inconsistency between the body of this Agreement and any schedules thereto, the provisions of the body of the Agreement shall prevail.

ATTESTED

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

The Parties hereto have executed this Agreement as of the date written above in Section 13.

The SPONSOR

Signature: _____
Name : N.Rajasekar
Title: ED, CFO & Secretary
Date: 07th Jan, 2019

Signature: _____
Name : Dr. Badri Narayan Patnaik
Title: Sr. GM & Head, Clinical R&D
Date: 07/01/2019

Witness:

Signature: _____
Name: Mr. I. Sreenivasa Murthy
Date : 07-01-2019

The INSTITUTION

Signature: _____
Name: Dr. M.V.Jali,
Title: Medical Director & CEO
Date: 31/12/18

The PRINCIPAL INVESTIGATOR

Signature: _____
Name: Dr. S.M. Dhaded,
Title: Principal Investigator
Date: 5/12/18

Witness:

Signature: _____
Name : Maruti Patil
Date: 5/12/18

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SCHEDULE A

- FINANCIAL CONDITIONS -

1-Clinical Trial Costs:

For sake of clarity, the Parties hereby agree that:

(i) "Evaluable Subject" shall mean a Subject per Protocol for the primary endpoint of the Clinical Trial [optional: i.e. having performed ...].

(ii) "Estimated Budget" shall mean the estimated total amount of Rs. 2,861,875 (Twenty Eight Lakhs Sixty One Thousand Eight Hundred and Seventy Five only) to be paid by the Sponsor to the Institution, split as follows:-

* Clinical trial set up costs (fixed amount): 60,000

* Training and Development cost (estimated amount): 100,000

* Subjects costs (estimated total amount) based on the following : -

  - an assumption of Seventy (70) Subjects included by the Principal Investigator
  - an estimated amount of 15,300 per Subject split as follows:

  - Per subject cost: **Stage I:** (70 subjects)
  . Visit # 1: 3000 rupees
  . Visit # 2: 2500 rupees
  . Visit # 3: 2500 rupees
  . Visit # 4: 3000 rupees

  - Per subject cost: **Stage II:** (70 subjects)
  . Visit # 5: 2150 rupees
  . Visit # 6: 2150 rupees

- Travel cost for subjects per visit : Rupees Five Hundred (Rs. 500)
- Institution overhead charges 25% : Rs 572,375

(iii) "Actual Budget" shall mean the real amount to be paid by the Sponsor to the Institution, i.e. the Estimated Budget reviewed according to actual (i) number of Subjects and visits per

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Subject performed, (ii) associated work per Subject carried out, and (iii) activities performed and related costs.

(iv) "Contracted Currency" shall mean the used for invoice's and payment's purpose.

(v) "Domestic Currency" shall mean the used for the purpose of the calculation of the above-mentioned Clinical Trial Costs.

(vi) "Exchange Parity" shall mean the conversion rate between Domestic Currency and Contracted Currency used when agreeing on the above-mentioned Clinical Trial Costs and calculated as follows:

2- Payments:

Payments by the Sponsor to the Institution shall be made as follows:

- Upon signing of the Agreement by both parties and after receipt of Shantha Biotechnics Private Limited Purchase Order number:10.% of Estimated Budget, corresponding to the Clinical trial set up costs.

- First Subject enrolled in Visit 1 at the Trial Site: 10% of Estimated Budget.

- Last Subject enrolled in Visit 1 at the Trial Site: 40% of Actual Budget (minus the 20% of the Estimated Budget already paid).

- Last Visit Last Subject: 20% of the Actual Budget.

- Database clean: 20% of Actual Budget.End of statistical analysis and in no case no later than 3 months after date base clean: the balance of the Actual Budget However, if less than 20 % of the Subjects enrolled are considered as Evaluable Subjects, the balance will not be paid to the Institution.

Institutional Charges of Rs.572,375/- will be paid directly to Institution in three installments to Director & Chief Executive, KLE Dr. Prabhakar Kore Hospital & MRC, Belagavi,

However, if less than 50% of the subjects enrolled is considered as Evaluable Subjects, the balance will not be paid to the Institution.

- Payment terms:

3.1- Invoices must be issued to the Sponsor in accordance with the payment schedule defined in above section 2

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3.2- Payments of any and all amounts due by the Sponsor will be made only upon receipt of the proper and detailed corresponding original invoices by the Institution (Sponsor's payment terms: 60 days from invoice's date), in the Contracted Currency by bank transfer to the following bank account opened in the country in which the Institution is located.

Account N°:	05042010003575,
Bank:	Syndicate Bank
Bank address:	Nehru Nagar, Belagavi
Branch code : :	000504
IFSC Code	: SYNB0000504
MICR Code	: 590025005
Beneficiary	: Dr. S.M.Dhaded
Institution	: KLE University's J.N Medical College.

Institution overhead charges (25%) will be paid as per the budget to the Institution as per the following bank a/c details;

Account N°	: 05042010031362
Bank	: Syndicate Bank,
Bank address	: Nehru Nagar, Belagavi.
Branch code	: 000504,
IFSC Code	: SYNB0000504
MICR Code	: **590025005**
PAN	: AAATK2644N
GST	: 29AAATK2644N6Z3
Beneficiary	: KLE Dr. Prabhakar Kore Hospital & MRC, Belgavi
Institution :	.KLE Dr. Prabhakar Kore Hospital & MRC, Belgavi

3.3- To be paid, any invoice must be approved in advance by P.Satyanarayana, Clinical Project Manager- Clinical Development

An electronic draft of any invoice in a .pdf format must thus be sent in advance for review and validation by email to

To: P.Satyanarayana
Email: Satyanarayana.Peesapati@sanofi.com;
Subject: Invoice

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Registrar
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3.4- Once validated in accordance with above section 3.3, the original paper version of the invoice shall be addressed to the Sponsor to the following address:

To: Shantha Biotechnics Private Limited
At: Clinical R&D Department
ADDRESS: 4th Floor, Vasantha Chambers, Fateh Maidan Road,
Basheerbagh, Hyderabad – 500 004, Telangana State, India.

3.5- To be paid the original invoice must reference the following:

- Complete Institution's Name, Address and Phone Number
- Invoice date
- Invoice number
- Shantha Biotechnics Private Limited Purchase Order Number to be communicated later on by the Sponsor
- Payment amount and currency
- Payment term /due date
- Shantha Biotechnics Private Limited contact name: P. Satyanarayana, Mob: +91-9704770731.
- Complete description of service rendered with reference to the agreement's article
- Method of payment (Wire)
- Wiring instructions, including bank name, address, account number
- Intracommunity VAT number if applicable [For European third party in European countries only]

Shantha Biotechnics Private Limited may reserve the right to send back to the Institution any invoice that would not mention any and all of the above-mentioned references.

In any case, penalties that may be due in case of breach by the Sponsor of the payment terms specified in the first paragraph of this section will be limited to 3 times the Indian Legal rate of interest.

4- Miscellaneous:

4.1-Each Party will bear its own costs (legal, tax, accounting and other fees) incurred with the drawing up and execution of the Agreement.

4.2-If relevant, the Institution shall be liable to pay any and all amounts to others involved in the Clinical Trial, and especially the Additional Personnel.

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5-Taxes:

Any amount due by the Sponsor shall be considered as inclusive of any and all applicable taxes, costs and/or charges (and any penalties thereon) that may be imposed by any governmental authority (hereinafter the "Taxe(s)"). The Parties further agree that if the Sponsor is legally required to pay any withholding tax in its country of residence such amount shall be deducted from the amount of money to be received by the Institution.

The Sponsor shall provide the Institution with any relevant blank forms and other documents as well as other assistance required by the tax authorities in order for the Institution to (i) attest its fiscal residence and (ii) obtain the application of the reduced withholding tax rate or the exemption of the withholding tax, according to the relevant bilateral convention for the prevention of double taxation.

At the request of the Institution, Sponsor shall forward to the Institution such relevant application forms and other documents for fulfillment.

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SCHEDULE B

- BUDGET -

Cost Head	Per Unit Cost	Units	No of units	No of Personnel	Total (INR)
Site Personnel Fees (Fixed Cost)					
Sub-PI	25,000	Month	12	1	300,000
Study Coordinator	10,000	Month	12	2	240,000
Field Staff	5,000	Month	12	2	120,000
Study Nurse	4,500	Month	10	1	45,000
Total Site Personal Fees					**705,000**
Per subject cost: Stage I:	**11,000**		As per Actuals		
Visit 1	3,000				
Visit 2	2,500				
Visit 3	2,500				
Visit 4	3,000		70		770,000
			As per Actuals		
Per subject cost: Stage II	**4300**				
Visit 5	2,150				
Visit 6	2,150		70		301,000
Subject Travel cost for Stage I	500	OPD	4	70	140,000
Subject Travel Cost for Stage II	500	OPD	2	70	70,000
Sub Total A (Subject Cost+ Travel Cost+ Site Personnel fees)					**1,986,000**
Administrative cost (Fixed cost)					
EC committee charges (Rs.75,000 + 18% GST)	88,500	No	1		88,500
EC fees for amendment submission	20,000	No	1		20,000
Xerox, Couriers, Internet, Phone and Miscellaneous	2,500	Month	14		35,000
Sub Total B (EC committee charges + Xerox, Couriers, Internet, Phone and Miscellaneous)					143,500
Training and Development Cost					100,000
Site setup Cost					60,000
Institutional overhead charges (25%)					572,375
Total (Estimated Budget)					**2,861,875**

Note 1. 10 % will be deducted as TDS 2. Taxes as applicable.

The Actual Budget will be calculated based on the actual (i) number of Subjects and visits per Subject performed, (ii) associated Work per Subject carried out. and (iii) activities performed and related costs as defined under Clause 1 (iii) of Schedule 1 (Financial Conditions).

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SCHEDULE C

- "Information Systems Usage Charter" -

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- Theft (copyright infringement) of information, and software
- Data disclosure from sanofi-aventis Group assets or concerning the company
- Users spoofing in order to hijack or send messages, or use Information Systems of sanofi-aventis Group without prior authorization
- Denial of service of Information Systems of the company due to by computer virus infections of servers and workstations, or a deliberate attack aiming to overload our internal network to incapacitate servers
- Diffuse or reproduce information protected by copyright
- Frauds or embezzlement
- Unethical use of electronic means of communications for the detriment of sanofi-aventis Group activities, resulting in a negative company image to the external world

Company protection strategy

To face the increase in risks that challenges information systems, sanofi-aventis Group had to put an adequate security organization in place.

The purpose of this security organization is to allow us to create a "**Space of Trust**", which means a standard set of information systems and telecommunication where data protection is effective.

This strategy relies on Information Systems security rules and specific Information Systems security policies (Email, Internet, etc.) describing procedures, means and usage rules.

These documents are available on the Intranet site IS@ (Heading: Information Systems/IS Security) and it is highly recommended that each user review this information.

Monitoring connections

Protecting the company interests against potential threats to its information systems requires the implementation of a security architecture (secure routers, firewalls, intrusion detection tools, anti-virus servers, encryption software, etc.).

This security architecture specifically makes it possible to identify and authenticate every user accessing the company's information systems.

In addition, for legal and security requirements, it must be possible at all times to audit any operation conducted by any user of the company's information systems.

These operations, which are tracked and archived by security equipment, may include the following information:

- User's identity
- Communication dates and times
- Sites visited and applications used
- Details of requests made
- Sizes of messages or volume transferred
- Subject of messages
- Duration of connections

The retention period of the various elements used to track a workstation's activity, depending on the type of operation, can be up to one year.

The information on each user is kept in the system's activity logs. This information is covered in a company statement to the applicable authorities, to maintain compliance with the various laws regarding the protection of nominative information.

In the event of a security incident, the confidentiality of private correspondences cannot be maintained or guaranteed due to research that may be required for local legislations. Therefore

the principle of secrecy of private mail may not be applicable and the actual body of messages as well as attachments can be subject to inspection.

Users' rules of behaviour

A. General rules

1. Respect for the sanofi-aventis Group Information Systems Security Policy

Use of the company Information Systems implies familiarity with the various documents comprising sanofi-aventis Group Information Systems Security Policy and respect for its rules. These documents are available on the Intranet IS@ (Heading: Information Systems/IS Security) site.

- *It is mandatory for all users to consult the documents in the company Information Systems Security Policy and respect its rules.*

2. Use of Information systems

The company makes hardware, software and tools available to users whose positions require them to have access to the company Information Systems in order to fulfill their missions. Any use of these computer facilities for unlawful purposes will incur the user's personal liability.

- *In principle, the computer facilities made available to users are reserved for professional use.*

3. Personal use

However, personal use of the company's information and communication systems can be tolerated provided that such use:

- *Is not contrary to public order or public morals*
- *In no case harms the company's interests or reputation*
- *Is confined to very moderate frequency and duration*
- *Scrupulously respects the security and safety rules stipulated above*
- *Does not affect normal traffic of business messages*

4. Reporting a security incident

It is mandatory that any security incident concerning the company's Information Systems be promptly reported to the Information Systems security function.

5. Protection of sanofi-aventis Group image

It is crucial that all users be aware of the fact that every Internet site keeps track of every visit. Information on the user's workstation, his preferences and above all, his domain name, i.e. the company's name, are kept in memory on the Internet servers visited.

- *As visits to Internet sites from the company's internal network show the name of sanofi-aventis Group, all users must take care not to visit sites whose content could harm the company image*
- *This principle is also applicable to email, Forums, blogs or any other forms of data exchange or data storage on the Internet*

6. Respect for national legislations

In addition to the specific rules listed above, users must also scrupulously respect the general rules regarding the violation of:

- *Personal rights stemming from the use of computer files and processing*
- *Confidentiality of telephone conversations and mail*
- *Privacy, personal representation and*
- *Human dignity, specifically information or messages which:*
  - *Question a person's honor or reputation*
  - *Are discriminatory or incite racial hate*

Similarly, legislation protecting the following must be closely respected:

- *Automated data processing systems*
- *Intellectual and artistic property, specifically copyright and neighbors' right;*
- *Patents*
- *Trademarks and other distinctive marks*
- *More generally, production secrets, trade secrets, and even national defense secrets*

B. Rules relating to the protection of workstations

7. Daily shutting down of the workstation

Workstations that are inactive outside of work hours must be switched off. Primarily, this measure helps prevent electrical incidents and the propagation of computer viruses. Moreover, switching on workstations at the start of the day facilitates the implementation of technical updates, which are generally prepared during the night.

- *Each user must switch off his/her workstation at the end of the day if there is no requirement to function outside of normal working hours*

8. Manual activation of the screen saver

To prevent any fraudulent use of a workstation or the data it contains, access to the workstation must be protected during the user's absence. Intentional activation of the screen saver makes it possible to lock access to the workstation.

- *Each user must lock access to his/her workstation whenever it is left unattended*

9. Backing up users' data

Data can be lost following a power outage or an accident, or as a result of an operating error or even a malevolent act. The Information Systems function makes servers available to users for storing their data.

- *Each user must take care to store his/her data on servers as specified by the Information Systems function.*

10. Prevention of laptop thefts

Given the potential significant damage that could result from the loss or theft of a laptop, it is crucial that their users strictly apply basic antitheft protection and safety measures.

- *Outside of work hours, all laptops must be stored in a locked cabinet*
- *During work hours, a suitable security cable delivered with the equipment must secure every laptop*
- *When traveling, it is mandatory that users keep their laptops with them or store them in a secure location*

11. Use of external electronic or magnetic media

External electronic or magnetic media used to store data require special vigilance. Since these media can be easily misplaced or stolen, it is crucial that any sensitive data they contain be protected.

- *It is mandatory that any sensitive data copied onto external media must be protected with the tools validated by the Information Systems function*

12. Encrypting data

For the company, information of an industrial, financial, commercial or contractual nature, data stemming from research or development, and data on employees represent assets that must be protected.

- *The encryption tools made available by the Information Systems function must be used whenever the confidentiality of information must be protected*

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13. Software Installation

The protection of the user's workstation against computer viruses and respect for copyright is achieved primarily through compliance of this workstation with the applications and software indicated by the Information Systems function.

- *Only authorized persons in the Information Systems function may install software on a workstation*
-

C. Rules relating to network access

14. Authentication of Information System access

Access to the company Information Systems requires the use of unique identifiers and personal passwords. Accordingly, unless proven otherwise, any connections made using these elements will be presumed to have been made by their holders.

- *To access Information Systems, users must use only the access identifiers given to them by administrators, and must keep passwords secret*

15. Accessing sanofi-aventis internal networks

Access points to the company internal networks, indicated and secured by the Information Systems function, guarantee that the company communications and data are secure and protected.

- *Communication with the company internal networks may only be done through the access points indicated and secured by the Information Systems function*

16. Accessing networks outside sanofi-aventis Group

Access points to networks outside the company, indicated and secured by the Information Systems function, guarantee that the company's communications and data are secure and protected.

- *Communication with networks outside the company may only be done through the access points indicated and secured by the Information Systems function*

D. Rules relating to using communication systems

17. Transferring large files on Internet

The use of Internet services, such as visiting sites, e-mail or file transfer must not have a significant effect on the availability of the computer network for other users. If required by performance conditions or security, the Internet connection may be cut without notice until the situation returns to normal.

- *Any transfer of large files (over 100 Mb) requires prior authorization from the appropriate management in the Information Systems function*

18. Monitoring messages from the Internet

Since there is no authentication of Internet e-mail, the sender's identity or the content of the message could be modified or contain computer viruses. Close attention must, therefore, be given to the authenticity of messages received.

- *Do not open Internet messages or attached files when these files are unsolicited or without any professional subject*

19. Monitoring messages sent over the Internet

The use of e-mail requires close attention when selecting e-mail recipients. A routing error to a recipient outside the company can, in some cases, prove prejudicial to the company.

- *Since users are responsible for the e-mails they send, it is crucial that they check to ensure that they are sending them to the correct address(es).*

20. Sending sensitive information over the Internet

The company's position in an increasingly competitive global market requires that everyone exercise strict control over information they send over the Internet.

- *Any discussion or publication over the Internet of company data and information is submitted beforehand to the appropriate level of management for approval*
- *Never fill out Internet questionnaires, as they could possibly be in support of a competitive watch that is targeting the company.*

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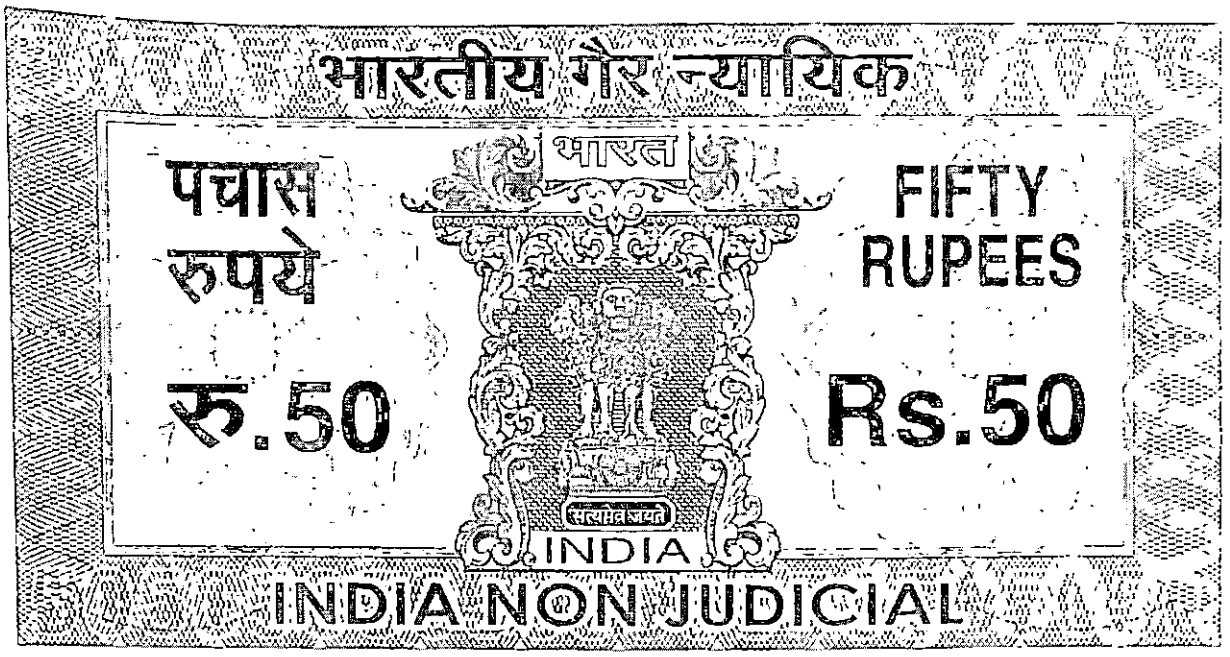

తెలంగాణ तेलंगाना TELANGANA

G 062116

S.No.17002 Date:10-05-2019
Sold to: M.Pandu Ranga Reddy
S/o Late M.Seetha Ram Reddy R/o Hyd
For Whom: M/s.BIOLOGICAL E. LIMITED, HYD

E.VENKATESH
LICENSED STAMP VENDOR
L.No.16-07-008/10,RL.NO.16-07-03/2019
5-3-856/17, G-17, NANDINI COMPLEX,
M.J.MARKET, HYD-12 PH:9866313526

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on 22nd day of May, 2019 ("**Effective Date**") by and between **Biological E. Limited,** a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/1&3, Azamabad Hyderabad 500020, Telangana, India ("**Sponsor**"), of the First Part; and **Dr. N.S.Mahantshetti**, a registered medical practitioner holding MCI registration number **22164,** currently working as Professor in Department ofPediatrics ,KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum("**Principal Investigator**")of the Second Part; and **KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum,**a hospital established registered under the laws of India, having its place of business and **KLES JNMC Dr Prabhakar Kore Hospital & Medical Research Centre,** a hospital established registered under the laws of India, having its place of business at Nehru Nagar, Belgaum 590010, Karnataka represented by its Medical Director, ("**Institution**") Third Part

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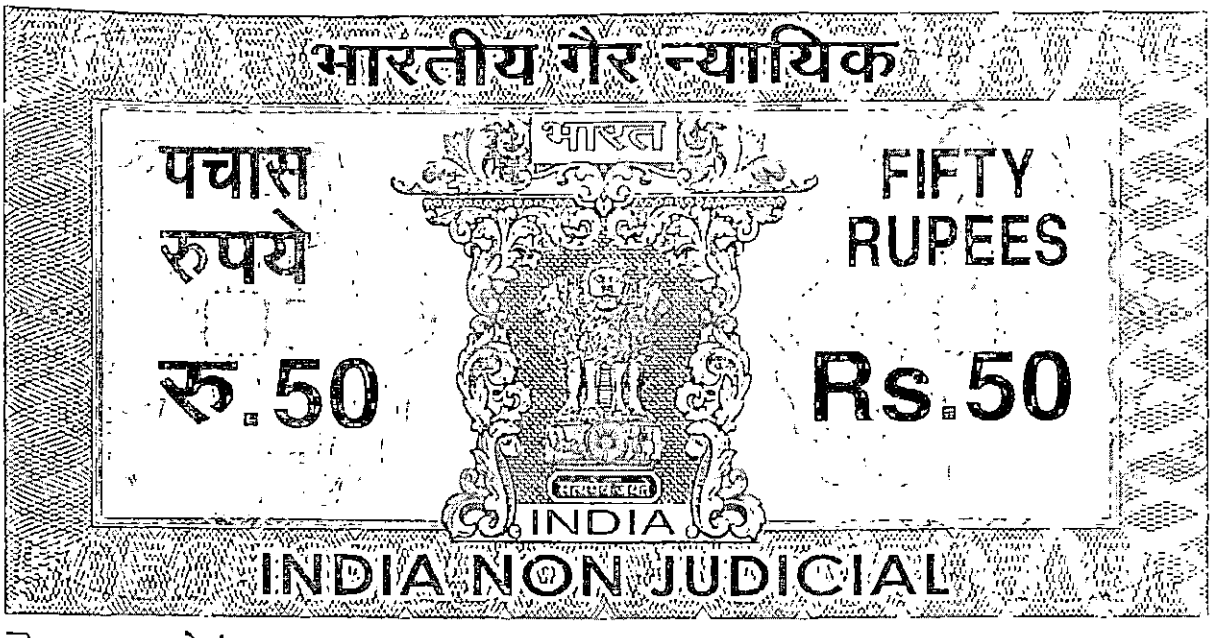

తెలంగాణ तेलंगाना TELANGANA

G 062115

S.No.17001 Date:10-05-2019
Sold to: M.Pandu Ranga Reddy
S/o Late M.Seetha Ram Reddy R/o Hyd
For Whom: M/s.BIOLOGICAL E. LIMITED, HYD

E.VENKATESH
LICENSED STAMP VENDOR
L.No.16-07-008/10,RL.NO.16-07-03/2019
5-3-856/17, G-17, NANDINI COMPLEX,
M.J.MARKET, HYD-12 PH:9866313526

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited is planning to develop Hepatitis A vaccine (Adsorbed) product and is desirous of testing the same in humans through a phase III Clinical Trial to be conducted in ten study centers;

B. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

C. The Sponsor has already identified the Principal Investigator based on her experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

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D. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed his willingness to the Sponsor to conduct the proposed Study;

E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and

F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. **Definitions**

1.1 **"Study" or "Clinical Trial"** shall mean study entitled:

"A single blind, parallel, randomised Phase-III comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-naïve children"and all the title amendments thereto as the Parties may from time to time agree in writing.

1.2 **"Protocol"** shall mean:

The description of the Study mentioned in the Study protocol number **BECT045/HepA-phase-III/CTP-02**and all amendments thereto as the Parties may from time to time agree in writing.

1.3 **"Study Drug" or "Investigational Drug"** shall mean:

Inactivated Hepatitis A Vaccine (Adsorbed)(Manufactured by Biological E. Ltd.).

1.4 **"Ethics Committee"** shall mean:

An independent bodyor an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

2. **Responsibility of the Principal Investigator and the Institution**

2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Pediatrics in the Institution, to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good

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Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research (**"Applicable Laws& Guidelines"**); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and

(iii) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.

2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.

2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.

2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be

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made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. Conduct of Clinical Trial

3.1 The Sponsor shall appoint it's employee to monitor the Clinical Trial and also reserves it's right to nominate any other person as monitor.

3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.

3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.

3.4 Principal Investigator shall ensure that the Audio Visual recording of the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain audio visual informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio-visual recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the Sponsor, Principal Investigator shall handover a copy of such recording for regulatory compliance or any order.

3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

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3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.

3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. Study Drug

4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.

4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. Visit and Inspection

5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;

ii. inspect and copy all data and work products relating to the Study, and

iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. Payment

6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement,

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Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.

6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.

6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. <u>Indemnification and Insurance</u>

7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug <u>except</u> to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

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a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "Claims") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

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8. **Publication of Results**

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. **Publicity and Product Promoting Activity**

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. **Confidentiality**

10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form ("**Confidential Information**").

10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and

(ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.

10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein.

ATTESTED

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

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Principal Investigator and the Institution shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

(a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;

(b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;

(c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

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11. Severability & Waiver and Assignment

11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.

11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. Validity & Termination

12.1 This Agreement shall become effective on the date first set forth above and shall continue for a period of 1 year thereof or until this Agreement is terminated due to:-

a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the Sponsor that business or scientific considerations require termination;

d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;

e. At the request of either DCGIor Ethics Committee;

f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;

g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;

12.2 The Sponsor may terminate this Agreement:

a) At any time upon thirty (30) days written notice to the Principal Investigator /Institution.

b) Immediately for safety reasons relating to the use of the Study Drug.

12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

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13. **Effect of Termination**

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. **Miscellaneous**

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses:-

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India

(ii) **To Principal Investigator:** Dr. NS Mahantshetti
Title: Professor
Address: KLEs JNMC Prabhakar Kore Hospital,
Belgaum
Telephone No.: 0674 2304400
Mobile: +91-8312477201
Fax No: +0674 2725228
Email id: niranjanakle@gmail.com

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(iii) **To Institution:** Dr. M. V. Jali
Title: Medical Director
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar,
Belgaum 590010, Karnataka
Telephone No.: 0831 - 2473777
Email: drmvjali@gmail.com

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	Principal Investigator	For and on behalf of Institution
Signature & Date	1/6/19 Signature & Date	Signature & Date
Name: Mr. Sultan Baig Title: Vice President- Finance	Name: Dr N S Mahantshetti Title: Professor	Name: Dr M.V. Jali Title: Medical Director
Seal:	Seal: Dr. N. S. Mahantashetti Professor Consultant Pediatrics KMC Reg. No. 22164 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.	Seal: Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI
Witness: 1. N.Eswara Reddy 2.	Witness: 1. Vishal Jakati 2.	Witness: 1. Ravana S Devanur 2.

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Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

BEGT045-HepA-PHASE-III STUDY BUDGET	
Cost Description	**Amount (INR)**
Investigator, co-investigator & study team fee(INR.16,000 per Subject x 52 subjects)	8,32,000
Study coordinator fee(INR.9,000 per month x 12 months)	1,08,000
Subject travel conveyance (Rs. 500 per subject x 4 visits x 52 subjects)	1,04,000
Audio Visual Consenting & Logistics	50,000
Study documents archival fee (for 15 years)	60,000
Sub Total	11,54,000
Institutional Overheads (25% on Investigator fees)	2,08,000
Total	13,62,000

Total Cost (in Words): Thirteen Lakhs sixty two thousand rupees only. (GST 18% extra as applicable by government laws, wherever applicable)
Budget Note:

- No charges will be paid for screen failure subjects
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	% of Total Cost
1	On Site Initiation	25%
2	On completion of 100% Subject Recruitment	25%
3	After Last Patient/subject Last Visit/Completion of all Data Query Resolutions and Database Lock	25%
4	After Site Close-out	25%

Based on the total agreed amount of Rs. 13,62,000/- for enrolling 52 subjects, the per subject cost would be Rs. 18,000/-(Investigator, co-investigator & study team fee + Subject travel conveyance).

All payments would be made based on actual number of subject's enrolled at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of:

- Payee Name: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- Bank Account Number: 910020034162231, IFSC code: UTIB0000048
- GST Registration Number: 27AADCG0363Q1ZA
- PAN of Payee: AADCG0363Q

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA48869020836090R
Certificate Issued Date	:	11-Feb-2019 02:48 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM3/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0830859957389302R
Purchased by	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Second Party	:	DR NIRANJANA S MAHANTSHETTI
Stamp Duty Paid By	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Shree Siddhivinayak Banjara
Multi Purpose Co-Op Society Ltd.
K. T. Patil Building Court Compound BGV

Authorised Signatory

Please write or type below this line

CLINICAL TRIAL SERVICE AGREEMENT

THIS CLINICAL TRIAL SERVICE AGREEMENT (hereinafter referred to as the "Agreement"), effective from the date of last signature (hereinafter referred to as the "Effective Date"), is entered into by and between,

Statutory Alert

1. The authenticity of this Stamp Certificate should be verified at 'www.shcilestamp.com'. Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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CMS Clinical Research Pvt. Ltd, an entity incorporated under the Newbridge Business Centre, 1st Floor, Inox Tower-B, Plot No. 17, Sector-16A, Film city, Noida, Uttar Pradesh 201301 (hereinafter referred to as "**CRO**" and which expression shall unless it is repugnant to this context or meaning thereof be deemed to include its successors, and permitted assigns) of the FIRST PART;

AND

and **KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010** for the project **BBIL/ROTAVAC 5CM/IV/2018.**

AND

and **Dr. Niranjana. S. Mahantashetti,** a qualified medical practitioner with registration number 22164 employed with KLE's Dr. Prabhakar kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India -("**Principal Investigator**"),

WHEREAS, Sponsor Bharat Biotech is a leading Biotechnology company involved in the research & development, clinical development and manufacturing of vaccines and bio-pharmaceuticals, and has considerable technology, trade secret, know-how and research experience in relation to the manufacturing and commercial production of vaccines and bio-therapeutics and has also established its marketing and distribution network for such product(s) in India as well as abroad;

Bharat Biotech has outsourced CRO all clinical trial and site management activities.

WHEREAS, CRO is engaged in the business of providing clinical trial project management, data management and bio-statistical services for the Pharmaceutical and Biotechnology industries;

WHEREAS, the CRO has engaged Dr. Niranjana .S. Mahantshetti situated at KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, belagavi-590010 ("**Site**") for conducting Clinical Trial of its **BBIL/ROTAVAC/III/2018** vaccine product under the title "**A Phase 3, Multicenter, A PHASE 3, MULTICENTER, OPEN-LABEL, RANDOMIZED CLINICAL TRIAL TO EVALUATE SAFETY AND IMMUNOGENICITY OF ROTAVAC® -20℃ AND ROTAVAC 5CM ADMINISTERED AT BIRTH (NEONATAL SCHEDULE) AND ADDITIONAL DOSE VERSUS INFANT SCHEDULE AGAINST ROTAVIRUS GASTROENTERITIS".** (hereinafter referred to as the "**Clinical Trial**"), and any amendments thereto;

WHEREAS, Sponsor requires services relating to site management & clinical research co-ordination activities generated in course of the Clinical Trial and wishes to outsource such services to CRO and requires it to perform services related to site management & administration support for the conduct of the Clinical Trial with the help of their clinical research coordinator, the Site or any person engaged for the sole purpose of the coordination of the Clinical Trial by the CRO.

WHEREAS, Sponsor desires to engage the CRO, and the CRO agrees for managing the

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investigational site according to the rules and regulations in full compliance of the ICH GCP guidelines and applicable regulatory authorities as specified in Clinical Trial Protocol(s);

NOW, THEREFORE, in consideration of the terms and conditions set forth herein, the parties agree as follows:

1. DEFINITIONS

The following words and phrases as used in this Agreement shall have the following meanings:

1.1 "Protocol" means document(s) that describes the objective(s), design, methodology, statistical considerations, and organization of the Clinical Trial including the document(s) contains a study plan, on which the Clinical Trial is based.

1.2 "Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation Subject administered the Study Drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended reaction (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Study Drug.

1.3 "Auditor" means a person being a representative of the Sponsor who is authorised to carry out a systematic review and independent examination of Clinical Trial and/or related activities and documents to determine whether the evaluated Clinical Trial and/or related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the Sponsor's Standard Operating Procedures (SOPs), ICH GCP and the applicable regulatory requirements.

1.4 "Clinical Trial" means an investigation to be conducted at a Trial site in accordance to an approved Protocol, as defined above.

1.5 "Co-investigator" means any individual member of the Clinical Trial team designated to assist and act on behalf of the Principal Investigator who is supervised by the Principal Investigator at the Trial site to perform trial-related critical procedures.

1.6 "GCP" (Good Clinical Practice) shall mean the regulations and guidelines established by the International Conference on Harmonization (ICH) and the specific regulating authorities of countries and economic affiliations worldwide that set the standards of good clinical practice for the Clinical Trials.

1.7 "GLP" (Good Laboratory Practice) shall mean the procedures for the conduct of non-clinical laboratory studies on a drug substance or medical device that assure the quality and integrity of safety data, which are generated for products regulated by the regulatory agencies to support an application for research or a marketing permit as the case may be.

1.8 "Informed Consent" shall mean consent obtained from a Subject that complies with guidelines established by the Declaration of Helsinki, International Conference of Harmonisation (ICH), and all the applicable laws, guidelines, and/or standards governing the participation of Subjects in trials.

1.9 "Confidential Information" means any and all information, data and material of any nature belonging to the Sponsor and/or its Affiliates which CRO may receive or obtain in connection with this Agreement, the release of which is likely to prejudice the commercial interest(s) of the Sponsor and/or the CRO respectively,

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Dr. V.A.Kothiwale
Registrar
Education and Research,

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or which is a trade secret, including Know-How. The term 'Confidential Information' also includes Protected Health Information which relates to any patient/Subject in a Clinical Trial or his/her treatment or medical history, or other information. Confidential Information does not include information:

(I) That is in the public domain at the time of its disclosure to CRO;

(II) Information that was evidenced by written records or other competent proof, in the CRO and/or Investigator's possession prior to this Agreement, without obligations of confidentiality (excluding study data); or

(III) that is in the public domain as a result of a third party's activity(s), through no act or omission of the Investigator, the CRO or any Study Personnel.

1.10 "Intellectual Property Rights" means patents, trademarks, trade names, service marks, domain names, copyrights, trade-secret, know-how, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered/granted and shall include applications for registration of any of them and shall also include those for which application for registration has not been applied.

1.11 "Know How" means all technical and other information, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protection/registration is granted or applied for, or whether or not protectable by any form of Intellectual Property Rights.

1.12 "Party" means either the Sponsor or the CRO, and except where otherwise provided "Parties" shall mean both of them.

1.13 "Inspector" means a person, acting on behalf of a Regulatory Authority, who conducts an official review of documents, facilities, records and any other resources that are deemed by the Regulatory Authority to be related to the Clinical Trial and that may be located at the Trial site.

1.14 Disclosing Party - For the purposes of this Agreement the Party disclosing the confidential information will be referred to as the "Disclosing Party"

1.15 Receiving Party - For the purposes of this Agreement the Party receiving the confidential information will be referred to as the "Receiving Party"

1.16 Regulatory Agency(s) - "Regulatory Agency(s)" shall mean any and all agencies/authorities of any country with jurisdiction to regulate, audit or otherwise review the research process, administration or facilities used in the conduct of the study and/or its result(s) under this Agreement.

1.17 Third Parties - "Third Parties" shall mean any person/s, other than the Sponsor, CRO, Principal Investigator or Subjects, and shall include a party performing paid-functions in connection with the study under this Agreement and requiring separate contractual agreements.

1.18 "Investigator(s)" shall mean the physicians primarily responsible for the conduct

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of the study at the Trial site(s), and shall include "Sub-Investigators" and "Co-investigators".

1.19 "Monitor" shall mean one or more person appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

1.20 "Principal Investigator" shall mean the person who has been mutually agreed upon by the Parties and who will lead and co-ordinate the work of the Clinical Trial at the Trial site(s) on behalf of the CRO or any other person as may be mutually agreed from time to time between the Parties as a replacement for the purpose of this Agreement.

1.21 "Trial site(s)" means any premises in which the Clinical Trial is being or will be conducted.

1.22 Serious Adverse Event (SAE)" shall mean only any untoward medical condition that occurs at any dose:

a. Results in death,
b. Is Life-threatening,
c. Requires inpatient hospitalization or prolongation of existing hospitalization,
d. Results in persistent or significant disability/incapacity, or
e. Is a congenital anomaly/birth defect.

1.23 "Study Drug" shall mean any drug(s) administered to Subjects pursuant to the Protocol.

1.24 "Study Personnel" means any person involved in or with the study team who is involved in conducting the study at the Trial site(s).

1.25 "Subject/s" means an individual, whether a patient or not, who participates in the Clinical Trial as a recipient of Investigational Medicinal Product.

1.26 Sub-Investigator means any individual member of the Clinical Trial team designated and supervised by the Principal Investigator and the Co-investigator at the Trial site(s) to perform trial-related critical procedures.

1.27 Institution (medical): Any public or private entity or agency or medical or dental facility where Clinical Trial(s) are conducted.

2.0 SERVICES AND OBLIGATIONS

2.1.Master Agreement

2.1.1 This Agreement is intended by the Parties to be an "umbrella" document which allows the CRO to manage one or more site(s) to conduct the Clinical Trial study without having to re-negotiate the basic terms and conditions contained herein.

2.1.2 Sponsor requires services relating to site management & clinical research coordination activities generated in course of its business and wishes to outsource such services to CRO and CRO desires to be hired to perform such services regarding the site management & administration support for the conduct of the Clinical Trial under this Agreement.

2.2. Conduct of Study

2.2.1 CRO represents that it has a written agreement in place with the Principal Investigator and the Site, which shall be in line of this Agreement, and detailing

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the modalities, roles, responsibilities and liabilities for the purpose of the conduct of the Clinical Trial as mentioned in this Agreement.

2.2.2 CRO represents and warrants that it has necessary expertise to perform its obligations under this agreement. The CRO shall be wholly responsible for any and all of its own acts and/or omissions and also by its representatives and the study coordinator under this Agreement.

2.2.3 CRO shall notify the Sponsor if the Principal Investigator or the Site ceases to be associated with the CRO at the earliest possible instance. If the dissociation is not resolved then pursuant to clause 9.2 of this Agreement the Sponsor may terminate this Agreement.

2.2.4 CRO hereby agree to conduct the study in accordance with this Agreement and the Protocol. CRO shall also follow, and shall ensure that the Study Personnel (defined in clause 2.2.5 of this Agreement) strictly comply with the Sponsor's study protocol, applicable regulations and guidelines pertaining to clinical trial.

2.2.5 CRO shall ensure that all individuals and entities that perform any portion of the study under the Investigator's supervision (all such individuals hereinafter referred to as the "**Study Personnel**") and conduct the study in accordance with the Protocol and the terms and conditions defined in this Agreement. Further, CRO shall ensure that all Study Personnel are trained in the Protocol and GCP.

2.2.6 CRO undertakes the responsibility and ensures the followings:

a. That the CRO is and remains free to participate in the Clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict the performance of the obligations detailed in this Agreement.

b. That the CRO is not involved in any regulatory or misconduct litigation, enquiry or investigation by CDSCO or any other regulatory authority(s). No data produced by the CRO in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

c. That the CRO has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available at the Trial site and ensure the continued support by medical and other staff of sufficient number and experience to enable the CRO to perform the site management efficiently and in accordance with its obligations under the Agreement.

d. That the CRO shall ensure obtaining and maintaining all approvals from the relevant Institutional Ethics Committee for the conduct of the Clinical Trial and shall keep the Sponsor fully apprised of the progress of Ethics Committee submissions and shall upon request provide the Sponsor with all correspondence relating to such submissions. The CRO shall not consent to any change in the Study Protocol requested by a relevant Ethics Committee without the prior written consent of the Sponsor.

e. That the CRO is solely responsible for obtaining and maintaining valid licenses, approvals, and other authorizations from the competent authorities, as may be required by the CRO for the conduct of the Clinical Trial under this Agreement, as per the applicable laws in India, including without limitation,

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intimation to State Biodiversity Board(s) for obtaining biological resources under the provisions of the Biological Diversity Act, 2002. Provided that any application under the Biological Diversity Act, 2002 may be submitted by the Sponsor directly. However, the CRO shall intimate the Sponsor and cooperate with the Sponsor and furnish all such information as may be necessary to obtain any biological sample. CRO shall immediately submit a copy of all such licenses, approvals, intimations and other authorizations, as required hereunder this clause, to the Sponsor.

f. CRO shall not obtain any biological sample without prior intimation to the Sponsor, and shall not proceed for obtaining any biological sample unless the Sponsor has confirmed to obtain any such biological samples to the CRO.

2.2.7 CRO shall further ensure that:

a. The Principal Investigator shall be responsible for the recruitment of subjects and performance of the Study in accordance with the agreed upon timelines and the Protocol, as well as for the completeness and correctness of all the data so collected.
b. The Site and the Principal Investigator ensures that the rights, safety and well-being of the study subjects are protected.
c. The Principal Investigator has started to conduct the Clinical Trial study after receiving a written approval from the Sponsor and as soon as all of the following events have occurred:
   i) The Protocol and Study have been approved by the responsible Ethics Committee(s) and the competent Regulatory Authority and registered under the Clinical Trial Registry of India;

   ii) The Trial site initiation visit at the Institution has been performed; and

   iii) Case Report Forms (as defined in clause 2.4.3 of this Agreement) and the investigational vaccine have been delivered to the Institution and/or the Investigator.

d. Investigator has to perform his obligations as per the applicable regulations and guidelines which shall be ensured and managed by CRO.

e. Investigator shall deal directly with the Sponsor for monitoring, data checking, data retrieval and other activities, as may be required, related with the study.

2.2.8 CRO ensures that any or all personnel including but not limited to the Principal Investigator, Sub-Investigator, Study Personnel and the CRO itself shall not undertake to or assist in or conduct or aid to conduct or be involved in, directly or indirectly in any possible manner, any clinical study which is same or similar to the subject matter of the Protocol or Clinical Trial of this Agreement.

2.2.9 CRO ensures that it is responsible for the co-ordination of the trial at the site.

ATTESTED

Dr. V.A.Kothiwale
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KLE Academy of Higher Education and Research
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Belagavi-590 010,Karnataka

2.3. Regulatory Compliance of Study

2.3.1. Each party shall perform its obligations under this Agreement with due diligence and in strict compliance with: (i)All applicable regulations to the conduct of Clinical Trial, including without limitation the Drugs and Cosmetics Act 1940, the Drugs and Cosmetics, Rules 1945, the Indian Council of Medical research guidelines and the Medical Council of India Act, 1956, (ii) All generally accepted standards of good clinical practice, (iii) The applicable laws related to data protection and data privacy, and (iv) Any other applicable laws, rules, guidelines and regulations (collectively, as amended from time to time, the "**Applicable Regulatory Requirements**").

2.3.2. Any modifications to the Protocol, if required, may only be made by the Sponsor and in accordance with the Applicable Regulatory Requirements.

2.4. **Study Subjects** - The estimated number of Subjects to be enrolled by the Investigator need to be in compliance with study. Detailed criteria of Subjects to be enrolled in the study are to be strictly in accordance with the Protocol. Sponsor reserves the right to unilaterally reduce or increase the number of subjects at any time and with immediate effect and/or to instruct the CRO and/or Investigator to discontinue recruiting Study Subjects.

2.5. Study Drug and Study Supplies

a. Sponsor agrees to provide the investigational vaccine at no-cost to the Site and/or the Investigator in volumes sufficient for the conduct of the Clinical Trial. Sponsor may also, at its sole discretion, provide additional materials, supplies and equipment (the "**Study Supplies**"). Immediately upon receipt of the Study Drug and/or any study supplies, CRO shall mediate the Site and/or the Investigator to provide Sponsor with a written acknowledgement. The Site and the Investigator shall maintain inventory and control of the investigational vaccine in accordance with: (i) Applicable Regulatory Requirements; (ii) In the manner outlined in the Protocol; and, (iii) According to any additional directions/documents provided by the Sponsor related to the storage (including temperature monitoring, if applicable), preparation and/or dispensing of the Study Drug.

b. CRO shall ensure that the Study Drug and the Study Supplies are solely used for the purposes of conducting the Clinical Trial in accordance with the Protocol and for no other purpose. Furthermore, CRO via the Investigator shall ensure that the investigational vaccine and the study supplies are not transferred to any third party. Unless stated otherwise in writing by the Sponsor, the investigational vaccine and the Study Supplies are and will remain the sole property of the Sponsor. CRO via the Investigator shall be responsible to the Sponsor for the investigational vaccine and the supplies entrusted to them and shall notify Sponsor immediately if any investigational vaccine or study supplies are lost, pilfered, damaged or destroyed.

c. Upon completion or termination of the Clinical Trial study or at Sponsor's instruction, CRO (via Investigator) shall deliver all remaining study supplies and/or all unused investigational vaccine to the address indicated by the Sponsor or destroy it/them, as instructed by the Sponsor and in accordance with the Applicable Regulatory Requirements. Neither CRO nor Site nor Investigator shall destroy any investigational vaccine or study supplies including documentation (study binders, submission binders etc.) without Sponsor's written consent.

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2.5.1. **Informed Consent**

a. The CRO (via Investigator) shall obtain, in compliance with all applicable regulatory requirements, an informed consent properly signed by or on behalf of each subject prior to the subject's participation in the Clinical Trial.

b. The CRO shall obtain Informed Consent after explaining the terms and meaning of the consent, from the Subject's parent/legally acceptable representative in writing, prior to any study-related procedures.

c. The CRO shall use the form of the informed consent (the "**Informed Consent Form**") provided by Sponsor and approved in compliance with all applicable regulatory requirements.

2.5.2. **Case Report Forms and Study Data**

a. Sponsor shall supply (or if electronic, provide access to) the forms to be used and completed by the Investigator to document a study Subject's participation in the study (the "**Case Report Forms**" or "**CRFs**"). The CRO shall ensure that the Investigator has records of all data generated as a result of conducting the Clinical Trial (the "**Study Data**") in a timely, accurate and complete manner in the form described in the study protocol and shall ensure that the Case Report Forms for each study Subject are duly signed and dated. To the extent the study requires completion of Case Report Forms, the CRO shall ensure that the Site and the Investigator have implemented and continue to maintain appropriate computer security sufficient to protect the confidentiality, integrity and availability of such Study Data in accordance with the Applicable Regulatory Requirements. The CRO is to ensure that unauthorized users access to the Electronic Data Capture (EDC) system if used in the study is not granted, and in particular, shall not be disclosed any username and/or passwords except only to the persons authorized to make entries and/or corrections on CRFs.

b. The CRO shall take reasonable and customary precautions to prevent the loss or alteration of any Study Data and shall be liable for any loss or alteration of the same. CRO acknowledges and agrees that the Sponsor shall exclusively own all Study Data.

2.5.3. Adverse Events

In case of any Adverse Event/s, CRO/Investigator shall immediately and fully inform Sponsor, the Ethics Committee(s) and competent authorities, of any significant risks, adverse events or unexpected results related to the study, according to the applicable regulatory requirements and applicable Protocol provisions.

2.5.4. Financial Disclosure

The CRO via Investigator shall complete and return financial disclosure document. This document shall disclose the financial interests which the Investigator and/or his/her family members may have with the Sponsor and/or the Study Drug. Such financial disclosure shall be kept updated for a period of one (01) year after Study completion.

3. BUDGETS AND PAYMENT

3.1 In consideration for performance of the CRO services, Sponsor shall compensate to CRO in accordance with the Budget and Payment Schedule hereto and made a

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part hereof (the "Budget") (Annexure-I), which shall be subject to revision from time to time, as may be required, by written consent of both the parties.

3.2 Targeted recruitment of 40 Subjects (per center) shall be completed within six (6) months from day of Site initiation. Towards consideration and expenses for conducting its activities under this Agreement, Sponsor shall pay upon achieving milestones:

a) 25% in advance during site initiation
b) 25% after completion of recruitment.
c) 35% after starting the last sample collection
d) 15% after study completion
e) Laboratory charges if any, for investigation during Clinical Trial and management of AEs /SAEs / treatment of any AE/ SAEs will be paid separately as per actual. In the event of any increase or decrease of Subjects the consideration payable will be adjusted proportionately.

3.3 Payments shall be made in accordance with the provisions set forth in the Budget, with the last payment being made after the Site Closeout Visit by the Sponsor.

3.4 Payments shall be made by Sponsor to CRO by cheques/online transfer.

3.5 Nothing in the foregoing provisions shall bar the Sponsor from withholding the payments or canceling the payment(s), at the sole discretion of Sponsor, in case of the material breach of any obligation under this Agreement, for any such period for which material breach has occurred or has been continuing, as the case maybe.

3.6 Any and all payments made under this Agreement shall be subject to the deduction of tax deductible at source. Taxes to be paid under this Agreement, as per the applicable laws, shall be paid by the Sponsor.

4 CONFIDENTIALITY

4.1. "Confidential Information" means all or any confidential or proprietary information or data, of any kind whatsoever and however memorialized, that is: (i) Disclosed by or on behalf of Sponsor and/or the Sponsor to the CRO, the Investigator or the Study personnel in connection with this Agreement or (ii) Obtained, developed or generated by the Institution, the Investigator and/or the Study personnel as a result of performing the Study under this Agreement. The Confidential Information shall include, without limitation, the Study, the Study Drug, the Protocol, the Investigator's Brochure, the study data, the Intellectual Property (as defined under Clause 5 of this Agreement) and information regarding the Sponsor, and/or their affiliates. All confidential information shall belong solely and exclusively to the Sponsor, as the case may be.

4.2. The CRO shall hold all confidential information in strict confidence and use all reasonable safeguards to prevent unauthorized use or disclosure. The CRO shall use the confidential information only as required for the purpose of this Agreement. The CRO shall limit their disclosure of the confidential information to those members of the Study personnel who 'need to know' the confidential information for the conduct of the Study and are subject to obligations of confidentiality not less stringent than those contained in this Agreement. The CRO shall advise the study personnel of the confidential nature of the confidential information and remain liable for any breach of the confidentiality provisions herein.

4.3. Should the CRO or the Investigator or any study personnel receive a court order or other legally binding request to disclose confidential information, the CRO shall

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immediately inform Sponsor upon the discovery of such request and before any confidential information is disclosed. The CRO shall cooperate with the Sponsor in any efforts to seek limitation or protection from the order demanding disclosure. In any case, the CRO shall disclose only the minimum amount of confidential information necessary to comply with such request only on the behest of its legal counsel.

4.4 The obligations of confidentiality exist at all times during this Agreement and shall survive the expiration or earlier termination of this Agreement for a period of ten (10) years, or in the case of any trade secret, for as long as such Confidential Information remains a trade secret.

5.0 INTELLECTUAL PROPERTY

The CRO acknowledges and agrees that the Sponsor shall have exclusive ownership rights to all study data, improvements, developments, discoveries, inventions, work, trade secret, know-how and other rights (whether or not patentable), created, developed, and/or reduced to practice as a result of or in connection with the conduct of the Study and/or the use of the investigational vaccine or the confidential information, together with all intellectual property rights relating thereto ("Intellectual Property"). The CRO shall promptly disclose in writing to the Sponsor all intellectual property made by the CRO, the Investigator and/or the Study personnel. All Intellectual Property and any information with respect thereto shall be confidential information subject to the obligations set forth in Article 4. At the Sponsor's request, the CRO shall ensure Investigator causes all rights titles and/or interests in and to any such intellectual property to be assigned to the Sponsor without additional investigator fee and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other document(s). In the event the Sponsor is unable for any reason, after good faith and all reasonable efforts, to secure the CRO's or the Investigator's signature on any document which the CRO or the Investigator is required to execute in accordance with the terms of this Article 4, the CRO shall ensure that Investigator hereby irrevocably designates and appoints the Sponsor and its duly authorized officers and agents to act for and on their behalf to execute, verify and file any such documents with the same legal force and effect as if executed by the CRO or the Investigator. To the extent that the applicable law does not allow the transfer of any of the intellectual property rights, the CRO and all study personnel hereby grant the Sponsor an exclusive, perpetual, irrevocable, worldwide, transferable, fully paid-up and royalty free license, with the right to sublicense to any third party, to use such intellectual property for any and all purposes

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6 PUBLICATION AND PUBLICITY

6.1. Publication - As this Study is part of a multicenter trial, publications derived from this Study may include input from the Investigator, his/her colleagues, other Investigators in this Study and the Sponsor's personnel. Such input will be reflected in publication as an acknowledgement. Selection of authors will be at the sole discretion of the Sponsor and governed by the Sponsor. CRO and/or any other study personnel other than Sponsor have no right to publish any study related data except for the Sponsor.

6.2. **Publicity** - The CRO shall not use Sponsor's name, the names of any of their employees, symbols, or trademarks in any advertising, sales promotional material, or press release without the prior written permission of Sponsor, as applicable.

7 INDEMNIFICATIONS, NOTIFICATION OF CLAIMS AND INSURANCE

7.1. Sponsor's Indemnity Obligations and Disclaimer

7.1.1. Sponsor expressly disclaims any and all liability whatsoever in connection with the study drug and the protocol, except to the extent that such liability that arises from (i) Any negligent or willful act or omission of Sponsor; or (ii) Any breach of this Agreement by Sponsor

7.2. The CRO's Indemnity Obligations - The CRO undertake to indemnify and hold harmless the Sponsor against any and all claims, damages, losses and costs (including reasonable attorneys' fees) arising out of (i) any breach of this Agreement by the CRO, or (ii) any negligence or willful act or omission of the CRO, the Investigator, study personnel or any of their officers, employees, contractors or staff or (iii) any unauthorized warranties made by the CRO or any Study personnel concerning the Clinical Trial.

7.3. Notification of Claims - The CRO shall and ensures that the Investigator shall immediately serve a notice in writing to Sponsor about any investigation, claim or legal proceeding(s) related to the study against the CRO, the Investigator, the study personnel and/or other staff in connection with the study. The CRO ensures all study personnel including the Investigator shall fully cooperate in all reasonable aspects upon request and on behalf of Sponsor in the investigation and/or defense of these claims or lawsuits.

7.4. Insurance

7.4.1. Sponsor shall ensure that it executes the mandatory Clinical Trial insurance required by the Applicable Regulatory Requirements, which shall not be less than Rs. 10,00,00,000 (Rupees Ten Crore only) for covering and damages, loss and for the purpose of indemnifying the Sponsor under this Agreement.

7.4.2. The CRO shall subscribe to, maintain and shall ensure that the Investigator subscribe to and maintains all insurance coverage, as required under any applicable law. They shall provide evidence(s) of such insurance(s) upon request of the Sponsor.

8 INSPECTIONS, AUDITS, MONITORING AND RECORDS

8.1. Regulatory Inspections - The CRO coordinating with the Investigator(s) shall promptly notify Sponsor of any inspection or investigation relating to the Study by any regulatory, governmental or law agency (including without limitation the Drug Controller General of India, the Ethics Committee, the

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Central Drugs Standard Control Organization, the State Drug Control, the EMEA and the US FDA) of which they become aware, Sponsor, and/or their representatives shall have the right to be present at and/or participate in any such inspection or investigation. Before CRO or Investigator submit any materials or information to an agency in connection with an inspection or investigation, Sponsor shall have the right, to review, provide and/or comment on any such materials and/or information.

8.2. **Monitoring and Audit by Sponsor** - Sponsor and their representatives may monitor, audit, and/or meet with the Investigator and the Study personnel at the investigating site during normal business hours and with reasonable frequency for audits and visits to monitor the progress of the study and review study records, documents, information, data, and materials (including the Study Data). The CRO ensures that the Investigator shall assist Sponsor and their representative(s) in scheduling such visits

8.2.1. Sponsor and their representative(s) shall be entitled to: (i) Examine and inspect the facilities required for the performance of the study; (ii) Inspect source documents; and (iii) inspect, request correction of and copy all study data (including, without limitation, Case Report Forms, original reports of laboratory tests and examination findings, and all other notes, charts, reports, or memoranda related to the study Subjects or to the conduct of the study), which Sponsor are authorized to access by the signed Informed Consent Form, and/or the applicable regulatory requirements. The Investigator shall cooperate with Sponsor and their representative(s) during audits and monitoring visits and in the resolution of any questions regarding the study data.

8.3. **Record Keeping** - The CRO ensures that the Investigator shall maintain accurate, complete and current records of all study data, including the Case Report Forms (or equivalent electronic data), relevant source documents and any other essential documents or materials as required by the protocol, the applicable regulatory requirements and Sponsor's instructions (collectively the "**Records**"). The CRO ensures that the Investigator shall keep all the Records in a safe and secure location for the period required by the applicable regulatory requirements, or for a period of five (05) years following the completion of the study, whichever is longer. The CRO and/or the Investigator may destroy the records at the end of the records keeping period on the condition that the Institution and/or the Investigator sends written notice to the Sponsor at least sixty (60) days prior to the date when the deletion/disposal will occur, and, if requested by the Sponsor, cooperates with the Sponsor in extending the record keeping period or shipping the records at another facility for storage.

9 TERM, TERMINATION AND SUSPENSION

9.1. Term - The Term of this Agreement shall commence on the date of the last date of Parties signatures. Unless terminated earlier in accordance with this Section 9, this Agreement shall remain in effect until the Clinical Trial is concluded with the submission of a final study report under the Protocol and is duly accepted by Sponsor, and Sponsor has performed a closeout visit at the Institution. The Sponsor shall mark the termination of the Agreement and the Clinical Trial via a letter of conclusion of the Clinical Trial to the Parties.

9.2 **Termination by Sponsor** - Sponsor may terminate this Agreement with immediate

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effect

a. If the CRO and/or the Investigator is in breach of this Agreement and fails to address such breach within Fifteen (15) calendar days from the receipt of the written notice.

b. If Sponsor in good faith believes the study drug or continuation of the study presents an unreasonable medical risk to the study Subjects or if there are efficacy or safety concerns

c. If the Clinical Trial study is terminated, suspended or not initiated at the Institutions for any reason,

d. If the Agreement between the Investigator, CRO and Sponsor regarding the study is terminated for whatsoever reason or

e. The CRO fails to perform the obligation as mentioned under Clause 2.2.3 of this Agreement. Sponsor, may also terminate this Agreement without cause upon thirty (30) calendar days' notice.

9.3 The Parties may terminate this Agreement at any time by mutual consent in writing.

9.4 Either Party may terminate this Agreement by giving a 60 days' advance written notice to the other Party.

9.5 **Surviving Clauses** – The termination or expiration of this Agreement shall not relieve either party of its obligation to the other with respect to the provisions and obligations including without limitation that of the Confidentiality, Payment, Intellectual Property, Indemnity etc., which shall survive by its nature. Subject to other terms and conditions of this Agreement, such clauses shall survive for a term of five (05) years even after the termination of this Agreement.

9.6 **Suspension of the Study** – The Sponsor may suspend the study at any time for any reason upon written notice; such suspension shall not be deemed as a breach of this Agreement by the Sponsor.

9.7 **Continuing Rights of Sponsor** – Upon termination of this Agreement due to any fault of CRO under this Agreement, the Sponsor may at its discretion, directly enter into such arrangements and/or agreements with the Investigator(s) and/or Study personnel or any other person competent to carry out such activities as may be required to complete the Clinical Trial study.

10 NON-DEBARMENT

The CRO represent and warrant that neither they nor any of the Study personnel is or ever has been debarred, disqualified, excluded and/or suspended to participate in clinical research by any competent authority or agency in any country, and that it shall not make use of, nor involve in this study any person or organization which is or has been debarred, suspended, excluded and/or disqualified by any regulatory authority to participate in clinical research. In the event the CRO or the Investigator or any person or organization involved in the study is or becomes threatened with or becomes debarred, disqualified, suspended or excluded during the study, the CRO shall notify sponsor in writing about this fact within Five (05) days of its discovery.

11 DATA TRANSFER

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11.1. The CRO undertake to protect the personal data of the study Subjects and to process them in accordance with the applicable data protection laws and regulations.

11.2. Both prior to and during the course of the study, the Investigator and the study personnel may provide Sponsor with personal data. Such data may include names, contact information, bank account details, work experience, qualifications, publications, resumes, educational background, performance information, facilities, staff capabilities, and other information relating to the study (the "Personal Data"). The CRO ensures that the Investigator shall use the Personal Data (including use, disclosure or transfer) as required for the following purposes (the "Purposes"):

a. The conduct of Clinical Trial,
b. Review by governmental or regulatory agencies, sponsor, and their agents, and affiliates,
c. Compliance with legal or regulatory requirements, and
d. Storage in databases for use in selecting investigators and institutions for future Clinical Trials. CRO represent that all study personnel have given express consent to the processing of their personal data for the purposes and shall notify Sponsor immediately if such consent has been withdrawn.

12. EXPERIMENTAL NATURE OF INVESTIGATIONAL PRODUCT

12.1. The CRO via Investigator acknowledge that the investigational vaccine is of experimental nature, and Sponsor do not make any warranties, express or implied, regarding the investigational product, including without limitation the implied warranties of merchantability and fitness for a particular purpose. The Institution and the Investigator acknowledge that Sponsor cannot guarantee the safety, non-toxicity, fitness or efficacy of the investigational medicinal product. The foregoing is not intended to, and does not negate Sponsor's liability under law for product liability claims arising out of the use or administration of the study drug in accordance with the Protocol and this Agreement.

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13. MISCELLANEOUS

13.1. No amendment to this Agreement (including its attachments) shall be effective unless such amendment is made in writing and signed by the parties hereto.

13.2. Obligation to protect Intellectual Property - CRO shall be responsible to bear the obligations to protect the intellectual properties, trade secret and know-how related to the product(s) and/or the Clinical Trial protocol coming from the Sponsor, and in addition to observance of the applicable international treaties and Indian laws, should not conduct and/or allow the revelation, use by the themselves and/or any other party for the intellectual properties, trade secret and know-how owned by the Sponsor. CRO shall not apply any patent, logo, trade name and/or trademarks related with the product(s) and/or Clinical Trial , any technique and/or process of the Sponsor in the name of the CRO himself and/or individual and/or party in any place in any country, and should not allow any individual and/or other party to conduct any application of here above any patent, logo, trade name and/or trademarks in relation with the product, any technique and process of the Sponsor. Sponsor exclusively reserves the rights of these applications, provided that the CRO breaches these terms, and the CRO shall bear the obligations of the indemnification relative to these conducts.

13.3. Entire Agreement/Amendments - This Agreement constitutes the entire agreement of the parties with regard to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between Owner and Recipient with respect thereto. This Agreement may only be amended, supplemented or changed by a written document signed by authorized representatives of both parties.

13.4. Severability - If any provision(s) of this Agreement shall be declared invalid by a court of competent jurisdiction, such determination shall not affect the remaining provisions of this agreement which shall remain in full force and effect. The parties hereto shall, however, replace the provision(s) declared invalid as aforesaid with legally valid provision(s) which reflect(s) the same purpose of the invalid provision(s) to the extent possible.

13.5. No Agency - This Agreement is entered into between the parties hereto on principal to principal basis. Nothing contained in this Agreement shall be construed to imply a joint venture, employment, partnership, or principal-agent relationship between the Institution/Investigator and Sponsor; and neither party hereto by virtue of this Agreement shall have the right, power or authority to act or create any obligation, express or implied, on behalf of the other party.

13.6. Assignment - The CRO may not assign any of their rights or subcontract obligations hereunder without the prior written consent of Sponsor. Even if Sponsor authorizes delegation or subcontracting in full or in part, the Institution and the Investigator remain fully responsible and liable for the performance of all delegated duties

13.7. Waiver - Any relaxation, forbearance, delay or indulgence on the part of The Company in enforcing any of the terms and conditions of this agreement, shall not prejudice, affect or restrict the rights of the Company hereunder nor shall any waiver by the Company of any breach hereof operate as a waiver of

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any subsequent or any continuing breach thereof.

14. APPLICABLE LAW AND PLACE OF JURISDICTION

14.1. This Agreement shall be governed by and construed in accordance with the laws of India, without regard to its conflict of law provisions.

14.2. Any claim or controversy arising out of or related to this Agreement or any breach hereof shall be submitted to the exclusive jurisdiction of the competent courts located at Delhi. Notwithstanding the foregoing, either Party may seek injunctive relief in a court of competent jurisdiction.

15. COUNTERPARTS

This agreement is signed and executed in Three (03) counterparts all of which constitute the original Agreement and to be retained by three the parties.

IN WITNESS WHEREOF, the Parties have signed this document with effect from the Effective date.

ACKNOWLEDGED AND AGREED BY

Dr. Niranjana. S. Mahantashetti
KLE's Dr. Prabhakar Kore Hospital & MRC. Nehru Nagar, Belagavi, 590010,
Karnataka, India
Contact No: +91-9448157237

Authorized Signatory:

15/02/2019
Date

ACKNOWLEDGED AND AGREED BY

For and on Behalf of KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India
The Institution

Dr. M. V. Jali, (MD, CEO)
KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi, 590010,
Karnataka, India
Contact No. 0831 - 2473777

Authorized Signatory:

15/02/2019
Date

ATTESTED

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ACKNOWLEDGED AND AGREED BY For CMS Clinical Research Pvt Ltd.

Name: Ms. Nidhi Singh
Title: Director Clinical Operations
Contact No.+91-7906261455

Singh

Authorized Signatory:

06/02/2019

Date

Annexure-I

Fee and Payment Schedule

I. Fees

All fees below are based on completion of certain task and recruitment of study subjects/ participant that are compliant with the Protocol.

Investigator name and address	Dr. Niranjana. S Mahantashetti, KLES Dr. Prabhakar Kore Hospital & MRC. Nehru Nagar, Belagavi-590010
Investigator Fees including overheads	INR 6,000/ subject
Subject TA	INR 500 / visit
Medical expenditure	As per actuals

All amounts stated in this Fee and Payment Schedule are inclusive of any or all applicable tax.

II. Payment

a. CRO shall make the payments in Indian Rupees according to Subject recruitment milestone achieved to Investigator.

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA48869020836090R
Certificate Issued Date	:	11-Feb-2019 02:48 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM3/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0830859957389302R
Purchased by	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Second Party	:	DR NIRANJANA S MAHANTSHETTI
Stamp Duty Paid By	:	CMS CLINICAL RESEARCH PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Shree Siddhivinayak Banjara
Multi Purpose Co-Op Society Ltd.
K. T. Patil Building Court Compound BGV

Authorised Signatory

Please write or type below this line

CLINICAL TRIAL SERVICE AGREEMENT

THIS CLINICAL TRIAL SERVICE AGREEMENT (hereinafter referred to as the "Agreement"), effective from the date of last signature (hereinafter referred to as the "Effective Date"), is entered into by and between,

ATTESTED

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Statutory Alert

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CMS Clinical Research Pvt. Ltd, an entity incorporated under the **Newbridge Business Centre, 1st Floor, Inox Tower-B, Plot No. 17, Sector-16A, Film city, Noida, Uttar Pradesh 201301** (hereinafter referred to as "**CRO**" and which expression shall unless it is repugnant to this context or meaning thereof be deemed to include its successors, and permitted assigns) of the FIRST PART;

AND

and KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010 for the project **BBIL/ROTAVAC 5CM/IV/2018.**

AND

and Dr. Niranjana. S. Mahantashetti, a qualified medical practitioner with registration number 22164 employed with KLE's Dr. Prabhakar kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India -("**Principal Investigator**"),

WHEREAS, Sponsor Bharat Biotech is a leading Biotechnology company involved in the research & development, clinical development and manufacturing of vaccines and bio-pharmaceuticals, and has considerable technology, trade secret, know-how and research experience in relation to the manufacturing and commercial production of vaccines and bio-therapeutics and has also established its marketing and distribution network for such product(s) in India as well as abroad;

Bharat Biotech has outsourced CRO all clinical trial and site management activities.

WHEREAS, CRO is engaged in the business of providing clinical trial project management, data management and bio-statistical services for the Pharmaceutical and Biotechnology industries;

WHEREAS, the CRO has engaged Dr. Niranjana .S. Mahantshetti situated at KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, belagavi-590010 ("**Site**") for conducting Clinical Trial of its **BBIL/ROTAVAC/III/2018** vaccine product under the title **"A Phase 3, Multicenter, A PHASE 3, MULTICENTER, OPEN-LABEL, RANDOMIZED CLINICAL TRIAL TO EVALUATE SAFETY AND IMMUNOGENICITY OF ROTAVAC® -20C AND ROTAVAC 5CM ADMINISTERED AT BIRTH (NEONATAL SCHEDULE) AND ADDITIONAL DOSE VERSUS INFANT SCHEDULE AGAINST ROTAVIRUS GASTROENTERITIS".** (hereinafter referred to as the "**Clinical Trial**"), and any amendments thereto;

WHEREAS. Sponsor requires services relating to site management & clinical research co-ordination activities generated in course of the Clinical Trial and wishes to outsource such services to CRO and requires it to perform services related to site management & administration support for the conduct of the Clinical Trial with the help of their clinical research coordinator, the Site or any person engaged for the sole purpose of the coordination of the Clinical Trial by the CRO.

WHEREAS. Sponsor desires to engage the CRO. and the CRO agrees for managing the

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investigational site according to the rules and regulations in full compliance of the ICH GCP guidelines and applicable regulatory authorities as specified in Clinical Trial Protocol(s);

NOW, THEREFORE, in consideration of the terms and conditions set forth herein, the parties agree as follows:

1. DEFINITIONS

The following words and phrases as used in this Agreement shall have the following meanings:

1.1 "Protocol" means document(s) that describes the objective(s), design, methodology, statistical considerations, and organization of the Clinical Trial including the document(s) contains a study plan, on which the Clinical Trial is based.

1.2 "Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation Subject administered the Study Drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended reaction (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Study Drug.

1.3 "Auditor" means a person being a representative of the Sponsor who is authorised to carry out a systematic review and independent examination of Clinical Trial and/or related activities and documents to determine whether the evaluated Clinical Trial and/or related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the Sponsor's Standard Operating Procedures (SOPs), ICH GCP and the applicable regulatory requirements.

1.4 "Clinical Trial" means an investigation to be conducted at a Trial site in accordance to an approved Protocol, as defined above.

1.5 "Co-investigator" means any individual member of the Clinical Trial team designated to assist and act on behalf of the Principal Investigator who is supervised by the Principal Investigator at the Trial site to perform trial-related critical procedures.

1.6 "GCP" (Good Clinical Practice) shall mean the regulations and guidelines established by the International Conference on Harmonization (ICH) and the specific regulating authorities of countries and economic affiliations worldwide that set the standards of good clinical practice for the Clinical Trials.

1.7 "GLP" (Good Laboratory Practice) shall mean the procedures for the conduct of non-clinical laboratory studies on a drug substance or medical device that assure the quality and integrity of safety data, which are generated for products regulated by the regulatory agencies to support an application for research or a marketing permit as the case may be.

1.8 "Informed Consent" shall mean consent obtained from a Subject that complies with guidelines established by the Declaration of Helsinki, International Conference of Harmonisation (ICH), and all the applicable laws, guidelines, and/or standards governing the participation of Subjects in trials.

1.9 "Confidential Information" means any and all information, data and material of any nature belonging to the Sponsor and/or its Affiliates which CRO may receive or obtain in connection with this Agreement, the release of which is likely to prejudice the commercial interest(s) of the Sponsor and/or the CRO respectively,

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or which is a trade secret, including Know-How. The term 'Confidential Information' also includes Protected Health Information which relates to any patient/Subject in a Clinical Trial or his/her treatment or medical history, or other information. Confidential Information does not include information:

(I) That is in the public domain at the time of its disclosure to CRO;

(II) Information that was evidenced by written records or other competent proof, in the CRO and/or Investigator's possession prior to this Agreement, without obligations of confidentiality (excluding study data); or

(III) that is in the public domain as a result of a third party's activity(s), through no act or omission of the Investigator, the CRO or any Study Personnel.

1.10 "Intellectual Property Rights" means patents, trademarks, trade names, service marks, domain names, copyrights, trade-secret, know-how, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered/granted and shall include applications for registration of any of them and shall also include those for which application for registration has not been applied.

1.11 "Know How" means all technical and other information, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protection/registration is granted or applied for, or whether or not protectable by any form of Intellectual Property Rights.

1.12 "Party" means either the Sponsor or the CRO, and except where otherwise provided "Parties" shall mean both of them.

1.13 "Inspector" means a person, acting on behalf of a Regulatory Authority, who conducts an official review of documents, facilities, records and any other resources that are deemed by the Regulatory Authority to be related to the Clinical Trial and that may be located at the Trial site.

1.14 Disclosing Party - For the purposes of this Agreement the Party disclosing the confidential information will be referred to as the "Disclosing Party"

1.15 Receiving Party - For the purposes of this Agreement the Party receiving the confidential information will be referred to as the "Receiving Party"

1.16 Regulatory Agency(s) - "Regulatory Agency(s)" shall mean any and all agencies/authorities of any country with jurisdiction to regulate, audit or otherwise review the research process, administration or facilities used in the conduct of the study and/or its result(s) under this Agreement.

1.17 Third Parties - "Third Parties" shall mean any person/s, other than the Sponsor, CRO, Principal Investigator or Subjects, and shall include a party performing paid-functions in connection with the study under this Agreement and requiring separate contractual agreements.

1.18 "Investigator(s)" shall mean the physicians primarily responsible for the conduct

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of the study at the Trial site(s), and shall include "Sub-Investigators" and "Co-investigators".

1.19 "Monitor" shall mean one or more person appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

1.20 "Principal Investigator" shall mean the person who has been mutually agreed upon by the Parties and who will lead and co-ordinate the work of the Clinical Trial at the Trial site(s) on behalf of the CRO or any other person as may be mutually agreed from time to time between the Parties as a replacement for the purpose of this Agreement.

1.21 "Trial site(s)" means any premises in which the Clinical Trial is being or will be conducted.

1.22 Serious Adverse Event (SAE)" shall mean only any untoward medical condition that occurs at any dose:

a. Results in death,
b. Is Life-threatening,
c. Requires inpatient hospitalization or prolongation of existing hospitalization,
d. Results in persistent or significant disability/incapacity, or
e. Is a congenital anomaly/birth defect.

1.23 "Study Drug" shall mean any drug(s) administered to Subjects pursuant to the Protocol.

1.24 "Study Personnel" means any person involved in or with the study team who is involved in conducting the study at the Trial site(s).

1.25 "Subject/s" means an individual, whether a patient or not, who participates in the Clinical Trial as a recipient of Investigational Medicinal Product.

1.26 Sub-Investigator means any individual member of the Clinical Trial team designated and supervised by the Principal Investigator and the Co-investigator at the Trial site(s) to perform trial-related critical procedures.

1.27 Institution (medical): Any public or private entity or agency or medical or dental facility where Clinical Trial(s) are conducted.

2.0 SERVICES AND OBLIGATIONS

2.1.Master Agreement

2.1.1 This Agreement is intended by the Parties to be an "umbrella" document which allows the CRO to manage one or more site(s) to conduct the Clinical Trial study without having to re-negotiate the basic terms and conditions contained herein.

2.1.2 Sponsor requires services relating to site management & clinical research coordination activities generated in course of its business and wishes to outsource such services to CRO and CRO desires to be hired to perform such services regarding the site management & administration support for the conduct of the Clinical Trial under this Agreement.

2.2. Conduct of Study

2.2.1 CRO represents that it has a written agreement in place with the Principal Investigator and the Site, which shall be in line of this Agreement, and detailing

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the modalities, roles, responsibilities and liabilities for the purpose of the conduct of the Clinical Trial as mentioned in this Agreement.

2.2.2 CRO represents and warrants that it has necessary expertise to perform its obligations under this agreement. The CRO shall be wholly responsible for any and all of its own acts and/or omissions and also by its representatives and the study coordinator under this Agreement.

2.2.3 CRO shall notify the Sponsor if the Principal Investigator or the Site ceases to be associated with the CRO at the earliest possible instance. If the dissociation is not resolved then pursuant to clause 9.2 of this Agreement the Sponsor may terminate this Agreement.

2.2.4 CRO hereby agree to conduct the study in accordance with this Agreement and the Protocol. CRO shall also follow, and shall ensure that the Study Personnel (defined in clause 2.2.5 of this Agreement) strictly comply with the Sponsor's study protocol, applicable regulations and guidelines pertaining to clinical trial.

2.2.5 CRO shall ensure that all individuals and entities that perform any portion of the study under the Investigator's supervision (all such individuals hereinafter referred to as the "**Study Personnel**") and conduct the study in accordance with the Protocol and the terms and conditions defined in this Agreement. Further, CRO shall ensure that all Study Personnel are trained in the Protocol and GCP.

2.2.6 CRO undertakes the responsibility and ensures the followings:

a. That the CRO is and remains free to participate in the Clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict the performance of the obligations detailed in this Agreement.

b. That the CRO is not involved in any regulatory or misconduct litigation, enquiry or investigation by CDSCO or any other regulatory authority(s). No data produced by the CRO in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

c. That the CRO has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available at the Trial site and ensure the continued support by medical and other staff of sufficient number and experience to enable the CRO to perform the site management efficiently and in accordance with its obligations under the Agreement.

d. That the CRO shall ensure obtaining and maintaining all approvals from the relevant Institutional Ethics Committee for the conduct of the Clinical Trial and shall keep the Sponsor fully apprised of the progress of Ethics Committee submissions and shall upon request provide the Sponsor with all correspondence relating to such submissions. The CRO shall not consent to any change in the Study Protocol requested by a relevant Ethics Committee without the prior written consent of the Sponsor.

e. That the CRO is solely responsible for obtaining and maintaining valid licenses, approvals, and other authorizations from the competent authorities, as may be required by the CRO for the conduct of the Clinical Trial under this Agreement, as per the applicable laws in India, including without limitation,

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intimation to State Biodiversity Board(s) for obtaining biological resources under the provisions of the Biological Diversity Act, 2002. Provided that any application under the Biological Diversity Act, 2002 may be submitted by the Sponsor directly. However, the CRO shall intimate the Sponsor and cooperate with the Sponsor and furnish all such information as may be necessary to obtain any biological sample. CRO shall immediately submit a copy of all such licenses, approvals, intimations and other authorizations, as required hereunder this clause, to the Sponsor.

f. CRO shall not obtain any biological sample without prior intimation to the Sponsor, and shall not proceed for obtaining any biological sample unless the Sponsor has confirmed to obtain any such biological samples to the CRO.

2.2.7 CRO shall further ensure that:

a. The Principal Investigator shall be responsible for the recruitment of subjects and performance of the Study in accordance with the agreed upon timelines and the Protocol, as well as for the completeness and correctness of all the data so collected.
b. The Site and the Principal Investigator ensures that the rights, safety and well-being of the study subjects are protected.
c. The Principal Investigator has started to conduct the Clinical Trial study after receiving a written approval from the Sponsor and as soon as all of the following events have occurred:
   i) The Protocol and Study have been approved by the responsible Ethics Committee(s) and the competent Regulatory Authority and registered under the Clinical Trial Registry of India;

   ii) The Trial site initiation visit at the Institution has been performed; and

   iii) Case Report Forms (as defined in clause 2.4.3 of this Agreement) and the investigational vaccine have been delivered to the Institution and/or the Investigator.

d. Investigator has to perform his obligations as per the applicable regulations and guidelines which shall be ensured and managed by CRO.

e. Investigator shall deal directly with the Sponsor for monitoring, data checking, data retrieval and other activities, as may be required, related with the study.

2.2.8 CRO ensures that any or all personnel including but not limited to the Principal Investigator, Sub-Investigator, Study Personnel and the CRO itself shall not undertake to or assist in or conduct or aid to conduct or be involved in, directly or indirectly in any possible manner, any clinical study which is same or similar to the subject matter of the Protocol or Clinical Trial of this Agreement.

2.2.9 CRO ensures that it is responsible for the co-ordination of the trial at the site.

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2.3. Regulatory Compliance of Study

2.3.1. Each party shall perform its obligations under this Agreement with due diligence and in strict compliance with: (i)All applicable regulations to the conduct of Clinical Trial, including without limitation the Drugs and Cosmetics Act 1940, the Drugs and Cosmetics, Rules 1945, the Indian Council of Medical research guidelines and the Medical Council of India Act. 1956, (ii) All generally accepted standards of good clinical practice, (iii) The applicable laws related to data protection and data privacy, and (iv) Any other applicable laws, rules, guidelines and regulations (collectively, as amended from time to time, the "**Applicable Regulatory Requirements**").

2.3.2. Any modifications to the Protocol, if required, may only be made by the Sponsor and in accordance with the Applicable Regulatory Requirements.

2.4. **Study Subjects** - The estimated number of Subjects to be enrolled by the Investigator need to be in compliance with study. Detailed criteria of Subjects to be enrolled in the study are to be strictly in accordance with the Protocol. Sponsor reserves the right to unilaterally reduce or increase the number of subjects at any time and with immediate effect and/or to instruct the CRO and/or Investigator to discontinue recruiting Study Subjects.

2.5. Study Drug and Study Supplies

a. Sponsor agrees to provide the investigational vaccine at no-cost to the Site and/or the Investigator in volumes sufficient for the conduct of the Clinical Trial. Sponsor may also, at its sole discretion, provide additional materials, supplies and equipment (the "**Study Supplies**"). Immediately upon receipt of the Study Drug and/or any study supplies, CRO shall mediate the Site and/or the Investigator to provide Sponsor with a written acknowledgement. The Site and the Investigator shall maintain inventory and control of the investigational vaccine in accordance with: (i) Applicable Regulatory Requirements; (ii) In the manner outlined in the Protocol; and, (iii) According to any additional directions/documents provided by the Sponsor related to the storage (including temperature monitoring, if applicable), preparation and/or dispensing of the Study Drug.

b. CRO shall ensure that the Study Drug and the Study Supplies are solely used for the purposes of conducting the Clinical Trial in accordance with the Protocol and for no other purpose. Furthermore, CRO via the Investigator shall ensure that the investigational vaccine and the study supplies are not transferred to any third party. Unless stated otherwise in writing by the Sponsor, the investigational vaccine and the Study Supplies are and will remain the sole property of the Sponsor. CRO via the Investigator shall be responsible to the Sponsor for the investigational vaccine and the supplies entrusted to them and shall notify Sponsor immediately if any investigational vaccine or study supplies are lost, pilfered, damaged or destroyed.

c. Upon completion or termination of the Clinical Trial study or at Sponsor's instruction, CRO (via Investigator) shall deliver all remaining study supplies and/or all unused investigational vaccine to the address indicated by the Sponsor or destroy it/them, as instructed by the Sponsor and in accordance with the Applicable Regulatory Requirements. Neither CRO nor Site nor Investigator shall destroy any investigational vaccine or study supplies including documentation (study binders, submission binders etc.) without Sponsor's written consent.

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2.5.1. **Informed Consent**

a. The CRO (via Investigator) shall obtain, in compliance with all applicable regulatory requirements, an informed consent properly signed by or on behalf of each subject prior to the subject's participation in the Clinical Trial.

b. The CRO shall obtain Informed Consent after explaining the terms and meaning of the consent, from the Subject's parent/legally acceptable representative in writing, prior to any study-related procedures.

c. The CRO shall use the form of the informed consent (the "**Informed Consent Form**") provided by Sponsor and approved in compliance with all applicable regulatory requirements.

2.5.2. **Case Report Forms and Study Data**

a. Sponsor shall supply (or if electronic, provide access to) the forms to be used and completed by the Investigator to document a study Subject's participation in the study (the "**Case Report Forms**" or "**CRFs**"). The CRO shall ensure that the Investigator has records of all data generated as a result of conducting the Clinical Trial (the "**Study Data**") in a timely, accurate and complete manner in the form described in the study protocol and shall ensure that the Case Report Forms for each study Subject are duly signed and dated. To the extent the study requires completion of Case Report Forms, the CRO shall ensure that the Site and the Investigator have implemented and continue to maintain appropriate computer security sufficient to protect the confidentiality, integrity and availability of such Study Data in accordance with the Applicable Regulatory Requirements. The CRO is to ensure that unauthorized users access to the Electronic Data Capture (EDC) system if used in the study is not granted, and in particular, shall not be disclosed any username and/or passwords except only to the persons authorized to make entries and/or corrections on CRFs.

b. The CRO shall take reasonable and customary precautions to prevent the loss or alteration of any Study Data and shall be liable for any loss or alteration of the same. CRO acknowledges and agrees that the Sponsor shall exclusively own all Study Data.

2.5.3. Adverse Events

In case of any Adverse Event/s, CRO/Investigator shall immediately and fully inform Sponsor, the Ethics Committee(s) and competent authorities, of any significant risks, adverse events or unexpected results related to the study, according to the applicable regulatory requirements and applicable Protocol provisions.

2.5.4. Financial Disclosure

The CRO via Investigator shall complete and return financial disclosure document. This document shall disclose the financial interests which the Investigator and/or his/her family members may have with the Sponsor and/or the Study Drug. Such financial disclosure shall be kept updated for a period of one (01) year after Study completion.

3. BUDGETS AND PAYMENT

3.1 In consideration for performance of the CRO services, Sponsor shall compensate to CRO in accordance with the Budget and Payment Schedule hereto and made a

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part hereof (the "Budget") (Annexure-I), which shall be subject to revision from time to time, as may be required, by written consent of both the parties.

3.2 Targeted recruitment of 40 Subjects (per center) shall be completed within six (6) months from day of Site initiation. Towards consideration and expenses for conducting its activities under this Agreement, Sponsor shall pay upon achieving milestones:

a) 25% in advance during site initiation
b) 25% after completion of recruitment.
c) 35% after starting the last sample collection
d) 15% after study completion
e) Laboratory charges if any, for investigation during Clinical Trial and management of AEs /SAEs / treatment of any AE/ SAEs will be paid separately as per actual. In the event of any increase or decrease of Subjects the consideration payable will be adjusted proportionately.

3.3 Payments shall be made in accordance with the provisions set forth in the Budget, with the last payment being made after the Site Closeout Visit by the Sponsor.

3.4 Payments shall be made by Sponsor to CRO by cheques/online transfer.

3.5 Nothing in the foregoing provisions shall bar the Sponsor from withholding the payments or canceling the payment(s), at the sole discretion of Sponsor, in case of the material breach of any obligation under this Agreement, for any such period for which material breach has occurred or has been continuing, as the case maybe.

3.6 Any and all payments made under this Agreement shall be subject to the deduction of tax deductible at source. Taxes to be paid under this Agreement, as per the applicable laws, shall be paid by the Sponsor.

4 CONFIDENTIALITY

4.1. "Confidential Information" means all or any confidential or proprietary information or data, of any kind whatsoever and however memorialized, that is: (i) Disclosed by or on behalf of Sponsor and/or the Sponsor to the CRO, the Investigator or the Study personnel in connection with this Agreement or (ii) Obtained, developed or generated by the Institution, the Investigator and/or the Study personnel as a result of performing the Study under this Agreement. The Confidential Information shall include, without limitation, the Study, the Study Drug, the Protocol, the Investigator's Brochure, the study data, the Intellectual Property (as defined under Clause 5 of this Agreement) and information regarding the Sponsor, and/or their affiliates. All confidential information shall belong solely and exclusively to the Sponsor, as the case may be.

4.2. The CRO shall hold all confidential information in strict confidence and use all reasonable safeguards to prevent unauthorized use or disclosure. The CRO shall use the confidential information only as required for the purpose of this Agreement. The CRO shall limit their disclosure of the confidential information to those members of the Study personnel who 'need to know' the confidential information for the conduct of the Study and are subject to obligations of confidentiality not less stringent than those contained in this Agreement. The CRO shall advise the study personnel of the confidential nature of the confidential information and remain liable for any breach of the confidentiality provisions herein.

4.3. Should the CRO or the Investigator or any study personnel receive a court order or other legally binding request to disclose confidential information, the CRO shall

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immediately inform Sponsor upon the discovery of such request and before any confidential information is disclosed. The CRO shall cooperate with the Sponsor in any efforts to seek limitation or protection from the order demanding disclosure. In any case, the CRO shall disclose only the minimum amount of confidential information necessary to comply with such request only on the behest of its legal counsel.

4.4 The obligations of confidentiality exist at all times during this Agreement and shall survive the expiration or earlier termination of this Agreement for a period of ten (10) years, or in the case of any trade secret, for as long as such Confidential Information remains a trade secret.

5.0 INTELLECTUAL PROPERTY

The CRO acknowledges and agrees that the Sponsor shall have exclusive ownership rights to all study data, improvements, developments, discoveries, inventions, work, trade secret, know-how and other rights (whether or not patentable), created, developed, and/or reduced to practice as a result of or in connection with the conduct of the Study and/or the use of the investigational vaccine or the confidential information, together with all intellectual property rights relating thereto ("Intellectual Property"). The CRO shall promptly disclose in writing to the Sponsor all intellectual property made by the CRO, the Investigator and/or the Study personnel. All Intellectual Property and any information with respect thereto shall be confidential information subject to the obligations set forth in Article 4. At the Sponsor's request, the CRO shall ensure Investigator causes all rights titles and/or interests in and to any such intellectual property to be assigned to the Sponsor without additional investigator fee and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other document(s). In the event the Sponsor is unable for any reason, after good faith and all reasonable efforts, to secure the CRO's or the Investigator's signature on any document which the CRO or the Investigator is required to execute in accordance with the terms of this Article 4, the CRO shall ensure that Investigator hereby irrevocably designates and appoints the Sponsor and its duly authorized officers and agents to act for and on their behalf to execute, verify and file any such documents with the same legal force and effect as if executed by the CRO or the Investigator. To the extent that the applicable law does not allow the transfer of any of the intellectual property rights, the CRO and all study personnel hereby grant the Sponsor an exclusive, perpetual, irrevocable, worldwide, transferable, fully paid-up and royalty free license, with the right to sublicense to any third party, to use such intellectual property for any and all purposes

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6 PUBLICATION AND PUBLICITY

6.1. Publication - As this Study is part of a multicenter trial, publications derived from this Study may include input from the Investigator, his/her colleagues, other Investigators in this Study and the Sponsor's personnel. Such input will be reflected in publication as an acknowledgement. Selection of authors will be at the sole discretion of the Sponsor and governed by the Sponsor. CRO and/or any other study personnel other than Sponsor have no right to publish any study related data except for the Sponsor.

6.2. **Publicity** - The CRO shall not use Sponsor's name, the names of any of their employees, symbols, or trademarks in any advertising, sales promotional material, or press release without the prior written permission of Sponsor, as applicable.

7 INDEMNIFICATIONS, NOTIFICATION OF CLAIMS AND INSURANCE

7.1. Sponsor's Indemnity Obligations and Disclaimer

7.1.1. Sponsor expressly disclaims any and all liability whatsoever in connection with the study drug and the protocol, except to the extent that such liability that arises from (i) Any negligent or willful act or omission of Sponsor; or (ii) Any breach of this Agreement by Sponsor

7.2. **The CRO's Indemnity Obligations** - The CRO undertake to indemnify and hold harmless the Sponsor against any and all claims, damages, losses and costs (including reasonable attorneys' fees) arising out of (i) any breach of this Agreement by the CRO, or (ii) any negligence or willful act or omission of the CRO, the Investigator, study personnel or any of their officers, employees, contractors or staff or (iii) any unauthorized warranties made by the CRO or any Study personnel concerning the Clinical Trial.

7.3. **Notification of Claims** - The CRO shall and ensures that the Investigator shall immediately serve a notice in writing to Sponsor about any investigation, claim or legal proceeding(s) related to the study against the CRO, the Investigator, the study personnel and/or other staff in connection with the study. The CRO ensures all study personnel including the Investigator shall fully cooperate in all reasonable aspects upon request and on behalf of Sponsor in the investigation and/or defense of these claims or lawsuits.

7.4. Insurance

7.4.1. Sponsor shall ensure that it executes the mandatory Clinical Trial insurance required by the Applicable Regulatory Requirements, which shall not be less than Rs. 10,00,00,000 (Rupees Ten Crore only) for covering and damages, loss and for the purpose of indemnifying the Sponsor under this Agreement.

7.4.2. The CRO shall subscribe to, maintain and shall ensure that the Investigator subscribe to and maintains all insurance coverage, as required under any applicable law. They shall provide evidence(s) of such insurance(s) upon request of the Sponsor.

8 INSPECTIONS, AUDITS, MONITORING AND RECORDS

8.1. Regulatory Inspections - The CRO coordinating with the Investigator(s) shall promptly notify Sponsor of any inspection or investigation relating to the Study by any regulatory, governmental or law agency (including without limitation the Drug Controller General of India, the Ethics Committee, the

Central Drugs Standard Control Organization, the State Drug Control, the EMEA and the US FDA) of which they become aware. Sponsor, and/or their representatives shall have the right to be present at and/or participate in any such inspection or investigation. Before CRO or Investigator submit any materials or information to an agency in connection with an inspection or investigation, Sponsor shall have the right, to review, provide and/or comment on any such materials and/or information.

8.2. **Monitoring and Audit by Sponsor** - Sponsor and their representatives may monitor, audit, and/or meet with the Investigator and the Study personnel at the investigating site during normal business hours and with reasonable frequency for audits and visits to monitor the progress of the study and review study records, documents, information, data, and materials (including the Study Data). The CRO ensures that the Investigator shall assist Sponsor and their representative(s) in scheduling such visits

8.2.1. Sponsor and their representative(s) shall be entitled to: (i) Examine and inspect the facilities required for the performance of the study; (ii) Inspect source documents: and (iii) inspect, request correction of and copy all study data (including, without limitation, Case Report Forms, original reports of laboratory tests and examination findings, and all other notes, charts, reports, or memoranda related to the study Subjects or to the conduct of the study), which Sponsor are authorized to access by the signed Informed Consent Form, and/or the applicable regulatory requirements. The Investigator shall cooperate with Sponsor and their representative(s) during audits and monitoring visits and in the resolution of any questions regarding the study data.

8.3. **Record Keeping** - The CRO ensures that the Investigator shall maintain accurate, complete and current records of all study data, including the Case Report Forms (or equivalent electronic data), relevant source documents and any other essential documents or materials as required by the protocol, the applicable regulatory requirements and Sponsor's instructions (collectively the "**Records**"). The CRO ensures that the Investigator shall keep all the Records in a safe and secure location for the period required by the applicable regulatory requirements, or for a period of five (05) years following the completion of the study, whichever is longer. The CRO and/or the Investigator may destroy the records at the end of the records keeping period on the condition that the Institution and/or the Investigator sends written notice to the Sponsor at least sixty (60) days prior to the date when the deletion/disposal will occur, and, if requested by the Sponsor, cooperates with the Sponsor in extending the record keeping period or shipping the records at another facility for storage.

9 TERM, TERMINATION AND SUSPENSION

9.1. Term - The Term of this Agreement shall commence on the date of the last date of Parties signatures. Unless terminated earlier in accordance with this Section 9, this Agreement shall remain in effect until the Clinical Trial is concluded with the submission of a final study report under the Protocol and is duly accepted by Sponsor, and Sponsor has performed a closeout visit at the Institution. The Sponsor shall mark the termination of the Agreement and the Clinical Trial via a letter of conclusion of the Clinical Trial to the Parties.

9.2 **Termination by Sponsor** - Sponsor may terminate this Agreement with immediate

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effect

a. If the CRO and/or the Investigator is in breach of this Agreement and fails to address such breach within Fifteen (15) calendar days from the receipt of the written notice,

b. If Sponsor in good faith believes the study drug or continuation of the study presents an unreasonable medical risk to the study Subjects or if there are efficacy or safety concerns

c. If the Clinical Trial study is terminated, suspended or not initiated at the Institutions for any reason,

d. If the Agreement between the Investigator, CRO and Sponsor regarding the study is terminated for whatsoever reason or

e. The CRO fails to perform the obligation as mentioned under Clause 2.2.3 of this Agreement. Sponsor, may also terminate this Agreement without cause upon thirty (30) calendar days' notice.

9.3 The Parties may terminate this Agreement at any time by mutual consent in writing.

9.4 Either Party may terminate this Agreement by giving a 60 days' advance written notice to the other Party.

9.5 **Surviving Clauses** – The termination or expiration of this Agreement shall not relieve either party of its obligation to the other with respect to the provisions and obligations including without limitation that of the Confidentiality, Payment, Intellectual Property, Indemnity etc., which shall survive by its nature. Subject to other terms and conditions of this Agreement, such clauses shall survive for a term of five (05) years even after the termination of this Agreement.

9.6 **Suspension of the Study** – The Sponsor may suspend the study at any time for any reason upon written notice; such suspension shall not be deemed as a breach of this Agreement by the Sponsor.

9.7 **Continuing Rights of Sponsor** – Upon termination of this Agreement due to any fault of CRO under this Agreement, the Sponsor may at its discretion, directly enter into such arrangements and/or agreements with the Investigator(s) and/or Study personnel or any other person competent to carry out such activities as may be required to complete the Clinical Trial study.

10 NON-DEBARMENT

The CRO represent and warrant that neither they nor any of the Study personnel is or ever has been debarred, disqualified, excluded and/or suspended to participate in clinical research by any competent authority or agency in any country, and that it shall not make use of, nor involve in this study any person or organization which is or has been debarred, suspended, excluded and/or disqualified by any regulatory authority to participate in clinical research. In the event the CRO or the Investigator or any person or organization involved in the study is or becomes threatened with or becomes debarred, disqualified, suspended or excluded during the study, the CRO shall notify sponsor in writing about this fact within Five (05) days of its discovery.

11 DATA TRANSFER

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11.1. The CRO undertake to protect the personal data of the study Subjects and to process them in accordance with the applicable data protection laws and regulations.

11.2. Both prior to and during the course of the study, the Investigator and the study personnel may provide Sponsor with personal data. Such data may include names, contact information, bank account details, work experience, qualifications, publications, resumes, educational background, performance information, facilities, staff capabilities, and other information relating to the study (the "Personal Data"). The CRO ensures that the Investigator shall use the Personal Data (including use, disclosure or transfer) as required for the following purposes (the "Purposes"):

a. The conduct of Clinical Trial,
b. Review by governmental or regulatory agencies, sponsor, and their agents, and affiliates,
c. Compliance with legal or regulatory requirements, and
d. Storage in databases for use in selecting investigators and institutions for future Clinical Trials. CRO represent that all study personnel have given express consent to the processing of their personal data for the purposes and shall notify Sponsor immediately if such consent has been withdrawn.

12. EXPERIMENTAL NATURE OF INVESTIGATIONAL PRODUCT

12.1. The CRO via Investigator acknowledge that the investigational vaccine is of experimental nature, and Sponsor do not make any warranties, express or implied, regarding the investigational product, including without limitation the implied warranties of merchantability and fitness for a particular purpose. The Institution and the Investigator acknowledge that Sponsor cannot guarantee the safety, non-toxicity, fitness or efficacy of the investigational medicinal product. The foregoing is not intended to, and does not negate Sponsor's liability under law for product liability claims arising out of the use or administration of the study drug in accordance with the Protocol and this Agreement.

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13. MISCELLANEOUS

13.1. No amendment to this Agreement (including its attachments) shall be effective unless such amendment is made in writing and signed by the parties hereto.

13.2. Obligation to protect Intellectual Property - CRO shall be responsible to bear the obligations to protect the intellectual properties, trade secret and know-how related to the product(s) and/or the Clinical Trial protocol coming from the Sponsor, and in addition to observance of the applicable international treaties and Indian laws, should not conduct and/or allow the revelation, use by the themselves and/or any other party for the intellectual properties, trade secret and know-how owned by the Sponsor. CRO shall not apply any patent, logo, trade name and/or trademarks related with the product(s) and/or Clinical Trial , any technique and/or process of the Sponsor in the name of the CRO himself and/or individual and/or party in any place in any country, and should not allow any individual and/or other party to conduct any application of here above any patent, logo, trade name and/or trademarks in relation with the product, any technique and process of the Sponsor. Sponsor exclusively reserves the rights of these applications, provided that the CRO breaches these terms, and the CRO shall bear the obligations of the indemnification relative to these conducts.

13.3. Entire Agreement/Amendments - This Agreement constitutes the entire agreement of the parties with regard to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between Owner and Recipient with respect thereto. This Agreement may only be amended, supplemented or changed by a written document signed by authorized representatives of both parties.

13.4. Severability - If any provision(s) of this Agreement shall be declared invalid by a court of competent jurisdiction, such determination shall not affect the remaining provisions of this agreement which shall remain in full force and effect. The parties hereto shall, however, replace the provision(s) declared invalid as aforesaid with legally valid provision(s) which reflect(s) the same purpose of the invalid provision(s) to the extent possible.

13.5. No Agency - This Agreement is entered into between the parties hereto on principal to principal basis. Nothing contained in this Agreement shall be construed to imply a joint venture, employment, partnership, or principal-agent relationship between the Institution/Investigator and Sponsor; and neither party hereto by virtue of this Agreement shall have the right, power or authority to act or create any obligation, express or implied, on behalf of the other party.

13.6. Assignment - The CRO may not assign any of their rights or subcontract obligations hereunder without the prior written consent of Sponsor. Even if Sponsor authorizes delegation or subcontracting in full or in part, the Institution and the Investigator remain fully responsible and liable for the performance of all delegated duties

13.7. Waiver - Any relaxation, forbearance, delay or indulgence on the part of The Company in enforcing any of the terms and conditions of this agreement, shall not prejudice, affect or restrict the rights of the Company hereunder nor shall any waiver by the Company of any breach hereof operate as a waiver of

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any subsequent or any continuing breach thereof.

14. APPLICABLE LAW AND PLACE OF JURISDICTION

14.1. This Agreement shall be governed by and construed in accordance with the laws of India, without regard to its conflict of law provisions.

14.2. Any claim or controversy arising out of or related to this Agreement or any breach hereof shall be submitted to the exclusive jurisdiction of the competent courts located at Delhi. Notwithstanding the foregoing, either Party may seek injunctive relief in a court of competent jurisdiction.

15. COUNTERPARTS

This agreement is signed and executed in Three (03) counterparts all of which constitute the original Agreement and to be retained by three the parties.

IN WITNESS WHEREOF, the Parties have signed this document with effect from the Effective date.

ACKNOWLEDGED AND AGREED BY

Dr. Niranjana. S. Mahantashetti
KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi, 590010,
Karnataka, India
Contact No: +91-9448157237

Authorized Signatory:

15/02/2019
Date

ACKNOWLEDGED AND AGREED BY

For and on Behalf of KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India
The Institution

Dr. M. V. Jali, (MD, CEO)
KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi, 590010,
Karnataka, India
Contact No. 0831 - 2473777

Authorized Signatory:

15/02/2019
Date

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ACKNOWLEDGED AND AGREED BY For CMS Clinical Research Pvt Ltd.

Name: Ms. Nidhi Singh
Title: Director Clinical Operations
Contact No.+91-7906261455

Authorized Signatory:

06/02/2019
Date

Annexure-I

Fee and Payment Schedule

I. Fees

All fees below are based on completion of certain task and recruitment of study subjects/ participant that are compliant with the Protocol.

Investigator name and address	Dr. Niranjana. S Mahantashetti, KLES Dr. Prabhakar Kore Hospital & MRC. Nehru Nagar, Belagavi-590010
Investigator Fees including overheads	INR 6.000/ subject
Subject TA	INR 500 / visit
Medical expenditure	As per actuals

All amounts stated in this Fee and Payment Schedule are inclusive of any or all applicable tax.

II. Payment

a. CRO shall make the payments in Indian Rupees according to Subject recruitment milestone achieved to Investigator.

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CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)
And
KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi(Institution)
And
Dr. Sameer Haveri (Principal Investigator)

FOR THE STUDY

Title of Study:	A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.
Protocol Number:	PMZ-2010/CT-3.1/2018
Version Number /Dated	Version 1.0/16 July 2018

ATTESTED
Sanjeev Kumar Sharma
Notary
Reg. No.-8228
Distt. Gautam Budh Nagar

Dr. Samee... Hospital &
Consultant ...
KMC Reg. ...
KLES Dr. ...
MBS ...

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on **02 Mar 2019** ("**Effective Date**") at Gautam Buddha Nagar **BY AND BETWEEN:**

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Registered Office at B-4, Sarita Vihar, New Delhi-110076 & Corporate Office at H-6, Site C, Surajpur Industrial Area, Greater Noida-201307, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**

AND

KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, an Institution having its office at Nehru Nagar, Belagavi-590010 (hereinafter referred to as **"KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre"**, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART;**
AND

Dr. Sameer Haveri a registered medical practitioner holding MCI registration number-**69382** is the Associate Professor-Department of Orthopedics, KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010 (hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART;**

Pharmazz, **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

RECITALS

1. WHERE (**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre**) is a pioneering institution of world-class investigator site in India, having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related to PMZ-2010 is a lyophilized Centhaquin Injection, as a resuscitative agent in hypovolemic shock.

3. Principal Investigator **Dr. Sameer Haveri, MS (Orthopedics)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Dr. Sameer Haveri** for conducting Clinical Trial Phase III study titled "A Prospective, Multi-

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Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.".at **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar Belagavi-590010.**

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) **"AGREEMENT"** shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists, marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) **"EFFECTIVE DATE"** shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network

ATTESTED Dr. Sa... Consultant KMC ... KLE ... Hospital &

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software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled **"A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment."** As defined in the Protocol.

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocol number PMZ-2010/CT-3.1/2018 (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"INVESTIGATIONAL DRUG"** shall mean: PMZ 2010 Lyophilized Centhaquin Injection 1.0 mg/vial"

i) **ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** Drug Controller General of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

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e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator to complete the following –

Responsibility of the KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre & Principal Investigator

The **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agrees to provide full support to the Principal Investigator at **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre , Nehru Nagar, Balagavi-590010** to conduct the Clinical Trial in **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** 's premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall be jointly and severally responsible

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a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

c) to fulfill all other terms and conditions stipulated herein and, in the Exhibits, hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial. (Exhibit G)

2.2 The Principal Investigator shall personally review all Case Report Forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/ eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analysis of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty-four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

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The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethics Committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **KLE's Dr.**

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Prabhakar Kore Hospital & Medical Research Centre as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** throughout the period of the Clinical Trial and with third party vendor or sponsor for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre.** The Pharmazz will provide the Study Drug to the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and

ATTESTED

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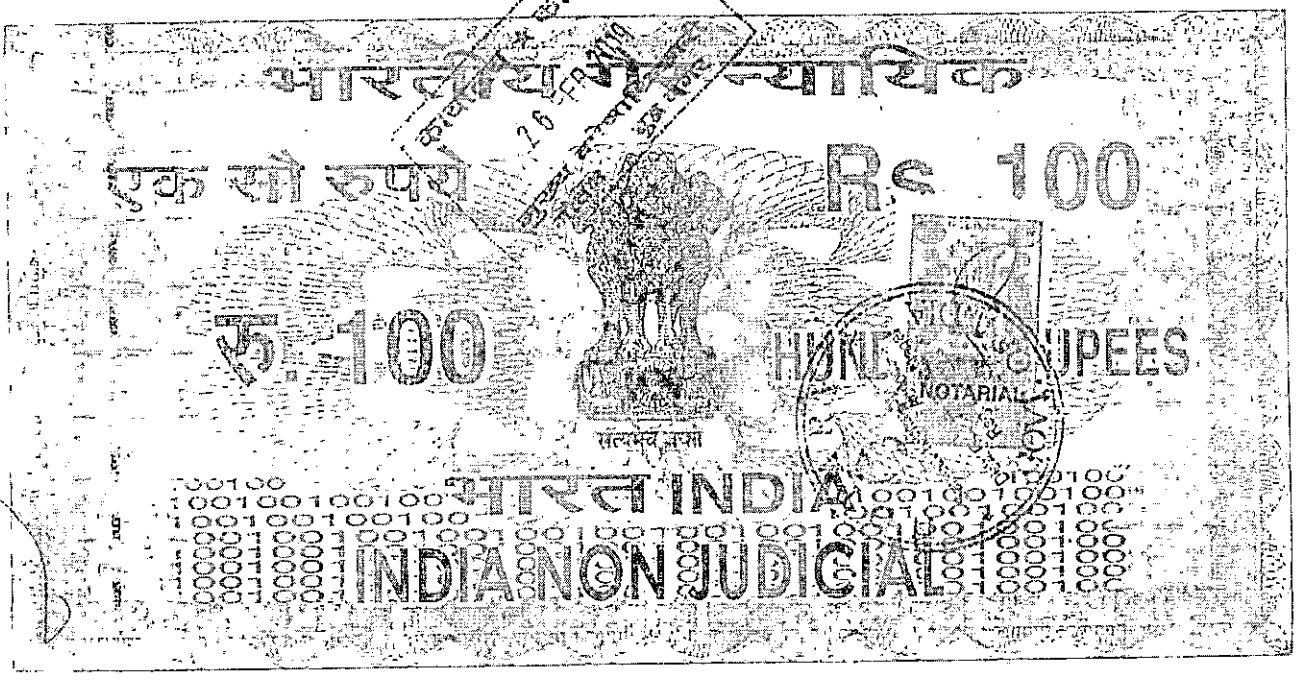

उत्तर प्रदेश UTTAR PRADESH ER 338440

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)
And
KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi(Institution)
And
Dr. Sameer Haveri (Principal Investigator)

FOR THE STUDY

Title of Study:	A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.
Protocol Number:	PMZ-2010/CT-3.1/2018
Version Number /Dated	Version 1.0/16 July 2018

ATTESTED
Sanjeev Kumar Sharma
Notary
Reg. No.-8228
Distt. Gautam Buddh Nagar

Dr. Sameer
Consultant C
KMC Reg
KLES Dr
M.D., Ped

Hospital &

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on **02 Mar 2019** ("**Effective Date**") at Gautam Buddha Nagar **BY AND BETWEEN:**

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Registered Office at B-4, Sarita Vihar, New Delhi-110076 & Corporate Office at H-6, Site C, Surajpur Industrial Area, Greater Noida-201307, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**

AND

KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, an Institution having its office at Nehru Nagar, Belagavi-590010 (hereinafter referred to as **"KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre"**, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART;**
AND

Dr. Sameer Haveri a registered medical practitioner holding MCI registration number-**69382** is the Associate Professor-Department of Orthopedics, KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010 (hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART;**

Pharmazz, **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

RECITALS

1. WHERE (**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre**) is a pioneering institution of world-class investigator site in India, having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related to PMZ-2010 is a lyophilized Centhaquin Injection, as a resuscitative agent in hypovolemic shock.

3. Principal Investigator **Dr. Sameer Haveri, MS (Orthopedics)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Dr. Sameer Haveri** for conducting Clinical Trial Phase III study titled "A Prospective, Multi-

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Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.".at **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar Belagavi-590010.**

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. **DEFINITIONS AND INTERPRETATION**

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) "**AGREEMENT**" shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists, marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) "**EFFECTIVE DATE**" shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network

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software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled **"A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment."** As defined in the Protocol.

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocol number PMZ-2010/CT-3.1/2018 (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"INVESTIGATIONAL DRUG"** shall mean: PMZ 2010 Lyophilized Centhaquin Injection 1.0 mg/vial"

i) **ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** Drug Controller General of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

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e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator to complete the following –

Responsibility of the KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre & Principal Investigator

The **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agrees to provide full support to the Principal Investigator at **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre , Nehru Nagar, Balagavi-590010** to conduct the Clinical Trial in **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** 's premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall be jointly and severally responsible

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a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

c) to fulfill all other terms and conditions stipulated herein and, in the Exhibits, hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial. (Exhibit G)

2.2 The Principal Investigator shall personally review all Case Report Forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/ eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analysis of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty-four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

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The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethics Committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **KLE's Dr.**

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Prabhakar Kore Hospital & Medical Research Centre as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** throughout the period of the Clinical Trial and with third party vendor or sponsor for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre.** The Pharmazz will provide the Study Drug to the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and

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other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.

3 **VISIT AND INSEPECTION**

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre 's** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study and audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 **RECORDS AND REPORTING**

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 **PAYMENT, PRICING TERMS**

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Dr. Sameer Haveri** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

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5.2 The Parties agree that the payment of the amount set forth in Exhibit B will be paid by the Pharmazz to the **Dr. Sameer Haveri** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Dr. Sameer Haveri** shall be paid by Pharmazz. This amount is based on the estimated number of subjects in the time duration as agreed by Principal Investigator as per site feasibility report Exhibit D. Any change in the estimated number of subjects will proportionally affect the amount of payment.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Dr. Sameer Haveri** under this Agreement. The Budget as reflected in Exhibit B is exclusive of taxes.

5.5 Site will raise GST invoices patient wise. All payments under this Agreement will be made within 30 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

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7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and PI

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b) **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking;

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** to Provide Access by the Pharmazz's Representatives All Original Medical Records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be affected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party

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and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

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The indemnity granted in this Article shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 8.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** here by irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre**; or (v) failure of the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The

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Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought, or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death during clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required.

b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

a) The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Pharmazz's activities and obligations contemplated in this Agreement.

b) The **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a professional indemnity liability insurance coverage from an Indian insurance company for the Study for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

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13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** along with its comments or modifications which shall be final and binding on the Principal Investigator/ KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third-party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

15. INTELLECTUAL PROPERTY RIGHTS

KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre agrees that all the Intellectual Property Rights with regard to **PMZ-2010** are and shall remain Pharmazz's exclusive property and understands that **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agree to keep confidential and secret all materials,

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documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form ("**Confidential Information**").

b) The Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall:

First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **KLE's Dr. Prabhakar Kore Hospital & Medical**

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Research Centre can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** or their successors or assigns;

ii. by written records were in the Principal Investigator/ KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre's possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** receives from a third party legally in a position to provide with information to the Principal Investigator/ KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or threatened) by the Principal Investigator/ **KLE's Dr. Prabhakar Kore Hospital & Medical**

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Research Centre or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

17. SEVERABILITY & WAIVER AND ASSIGNMENT

a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing.

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of

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general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre** shall have any authority to represent or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking, annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received

Dr. [illegible]
Consultant [illegible]
KLE Reg. No. 6[illegible]
Dr. Prabhakar Kore [illegible]

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and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre**	**Principal Investigator**
Mr. Sunil Gulati COO	**Dr. M. V. Jali** Medical Director	Dr. Sameer Haveri Principal Investigator
Pharmazz India Pvt. Ltd. B-4, Sarita Vihar, New Delhi- 110076 **Email:** sunil.gulati@pharmazz.com	KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010. **Email:** medicaldirector@klehospital.org	Department of Anesthesiology, KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010 **Email: drsameerhaveri@gmail.com**

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Gautam Buddha Nagar and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Gautam Buddha Nagar courts shall have exclusive jurisdiction in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and

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to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	**For KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre**	**Principal Investigator**
Signature:	Signature:	Signature: .....
Name: Mr. Sunil Gulati	Name: **Dr. M. V. Jali**	Name: Dr. Sameer Haveri
Title: COO	Title: Medical Director	Title: Principal Investigator

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Consultant Gen. Surgeon
KMC Reg. No 66392
Dr. Prabhakar Kore Hospital &

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Annexures-

1. Exhibit A- Clinical Trial Protocol
2. Exhibit B- Budget & Payment schedule
3. Exhibit C- Principal Investigator's Document
4. Exhibit D- Site Feasibility Questionnaire
5. Exhibit E- Insurance Policy for Clinical trial
6. Exhibit F- DCGI CT-NOC
7. Exhibit G- EC Registration Letter

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Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

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Exhibit B

(Budget and Payment Schedule)

Total duration of Study		Approx. 15 months
Subject enrollment duration		9 months
Total number of subjects (for all sites)		105
Payment Head		Total
Professional Fee	PI and Research Staff	25,000
Fees	Un blinded CRC	5000
Fees	Clinical Research Coordinator	8000
Institutional Overhead	25% of Professional Fee	9500
Patient Related expenses	Including Travel @1000 per visit	2000
Estimated Total Cost per trial Subject		49,500
Estimated number of trial Subject in 2 months		10
Estimated total of all subjects		4,95,000

- Professional fees include all staff related fees.
- GST invoices will be raised for the payment subject wise.

Payee Details

Payee Name	Sameer Mahammadali Haveri
Name of the Bank & Branch	State Bank of India
A/C No:	33052509079
IFSC	SBIN0008789
MICR	590002008
PAN No./TAN No,	ADKPH3464L
GST (if applicable)	NA

KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi

Dr. Sameer Haveri
Consultant Orthopaedics
KMC Reg. No. 68382
KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

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Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

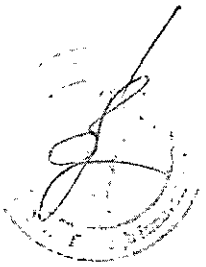

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Exhibit-D

Site Feasibility Questionnaire Filled and Accepted by PI

REFERENCE ENCLOSED

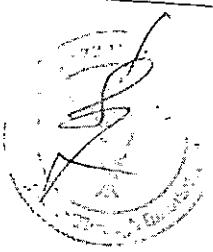

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Exhibit-E

Insurance Policy for Clinical Trial

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Exhibit-F

DCGI CT-NOC Letter

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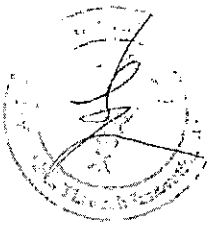
Exhibit-G

EC Registration letter

REFERENCE ENCLOSED



ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA67313628529839R
Certificate Issued Date	:	06-Mar-2019 03:13 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM30/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0866564545504921R
Purchased by	:	Dr SAMEER HAVERI
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Dr SAMEER HAVERI
Second Party	:	MD AND CE KLES DR PRABHAKAR KORE HOSPITAL BELAGAVI
Stamp Duty Paid By	:	Dr SAMEER HAVERI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Issued by
The Judicial Employees
Co-operative Credit Society Ltd.
Dist. Court Compound, Belagavi
Authorised Signatory

Please write or type below this line

TO,

THE MD & CE,

KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,

NEHRU NAGAR, BELAGAVI-590010

SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE CLINICAL TRIALS AND RESEARCH PROJECT BY DR. SAMEER HAVERI

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at www.shcilestamp.com. Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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Sir,

I **Dr.Sameer Haveri** the undersign is Principal investigator for the clinical trial"A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment."I haveco-investigator is Dr. PrakashMahantshetti and Research Coordinator is Ms. Seema Khanagaonkar.

I hereby give an undertaking that I will conduct the investigations/clinical trials as per the agreed terms and deposit 25% of the total funds (as and when received from time to time) to the second party (Medical Director & CE KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi) to the institution as mentioned in the Judicial agreement made. The payment due will be paid within 3 to 4 working days on receipt of the payment from the sponsors.

I will maintain records of all the receipts from the third party as well as payments to the second party throughout the trial period and submit a final report about the finances including institutional charges, when I conclude the trial.

Date: 11-03-2019

Place: Belagavi

Signature of PI

Dr. Sameer Haveri
Consultant Orthopaedics
KMC Reg. No. 68382
KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

ATTESTED

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Belagavi-590 010,Karnataka

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महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ AR 284803

5 MAR 2019

98206 ..... रु. रु.अक्षरी.....

दस्ताचा प्रकार .....Agreement.....

दस्त नोंदणी करणार आहेत का ? होय/नाही

मिळकतीचे वर्णन .....

मुद्रांक विकत घेणाऱ्याचे नांव Serum Institute of India Pvt. Ltd.

पत्ता .....

दुसऱ्या पक्षकाराचे नांव .....

हस्ते व्यक्तीचे नांव व पत्ता .....

किरण देवराम लाडकत
परवाना क्र. २२०११२५
मुद्रांक विकत घेणाऱ्याची सही जि.प. अंडर ग्राउंड, मंगळवार पेठ, पुणे-११

कुणा कारणासाठी सदरची मुद्रांक खरेदी केला, त्याची त्यास कल्पनासाठी मुद्रांक खरेदी केल्याचा तारीख व नोंदणीकरण आहे.

- 5 MAR 2019

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of _____ day of _____ (hereinafter "Effective Date") by and between:

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter "CRO"), acting on behalf of **Serum Institute of India Pvt. Ltd.** a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter "Sponsor");

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Dr. Niranjana Mahantshetti, Professor, Department of Pediatrics, JNMC Campus, Nehru Nagar, Belagavi, Karnataka 590010, hereinafter referred to as "Investigator"; AND

KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi is an institution functioning as per the provisions of the Societies Registration Act, 1860 having its Registered Office at JNMC Campus, Nehru Nagar, Belagavi, Karnataka 590010, represented by its Director Dr. M.V Jalli, KLE's Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar Belagavi-590010 (which expression shall where the context so admits include its successors and permitted assigns) hereinafter referred to as Institution.

CMS Clinical Research Pvt. Ltd. a company incorporated under of Companies Act 2013, having its registered office at Flat No.312, Sy No.56, Potlapally Residency, Miyapur Hyderabad- 500041 India and place of business at New Bridge Business Centre, Inox Tower, Plot-17A, Sector-16, Film city, Noida-201301 India hereinafter referred to as "Site Management Office or SMO"

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled: **"Phase 3, Randomized, Double-Blind Study to Evaluate the Immunogenicity, Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants."**, Protocol no. – PCV-10-003, Version 4, dated 25-JAN-2019 ("the Protocol") *and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;*

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **PCV-10-003**, *Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.*

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

WHERE AS, SMO is in the business of providing site management services and Institution and Investigator has approached Sponsor/CRO that it intends to appoint SMO to provide them certain site management services for this Protocol which includes ensuring overall day-to-day support for the site management and administration activities by providing the team of Clinical Research personnel including Coordinators to the institution, and performing all the protocol related and operational activities in compliance with ICH Guidelines on Good Clinical Practice, Good Laboratory Practice, including the Declaration of Helsinki, all applicable local regulation and guidelines including but not limited to Indian GCP and Schedule-Y.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth Sponsor, CRO, Investigator and Institution and SMO agree as follows.

Sponsor, CRO, Investigator and Institution and SMO are sometimes hereinafter individually referred to as a Party and collectively as Parties.

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Article 1 – The Study

1.1 The Institution, the Investigator and SMO undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time. It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Institution, the Investigator and SMO undertake to conduct the Study in an efficient and professional manner under the provisions of this Agreement and will use their best efforts to complete the Study within the time period estimated as mentioned in Schedule C.

1.3 Parties agree to coordinate the day-to-day management of the Study with each other and to comply with and perform their respective responsibilities, including identification of the lead Party for certain activities set forth in the Task Responsibility Matrix as mentioned in Schedule D.

1.4 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the Study.

1.5 The Study shall be carried out at the Institution under the review of its Ethics Committee/Institutional Review Board or an appropriate independent review committee of scientists and other qualified individuals as set forth in the Declaration of Helsinki (any such Board, body or committee to be referred to hereinafter as "IRB"), in compliance with the applicable local regulation, Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (and any subsequently approved Protocol amendments), and the terms of this Agreement and under the supervision of the Investigator.

1.6 Before commencing the Study, the Investigator will seek approval to conduct the Study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the party being referred to. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

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1.7 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.8 Institution, Investigator and SMO shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions in writing or over an email and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

1.9 Institution, Investigator and SMO shall not charge any Study Subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

1.10 The Investigator hereby warrants that he/she has received a copy of the Investigator Brochure and has read and understood its contents.

1.11 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.12 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

1.13 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution and Investigator hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.14 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer,

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cede or assign, directly or indirectly, the rights granted herein without the express written authorization of the CRO. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of Subjects into the Study shall immediately cease and decision on the continuation of Subjects already recruited in the Study will be taken jointly by CRO & Sponsor on a case to case basis.

1.15 The Institution, the Investigator and SMO shall comply with ICH/GCP, the Protocol and all applicable laws, rules, regulations and documentation of the Study (hereinafter "Regulatory Requirements") in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

(a) The Institution, the Investigator and SMO shall, as the same may be required of them by Regulatory Requirements, or specific instruction of CRO prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the Subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(b) The Institution, Investigator and SMO shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure);

(c)The Institution, Investigator and SMO shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of 'Adverse Events' and 'Serious Adverse Events' and the reporting procedure are included in the Protocol.

(d) Upon reasonable notice and at reasonable times during the term of this Agreement, Institution, the Investigator and SMO shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements. CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, Subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

(e) The Investigator will keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor) in accordance with Regulatory Requirements.

1.16 Institution, Investigator and SMO agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

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1.17 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.18 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution, Investigator and SMO may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.19 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study Subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study Subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.20 Institution/Investigator/SMO agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the Subjects in accordance with the requirement set out in the Protocol.

1.21 Institution/Investigator agree that they shall be jointly and severally responsible for securing all the performance and any or all the breaches, acts, actions, non actions, inactions taken by and/or non performance by SMO during the course of this agreement for the task(s) delegated by Institution/Investigator to SMO time to time. Institution/Investigator agree that they shall notify the Sponsor/CRO immediately upon discontinuation of the services of SMO under this Agreement if any. Institution/Investigator agree further that such discontinuation of the services of SMO if any under this Agreement, shall not have any impact on the Study to be conducted by Institution and Investigator.

Article 2 – Compensation

2.1 Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2.2 The Investigator /Institution/SMO shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

2.3 In full and complete consideration of Investigator's, Institution's and SMO's participation in the Study and of their covenants and obligations hereunder, and to cover

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their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B hereto. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities.

2.4 Institution agrees to apply all funds received from CRO, including all interest accrued on such funds, if any, toward the performance of the Study. Within the Study Budget as provided in Schedule B, Institution may adjust budget line item amounts as reasonably necessary for performance of this Agreement; provided, however, that such adjustments shall not exceed ten percent (10%) of any line item without the prior written approval of Sponsor. Without the prior written approval of Sponsor/CRO, the total payments to Institution shall not exceed the amounts set forth in the Study Budget.

2.5. If a Subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

2.6 For all Subjects who fail to get enrolled (Screen failure), the amount payable will be Rs. 3000 per Subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 20% of randomized Subjects at site.

2.7 There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

2.8 All payment obligations are conditioned upon Institution's, Investigator's and SMO's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator/SMO will repay to CRO any payments for Study visits, procedures, or other work associated with a Study Subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the Subject was not conducted by Investigator, sub investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

2.9 Investigator, Institution and SMO are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution/SMO under this agreement.

2.10 The payments represent all Study costs, and no other money will be payable by CRO.

2.11 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator

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/ Institution directly or through SMO. Invoices shall be addressed to CRO and be sent at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.
702, Dosti Pinnacle, Wagle Estate
Thane – 400 604, India
Ashish S. Rasam (Project Manager)
Phone: +91 22 67776354/ Mb: 9833067704
Email: ashish.rasam@diagnosearch.com

Mandar Vaidya
Director – Operations
Phone: + 91 22 67776314
Email: mandar.vaidya@diagnosearch.com

2.12 All amounts payable to the SMO/Investigator / Institution will be subject to Tax Deduction at source as required by the relevant tax provisions

2.13 It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - **"Supply to SEZ Unit or SEZ Developer for *Authorised Operations* under Bond or Legal Undertaking without payment of *Integrated Tax*."** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - **"Supply to SEZ Unit or SEZ Developer for Authorised Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and Sponsor will not reimburse GST paid."** Further these invoices should also mention GSTIN No 27AABCS4225M2Z6 of our SEZ unit.

(iii) However, Client shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.14 Cheques should be drawn by CRO and made payable to CMS Clinical Research Pvt. Ltd. and delivered to the following address:

Kind Attn: Dr. Anit Singh, MD
CMS Clinical Research Pvt. Ltd,
New Bridge Business Centre, Inox Tower, Plot-17A,
Sector-16, Film city, Noida-201301

2.15 Payments of invoice amount by CRO to SMO as prescribed under Clause 2.14, against the invoices raised by Institution /Investigator, shall be the valid discharge of the

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payments obligations by Sponsor/CRO under this Agreement. Neither Institution nor Investigator, shall raise any dispute to Sponsor/CRO about the non or inappropriate receipt of the amount from SMO as contemplated under this agreement. Also the non receipt of the amount from SMO shall not be a ground for the Institution and/or Investigator to discontinue the performance or termination of this agreement.

2.16 Institution/Investigator agree that it shall be their exclusive responsibility to settle service charges to SMO for the services performed during the course of this agreement for the task(s) delegated by Institution/Investigator to SMO without recourse to Sponsor/CRO.

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator , sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator shall deal with all issues relating to the employment or engagement of the Institution/Investigator staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

3.3 The Investigator and the Institution will take appropriate steps to inform each physician, Study staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement. "**Study Staff**" mean the individuals providing services under the supervision of the Investigator with respect to the conduct of the clinical study, including without limitation sub-investigators, study coordinators, and other trial Site employees, agents, any support staff etc.

3.4 During the term of the Agreement, Institution, Investigator and SMO agree to permit representatives of the CRO and the Sponsor to examine at any reasonable time during normal business hours the facilities where the Study is being conducted, the Study data including original patient records and any other relevant information necessary to confirm that the Study is being conducted in conformance with the Protocol and in compliance with applicable laws and regulations. Institution, Investigator and SMO shall notify Sponsor / CRO in writing within three (3) business days of becoming aware of any FDA or other government inspection or inquiry concerning the Study or within twenty four (24) hours of any surprise government inspection or inquiry concerning the Study. Investigator, Institution and SMO agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

ATTESTED

Dr. V.A.Kothiwale
Registrar

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB/IEC.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data generated hereunder shall become the property of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution. Investigator and SMO shall provide such expense statements /reports to Sponsor as CRO /Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one (1) year thereafter, Investigator and each Sub-investigator shall update such forms promptly and provide same to CRO/Sponsor as may be requested by Sponsor or whenever any material change occurs in the information disclosed by a previous form.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of fifteen (15) years from conclusion of the Study. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 All Study data and reports and any other information that generated, provided to and created by Investigator or Institution or SMO, in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times. The Parties hereby agree that, subject to the applicable laws and requirements and each Party's rights and obligations under this Agreement Sponsor shall be the sole owner of all the information mentioned above and shall have the unrestricted right during and after the term of this Agreement, to use the same for any purpose. "Study data" shall mean all records and reports, (other than Study Subject's medical records). generated, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) etc.

4.8 The Investigator agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Bond

Indian-Non Judicial Stamp
Haryana Government

Date :01/04/2019

Certificate No. G0A2019D461

GRN No. 45348385

Stamp Duty Paid : ₹ 101
(Rs. Only)

Penalty :₹ 0
(Rs. Zero Only)

Deponent

Name: Kendle India Pvt ltd
H.No/Floor : Na
City/Village : Gurugram
Phone : 0

Sector/Ward :
District : Gurugram

Landmark : Na
State : Haryana

Purpose : AGREEMENT **to be submitted at Concerned office**

Confidential

SITE MANAGEMENT ORGANIZATION SERVICES AGREEMENT

Protocol # XBR1001 ("Protocol")

"Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration" ("Trial")

This SMO Services Agreement ("Agreement"), dated as of the date of last signature and effective as of 25/May/2019 ("Effective Date") between

Syneos Health UK Limited, with principal offices located in the United Kingdom at Farnborough Business Park, 1 Pinehurst Road, Farnborough, Hampshire, GU14 7BF, including its affiliates, subsidiaries, and specifically its parent company Syneos Health, LLC ("CRO")

and

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, with a place of business at **Nehru Nagar, Belagavi-590010, Karnataka, India** ("Institution")

and

Dr. Smitha K S, with a place of business at **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India** ("Principal Investigator").

and

Ardent Clinical Research Services with a place of business at **Office No. 318, 3rd Floor, Next to Franklin Institute, Connaught Place, Bund Garden Road, Pune-411001.** ("SMO Service Provider").

"Party" means CRO, Institution, Principal Investigator or SMO Service Provider equally, and "Parties" shall mean all of them.

ATTESTED

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BACKGROUND

By separate agreement, Xbrane Biopharma with a principal place of business at Banvaktsvägen 22, 171 48 Solna, Sweden ("Sponsor") has engaged Syneos Health, LLC, a contract research organization, with a principal place of business in the United States at 1030 Sync Street, Morrisville, North Carolina 27560 USA acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including but not limited to negotiations and execution of the Agreement and payment administration for services performed and described hereunder.

WHEREAS Sponsor wishes to support the Institution and Principal Investigator need of service listed under Attachment A (Services) and Institution and Principal Investigator desire to engage SMO Service Provider to provide such service to the Institution and Principal Investigator.

In consideration of the mutual promises and benefits contained in this Agreement, the SMO Service Provider agrees to provide services ("Services") as described in Attachment A to this Agreement and contained in the Protocol for the patients enrolled in the Trial by the Principal Investigator at the Institution ("Trial Subjects") as follows:

1. Services. SMO Service Provider shall and shall ensure that SMO Service Provider's personnel performing the Services (including but not limited to Trial Nurses, technicians, Trial Coordinators as understood from Attachment A) ("SMO's Staff"), perform the Services in accordance with all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (2013), all applicable laws and guidance relating to clinical trials of medicines and all applicable laws relating to human rights, supply of medicines legislation, legislation relating to human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of Trial Subject information inclusive but not limited to the EU General Data Protection Regulation - GDPR ("Applicable Law") and Principal Investigator's reasonable instructions. Principal Investigator is responsible to ensure that the SMO's Staff are qualified by training and education to perform study tasks delegated by the Principal Investigator to the SMO's Staff; as well for the initial and ongoing study training of the SMO's Staff. Furthermore the Principal Investigator is responsible for the oversight of the SMO Service Provider's activities ensuring they are conducted according to the Protocol, Agreements and any study specific instructions as well as per the regulatory requirement and ICH GCP. The Services shall be performed at location mutually agreeable to SMO Service Provider and Sponsor. SMO Service Provider acknowledges that the Sponsor will own the results of the Services hereunder.

2. Payment.

2.1. Compensation for Services provided under this Agreement will be made by way of payments in accordance with Attachment B (Payment Terms) and Attachment C (Financial Arrangements Worksheet).

2.2. All Parties acknowledge that amounts set forth in Attachment B represent fair market value of the services provided by Institution and Principal Investigator or SMO Service provider and SMO's Staff for conducting the Trial to the best of their knowledge. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the Parties. Neither the Institution and Principal Investigator nor SMO Service provider or SMO's Staff will directly or indirectly seek or receive compensation from Trial Subjects or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Sponsor or its designee, including, but not limited to, Sponsor or comparator drugs, Trial Subject screening,

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infusions, physician and nurse services, diagnostic tests, and Sponsor drug and/or comparator drug administration. Once the designated payees have been paid for the performance of the Trial, neither CRO nor Sponsor shall have any further obligation or liability whatsoever to pay Institution and Principal Investigator or SMO Service provider and SMO's Staff. If any dispute arises as to distribution of payments, SMO services provider and affected payees shall attempt to resolve such dispute in good faith. Pending such resolution, CRO may retain any disputed funds or further payments.

3. Term and Termination.

3.1. This Agreement shall be deemed to have commenced on the Effective Date, and shall continue until the Services are completed to Sponsor's reasonable satisfaction unless earlier terminated as provided below.

3.2. Sponsor reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to SMO Service Provider.

3.3. Sponsor further reserves the right to terminate the Trial immediately upon written notification to SMO Service Provider for causes that include: (i) material unauthorized deviations from the Protocol or reporting requirements; (ii) circumstances that in Sponsor's opinion pose risks to the health or wellbeing of Trial subjects; (iii) or regulatory agency actions relating to the Trial or the Sponsor drug or comparator drug; (iv) the SMO's Staff fails to provide service satisfactory to the Principal Investigator/ Institution and the SMO Service Provider fails to correct such failure by coaching the SMO's Staff or by replacing SMO's Staff with acceptable personnel within the prescribed time as outlined by CRO in writing; (v) SMO Service Provider fails to provide Services in accordance with Attachment A of this Agreement or materially breaches any provision of this Agreement.

4. Obligations of SMO Service Provider.

4.1. SMO Service Provider shall pay all wages, all taxes, social security, other employment benefits and severance payment (if any) to SMO's Staff according to local laws and regulations.

4.2. SMO Service Provider shall be fully responsible for handling the contribution to SMO's Staff taxation and pension.

4.3. SMO Service Provider shall assist Principal Investigator in evaluating SMO's Staff performance and in communicating with and counseling SMO's Staff.

4.4. SMO Service Provider may not reassign the conduct of the Trial to a different SMO's Staff without prior written authorization from Principal Investigator. Any replacement of SMO's Staff will be required to agree to the terms and conditions of this Agreement in a separate writing. In the event Sponsor or Principal Investigator does not approve a replacement SMO's Staff, CRO, on behalf of Sponsor, may terminate this Agreement in accordance with the Termination provisions above.

4.5. SMO Service Provider will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with Applicable Law and guidelines relating to clinical trials for all SMO's Staff conducting the Trial.

5. Personal Data Protection and Privacy. The Parties recognize a common goal of securing all personal data and holding such information in confidence and protecting it from unauthorized disclosure. The Parties represent and warrant that they will comply with the provisions of Applicable Law relating to the confidentiality, privacy and security of such personal data. In addition, the SMO

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Service Provider shall comply with the following provisions:

5.1. Authorization to Use and Disclose Health Information. Institution and Principal Investigator shall provide an appropriate privacy notice to each Trial subject and obtain a written privacy authorization from each Trial subject, complying with Applicable Law, which will enable Institution and Principal Investigator to provide Sponsor and other persons and entities designated by Sponsor access to completed case report forms ("CRFs"), source documents and all other information required by the Protocol. If such an authorization is separate from the informed consent form ("ICF"), Institution and Principal Investigator will only use the authorization that is approved by Sponsor, independent ethics committee and/or applicable regulatory authority (if applicable).

5.2. Use of Trial Subject Personal Data. SMO Service Provider will use the personal data obtained from the Trial subjects in connection with the Trial for no purposes other than outlined in the Protocol and shall manage such personal data in accordance with Applicable Law.

5.3. Disclosure of Trial Subject Personal Data. SMO Service Provider shall not disclose personal data to CRO or the Sponsor except as is required to satisfy the requirements of the Protocol, for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by a Trial subject in connection with the Trial. In all such cases of disclosure, the SMO Service Provider shall respect the "data minimization" principle of privacy, including but not limited to the following example: actual Trial subject names shall not be included on any invoices for payment submitted by the designated payees.

5.4. Personal Data of the SMO's Staff, the Principal Investigator, other research staff and other employees/contractors of the SMO Service Provider and Personal Data of CRO's employees/contractors.

a. Both prior to and during the course of the Trial, the Institution, the Principal Investigator, the SMO Service Provider, the SMO's Staff and other employees/contractors of the SMO Service Provider may be called upon to provide personal data about the SMO's Staff, the Principal Investigator, other research staff and other employees/contractors of the SMO Service Provider to the Sponsor and other third parties involved in the conduct of the Trial, including CRO. Such personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and/or information relating to payments made pursuant to this Agreement. The SMO Service Provider shall provide the information reasonably requested by Sponsor and/or CRO and shall authorize the processing and storage of certain personal data about SMO's Staff, the Principal Investigator other research staff and other employees/contractors of the SMO Service Provider to the extent permitted by Applicable Law for the following purposes:

(1) the conduct of clinical trials;

(2) verification by government or regulatory agencies, the Sponsor, CRO, and their agents and affiliates;

(3) compliance with legal and regulatory requirements;

(4) publication on www.clinicaltrials.gov and other websites and/or databases that serve a comparable purpose;

(5) storage in databases to facilitate the selection of investigators for future clinical trials; and

(6) anti-corruption compliance.

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SMO Service Provider shall give an appropriate privacy notice and obtain consent as required from SMO's Staff and other employees/contractors of the SMO Service Provider for the processing of their personal data under Applicable Law.

b. SMO Service Provider shall process personal data relating to CRO's employees/contractors only to the extent, and in such a manner as is necessary for the purposes of this Agreement. The SMO Service Provider shall not transfer personal data relating to CRO's employees/contractors to a third party without the prior written consent of CRO.

c. Each Party warrants that it will take technical and organizational measures against unauthorized or unlawful processing, accidental loss, destruction, and/or damage of personal data from another Party.

6. Confidentiality.

6.1. During the course of the Trial, SMO Service Provider may receive or generate information that is confidential to Sponsor or a Sponsor affiliate.

6.2. Definition. Except as specified below confidential information ("Confidential Information") includes all information provided by Sponsor or CRO, or developed for Sponsor, Inventions (hereinafter defined), and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with the Sponsor, commercialization and Trial strategies, trade secrets and know-how disclosed by Sponsor to SMO Service Provider directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

6.3. Exclusions. Confidential Information does not include information that is: (i) in the public domain prior to disclosure by Sponsor or CRO; (ii) becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by SMO Service Provider; (iii) is already known to SMO Service Provider at the time of disclosure and is free of any obligations of confidentiality; (iv) or is obtained by SMO Service Provider, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

6.4. Obligations of Confidentiality. Unless Sponsor provides prior written consent, SMO Service Provider may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may SMO Service Provider disclose Confidential Information to any third party except as authorized in this Agreement or as required by Applicable Law. Required disclosure of Confidential Information to the independent ethics committee or to an applicable regulatory authority is specifically authorized.

6.5. Disclosure Required by Applicable Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as SMO Service Provider notifies Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

6.6. Survival of Obligations. For Confidential Information other than Trial data, these obligations of non-use and nondisclosure survive termination of this Agreement and continue for a period of five (5) years after termination.

6.7. Return of Confidential Information. If requested by Sponsor or CRO in writing, SMO Service Provider will return all Confidential Information except that required to be retained at the SMO

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Service Provider by Applicable Law. However, SMO Service Provider may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

6.8. General Data. All documents, protocols, data, know-how, methods, operations, formulas and Confidential Information provided to SMO Service Provider are and shall remain Sponsor's sole property.

7. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), SMO Service Provider will promptly inform Sponsor. SMO Service Provider will assign all interest in any such Invention to Sponsor, free of any obligation or consideration beyond that provided for in this Agreement. SMO Service Provider will provide reasonable assistance to Sponsor in filing and prosecuting any patent applications relating to Invention, at Sponsor's expense.

8. Representations and Warranties.

8.1. SMO Service Provider represents and warrants that it is not bound by any other agreement, which could prevent, or be violated by, or under which there would be a default as a result of, the execution and performance of this Agreement and SMO Service Provider will not enter into any such conflicting agreements during the term of this Agreement.

8.2. Neither SMO Service Provider nor any SMO's Staff nor any of its independent contractors, or subcontractors providing Services in connection with the performance of this Agreement on behalf of SMO Service Provider has been debarred or disqualified as a professional under the provisions of any Applicable Law. In the event that, during the term of this Agreement, SMO Service Provider or any SMO's Staff or any of its employees, independent contractors, or subcontractors providing services in connection with the performance of this Agreement on behalf of SMO Service Provider is debarred or disqualified or receives notice of an action or threat of an action with respect to debarment or disqualification, SMO Service Provider shall notify CRO and Sponsor immediately.

9. Indemnification.

9.1. SMO Service Provider shall defend, indemnify and hold harmless Sponsor and its affiliates, shareholders, officers, directors, employees, agents, successors and assigns (collectively, the "Sponsor Indemnities") from and against any and all liabilities, claims, actions or suits resulting from any third party claim made or suit brought against Sponsor Indemnities arising out of:

a. the gross negligence or wrongful act or omission of SMO Service Provider or any individual acting on behalf of SMO Service Provider in the performance of this Agreement, or

b. any breach of this Agreement by Service Provider.

9.2. SMO Service Provider further agrees to indemnify and hold harmless the Sponsor and its affiliates, Institution and Principal Investigator against any and all liability for claims by an employee or independent contractor of SMO Service Provider asserting an employment relationship with Sponsor.

9.3. The Parties agree that CRO expressly disclaims any and all liability whatsoever in connection with payments distribution done by SMO Service Provider, the Sponsor drug or the Protocol except to the extent that such liability arises from CRO's negligent act, omission or willful misconduct.

9.4. The obligations of this clause shall survive termination of this Agreement.

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9.5. Sponsor agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Trial investigators; any institution at which the Trial is conducted, SMO, its officers, agents, and employees; and the IEC and/or RA that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities and/or expenses arising out of a Trial Subject Injury (hereinafter defined), the design of the Trial, or the specifications of the Protocol and for which the Sponsor is legally liable.". Trial Subject Injury means a physical injury or drug-related psychiatric event caused by administration or use of the Sponsor Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial ("Trial Subject Injury"). Sponsor further agrees to reimburse Institution, SMO and/or Principal Investigator for the actual cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject Injury and which otherwise would have been charged to the Trial Subject. Sponsor further agrees that in case of trial related injury or death of any study subject financial compensation will be provided by the Sponsor in accordance with the Indian regulations based on the final order received from the regulatory authority of India. Institution, SMO and Principal Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any Trial Subject Injury. Institution,SMO and Principal Investigator further agree to promptly notify Sponsor of any Trial Subject Injury.

10. Independent Contractor. The relationship of SMO Service Provider to Sponsor is one of independent contractors and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

11. Sponsor as Third Party Beneficiary. The Parties to this Agreement recognize and agree that Sponsor takes the benefit of this Agreement as a third party beneficiary and agree that Sponsor may enforce such rights either directly itself or indirectly through CRO.

12. Consequential Damages. Neither Sponsor nor CRO shall be responsible to SMO Service Provider for any lost profits, lost opportunities, or other indirect, consequential or other punitive damages.

13. Force Majeure. Neither Party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other Party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) calendar days, then the Parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

14. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing.

Sponsor:
Xbrane Biopharma
Banvaktsvägen 22,
171 48 Solna, Sweden
Attention: Dina Jurman, M. Sc.
Telephone: +46 70 266 84 58
Email: dina.jurman@xbrane.com

With a copy to:
Syneos Health, LLC

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka
520

1030 Sync Street
Morrisville, North Carolina 27560 USA
Re: Project Code 1009980
Attention: Site Contracts Department

Ardent Clinical Research Services
Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune-411001
Pune, Maharashtra 400001, INDIA
Attention: Mr. Chandu Devanpally
Telephone: 09545817447
Email: cdevanpally@ardent-cro.com

Institution:
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre
Nehru Nagar, Belagavi-590010, Karnataka, India Belagavi-590010, Karnataka, India
Attention: DR. M. V. JALI, Medical Director and Chief Executive
Telephone: 0831 247 3777
Email: kleguag@klehospital.org

Principal Investigator:
Dr. Smitha K S
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre: Nehru Nagar, Belagavi-590010, Karnataka, India
Belagavi-590010, Karnataka, India
Telephone: 08312470400
Email: smt_ks@rediffmail.com

Any Party may change its address or number for notice by giving notice in accordance with this Section 14.

15. Miscellaneous Provisions.

15.1. In case any one or more of the provisions of this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Agreement shall not in any way be affected or impaired.

15.2. No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

15.3. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

15.4. This Agreement represents the entire and integrated agreement between the Parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

15.5. This Agreement shall be construed, interpreted and enforced in accordance with the laws of India.

[SIGNATURE PAGE FOLLOWS]

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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In the event that the Parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the Parties agree that, upon being signed by all Parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence of a binding agreement with the expectation that original documents may later be exchanged in good faith.

Agreed to and accepted:

PRINCIPAL INVESTIGATOR

Signature

Printed Name - Dr. Smitha K S

Title - Principal Investigator

Date 12/Jun/2019

CRO

Signature

Printed Name – Inderbir Singh

Title –Senior Director , Data Management

Date 07/JUN/2019

INSTITUTION

Signature

Printed Name - Dr. M V Jali

Title - Medical Director and Chief Executive

Date

Dr. M. V. JALI
MD. FRCP (London)
Medical Director & Chief Executive
Chief Consultant & Diabetology
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre,
Belagavi.

SMO SERVICES PROVIDER

Signature

Printed Name - Chandu Devanpally

Title - Director

Date 12 | June | 2019

ATTESTED

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Belagavi-590 010,Karnataka

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ATTACHMENT A

SERVICES

A-1. Project feasibility, investigator selection, submission of documents for Institutional Review Board or Independent Ethics Committee (IRB/IEC) approval, patient follow-up, supply of study coordinators, human resource management

A-2. For payment term, refer to attachment B and C

ATTESTED
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ATTACHMENT B

PAYMENT TERMS

B-1. General Terms. Payee (hereinafter defined) will be compensated as outlined on Attachment C for Trial Subjects properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator. SMO Service provider and SMO's Staff, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled in the Trial in violation of the Protocol.

B-2. Payment Terms. Payments for each Trial Subject will be made quarterly and based on CRF data entered by Institution and/or Principal Investigator supporting enrolled Trial Subject visitation. Institution and/or Principal Investigator will make all reasonable efforts to ensure data entry is completed within forty-eight (48) hours of the patient visit completion. Payments will be made for completed visits and treatment related costs in accordance with Attachment C, unless otherwise noted in the Agreement. For each payment, including any Screen Failures (as defined below) that may be payable under the terms of this Agreement, Payee will be paid the total amount earned, less 10%, for the Final Payment (hereinafter defined). On-site monitoring will occur approximately every three (3) months based on site enrollment and completion of data entry. Institution and/or Principal Investigator agree to conduct expedited data entry and query resolution for Interim Analysis as defined in the Protocol in addition to final database lock. This also includes submission of relevant images to the central reading center and query resolution. The site monitor will communicate with the Institution and/or Principal Investigator with regards to expected timelines in such cases.All queries must be resolved within five (5) business days of receipt by Principal Investigator, SMO Service provider and/or SMO's Staff any time during the Trial. Payee must submit any final invoices within thirty (30) calendar days after the close-out visit of the Trial at the Institution. Any invoices received thereafter may not be paid. Payee will have sixty (60) calendar days after the date of the close-out visit of the Trial at the Institution to dispute any payment discrepancies or missing payments.

B-3. Pass-Through Payments from Sponsor. Payments due under this Agreement are pass-through payments from Sponsor that will be sent after such payments are received by CRO from Sponsor. CRO shall have no liability for any failure to make payments if required funding is not provided to CRO in advance by Sponsor.

B-4. Non-Procedural Costs. Payee will be paid for additional non-procedural costs that are pre-approved by Sponsor, as set forth in Attachment C. To request payment for such costs, Payee will remit an itemized invoice to Sponsor or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment C.

B-5. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Sponsor review. The final payment ("Final Payment") will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Sponsor Drug is returned; and all close out issues are resolved and procedures completed, including final independent ethics committee and/or applicable regulatory authority notification, if applicable. All queries must be resolved within five (5) business days of receipt by /Principal Investigator, SMO Service provider and/or SMO's Staff. Sponsor or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any. Payee will promptly reimburse Sponsor any unearned or overpaid amounts previously paid to Payee within thirty (30) calendar days of notification by Sponsor or designee.

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi

B-6. Taxes.

(1) Payments shown in Attachment C do not include good and services tax (" GST "). If the Payee is GST registered, and if GST is required under the Applicable Law, GST should be added and shown on the invoice by the Payee at the applicable GST rate, along with Payee's GST registration number. If GST reverse charge mechanism applies under Applicable Law, Payee will not add GST to the invoice, and the appropriate wording should be displayed on the invoice in accordance with Applicable Law.

(2) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable authority with respect to or measured by compensation paid to Payee under this Agreement. CRO or Sponsor will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this Agreement, to the relevant taxation authorities as required by Applicable Law.

B-7. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial ("Screen Failure"). Screen Failures will be reimbursed, if at all, as outlined in Attachment C.

B-8. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures not covered under Attachment C. Payment for any necessary procedure due to Trial Subject safety will be reimbursed at the agreed upon unit cost in Attachment C, if available, or if there is no such unit cost in Attachment C, Payee will be compensated based on actual costs incurred by Principal Investigator, SMO Service provider and/or SMO's Staff, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Sponsor's or CRO's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Sponsor will be notified as soon as practicable after the fact.

B-9. Payee. The payments will be made to the following Payee and address:

Payee Name: Ardent Clinical Research Services
Payee Address: Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune-411001
Payee Tax Identification Number: 27APQPD7081M1Z9

Payee Bank Account Details:
Bank Name: HDFC Bank
Bank Address: B.T.Kawade road, Ghorpadi, Pune, Maharashtra, INDIA, 411 001,
Bank Account Number: 50200007013912
IBAN Number: NA
SWIFT Code: HDFCINBBPNE
Email address for remittance information: cdevanpally@ardent-cro.com

In case of changes in the Payee's bank account details, Payee is obliged to inform CRO in writing, but no amendment to this Agreement shall be required.

B-10. Invoices. All invoices must be issued and forwarded to the following as instructed:

Attn. Investigator Payment Department
Syneos Health UK Limited
Farnborough Business Park
1 Pinehurst Road
Farnborough
Hampshire

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

ગુજરાત गुजरात GUJARAT

નંબર : 8074 રૂા.

BU 452991

તારીખ : 8 APR 2019

નામ : LAMBDA THERAPEUTIC RESEARCH LTD.

ઠેકાણું : Plot No. 38, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad

કે. આર. ચાવડીયા
લા. નં. એસ. બી. ૨૪૬, ૨૪૭/૧૯૯૬
અમદાવાદ નારણપુરાના સહીંતી
લેનારની સહી.....

Clinical Trial Agreement

BETWEEN:

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey No 388,
Near Silver Oak Club, S G Highway, Gota,
Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for
Intas Pharmaceuticals Limited
Intas Pharmaceuticals Ltd.,
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad-380 054, India
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

Dr. A. Uppin, Belagavi

LAMBDA Research Accelerated

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

AND

Dr. Archana M. Uppin
KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar, Belagavi-590010,
Karnataka .
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar,
Belagavi-590010,
Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey No 388,
Near Silver Oak Club, S G Highway, Gota,
Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for
Intas Pharmaceuticals Limited
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Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad-380 054, India
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND

Dr. Archana M. Uppin
KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar, Belagavi-590010,
Karnataka .
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar,
Belagavi-590010,
Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

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Belagavi-590 010,Karnataka

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WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.;

Intas Pharmaceuticals Limited. Has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs ."** and,

The Principal Investigator, having reviewed the Protocol for the Clinical Trial, the Investigator brochure / Prescribing information and sufficient information regarding the Investigational Product in order to evaluate and determine its interest in participating in the Clinical Trial, wishes to participate in the Clinical Trial and the Principal Investigator assures that he/she has sufficient authority, Competence and experience in conducting clinical trials.

The Institution has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Principal Investigator; and the Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1. Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	Test Product (T) = Tacrolimus lipid tablets 1 mg. Reference Product (R) = Prograf 1 mg, three capsules.
"CRF"	means the case report form in a format prepared by Sponsor and documenting the administration of the Investigational Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;
"CRO"	Contract/Clinical Research Organization

"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and its latest amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP & study protocol.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.
Agent	shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise, to include without limitation any pharmacist, clinical chemist, nurse or other health professional.
Agreement	means this agreement comprising its clauses, schedules and any appendices attached to it, including the Protocol and including any amendments to the Agreement agreed between the Parties;
Auditor	means a person who is authorized to carry out a systematic review and independent examination of clinical trial related activities and documents to determine whether the evaluated clinical trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the applicable regulatory requirements
	means the investigation to be conducted at the Trial Site in accordance

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LAMBDA

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Belagavi-590 010,Karnataka

Clinical Trial	with the Protocol
Clinical Trial Subject	means a person enrolled to participate in the Clinical Trial
Confidential Information	means information provided by a Party (the Disclosing Party) to the other Party (the Receiving Party) or to any other of such Receiving Party's employees or agents, and means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of the Disclosing Party or the Disclosing Party's Affiliates that are provided in connection with this Agreement or the Clinical Trial. Sponsor's Confidential Information shall include Clinical Trial data, results, or reports created by Institution, Principal Investigator, or Research Staff in connection with the Clinical Trial (except for a Clinical Trial Subject's medical records); and cumulative Clinical Trial data, results, and reports from all sites conducting the Clinical Trial
Intellectual Property Rights	means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
Investigational Product	means the Study Drug identified above and the control material, as further detailed in the Protocol;

2. Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the

Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 10 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s) , confirmation of adequate site facilities, etc.);

b) progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) ensuring direct access by monitors, auditors and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure.

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol.

i) In case if any of the delegated research staff at site gets relieved from his/ her services the Investigator/ Institution shall appoint the relevant function or make the alternate arrangement in shortest possible time so as the trial related activity does not get affected.

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j) The Investigator / institution shall make and retain records (study documents including source data/patient medical documents) of the Clinical Trial as required by the Protocol, applicable Law, and in accordance with the Institution's standard archiving procedures (SOP). Institution will retain such records for a minimum of fifteen (15) years from the date of database closure or as per the local regulatory requirements. Such archival shall be done either at the institution or at the third party agency. At least Sixty (60) days prior to the expiry of such retention period, Sponsor/ CRO will contact Institution. If requested by Sponsor/CRO, Institution shall retain the records for a longer period of time at Sponsor's expense.

k) Place of archival of retention records and the amount incurred should be discussed during the CTA execution as per Institution's standard archiving procedures (SOP). Cost of Archival fees, if applicable will be paid at the time of close out before close out visit as agreed and mentioned in CTA or as per site SOP.

l) If any services or activities including the diagnostic test or clinical procedure required by the protocol are being outsourced by Investigator /Institution to the other facilities/ institutions then this should clearly be documented via an agreement / MOU. The Investigator /Institution shall provide LAMBDA with a copy of the said agreement / MOU.

2.8 All SAEs has to be promptly reported by the Investigator to Regulatory, LAMBDA and/or Sponsor and to the Ethics Committee. The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation i.e. within 24 hours (of occurrence or knowledge or becoming aware) to applicable regulatory, LAMBDA/Sponsor, IEC and Institution by Investigator; and further follow up reporting will be done as per the regulatory guidelines prescribed in Schedule-Y(of occurrence or knowledge or becoming aware) to ethics committee and Regulatory Authority (DCGI) via first draft report. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

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2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3. **CRO responsibilities**

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI, and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Sponsor/Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4. **Performance standards of the work to be conducted by the Investigator**

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least 03 eligible Patients within **01** month; minimum expected recruitment rate from the site is **02 to 03 For PK Patients & 04 to 05 for Non PK Patient in 01 months** on average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of **08** months depending on the complexity of the project and date of initiation; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

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2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3. CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI, and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Sponsor/Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

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"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

LAMBDA Research Accelerated ATTESTED

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4.2 In the event that the study is part of a multi-center, multi-national trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within 3 working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5. **Payment terms**

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B.

5.2 3 Original wet ink copies of the CTA would be in place.

6. **Period of validity of the Agreement**

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

a) Archival of study documents including source data as referred to in para 2.7 & 14
b) Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
c) Confidentiality as per para 11

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6.3 In case of early termination of trial at site, due to any clause, data and documents are to be archived at Site (PI's /Institution /third party). This shall be discussed during the execution of CTA and should be clearly documented in the CTA. . The said data must be archived for at least fifteen (15) years or for the period required by applicable regulatory authority following termination of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements. In case of early close out/termination the validity of the agreement would remain for 5 years

7. **Data ownership / Intellectual property rights**

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will

execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor

8. Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9. Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor (on behalf of LAMBDA) will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor (on behalf of LAMBDA) will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor (on behalf of LAMBDA) will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10. Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

11. Confidentiality

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise

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mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

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11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12. Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13. Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14. Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

a) Investigator or Institution fails to recruit patients within **60 days** of site initiation visit.
b) The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
c) Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
d) LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
e) The total number of patients required to be randomised is reached before the end of the recruitment period.
f) The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
g) The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA. On termination / completion of trial or expiration of this Agreement all unused Investigational Product shall, either be returned to the Lambda Pharmacy /
Sponsor or disposed of in accordance with the Protocol or the Sponsor's written Instructions.

14.1 On Completion, Early Termination of the Trial:

a) Upon completion of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and Sponsor shall co-operate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the and drawing appropriate conclusions.

b) The Investigator/ Institute shall permit authorized representatives of the Ethics Committee and Competent Authorities to have access to, copy and verify information relating to the Clinical Trial, as required by and in accordance with applicable Law. Furthermore Sponsor and/or CRO acknowledges and agrees that the Institution executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site. Institution acknowledges that the Clinical Trial is subject to inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial.

c) On completion, termination of the Trial, following termination or expiration of this Agreement Investigator/ Institution shall upon request immediately deliver to the LAMBDA/Sponsor all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes. Furthermore the Site Parties shall immediately deliver to the Sponsor any equipment provided to them for the conduct of the trial at the site.

d) Upon notice of termination of trial or this Agreement, Investigator/Institution will not recruit and/or enroll additional Clinical Trial subjects, and will cooperate with the Sponsor in the orderly discontinuation of the Clinical Trial, including, without limitation, discontinuing Investigational Product as soon as medically appropriate, allowing Sponsor and/or CRO access to records and facilities as required for Clinical Trial close-out procedures at mutually agreed times, and requiring Principal Investigator to complete any

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actions required in compliance to ICH GCP and Local regulations by the role Principal Investigator.

e) In all circumstances causing the early termination of trail and, LAMBDA shall confer with the Principal Investigator/ Institution and use their best endeavors to minimize any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial. Parties (LAMBDA, Investigator and Institution) agree that in case of early termination of this Agreement, they will in good faith make arrangements concerning the continuation of the treatment of the enrolled patients if such is in their medical best interest. Furthermore the Investigator and Institution shall ensure that the rights, safety and well-being of the trial subjects are protected in all circumstances.

14.2 Termination of Trial/ Trial Agreement by Investigator or Institution:

a) The Institution and/or the Principal Investigator shall notify the Sponsor and/or CRO if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Institution and/or Principal Investigator shall use all reasonable endeavors to find a qualified successor acceptable to the LAMBDA, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. In the event Principal Investigator is for whatever reason unable or unwilling to appoint a successor personally, the Institution will have the right to recommend a suitable successor and the Institution will make all possible efforts to appoint the successor/ PI to conduct the study.

b) In case if the Institution is unable to carry out the ongoing trial for any reasons the Institution will make all the necessary arrangement to ensure that the enrolled trail patient can receive the best medical care, In case if the patients still want to continue in the study, they can be referred to the other Institution/ Investigator. In all such cases Institute/investigator will be responsible for the safety follow and further medical care of the patients for the period as appropriate as per the study drug and the nature of the study. In case if the trail subject do not wish to continue with the trial at referred site and the site has to be closed data retention, patient safety and maintenance of study data for the required period as required by the applicable regulatory authority would be the responsibility of the Institution.

15. Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least fifteen (15) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

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15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16. Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17. Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18. Notice

18.1 All notices shall be delivered to the following addresses:

CRO	:	Lambda Therapeutic Research Ltd
Address	:	Plot No. 38, Survey No 388, Near Silver Oak Club, S.G.Highway, Gota, Ahmedabad 382481, Gujarat, India.
Telephone	:	+91 79 4020 2020
Fax	:	+91 79 4020 2021
Contact Person	:	**Dr. Kiran Marthak**
Investigator	:	**Dr. Archana M. Uppin**
Address	:	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka India
Telephone	:	+91-831-2470400
Fax	:	+91-831-2493099
Institution Contact Person:	:	Dr M.V. Jali
Address	:	KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi -590010 Karnataka India
Telephone	:	+91-831-2473777

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Fax : ! +91-831-2470732

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19. Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ **Date:** 28 May, 2019

Dr. Jogesh Mahajan / Mr. Gautam M Vaghela
Lambda Therapeutic Research Ltd

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Witness:

Sign: _____ **Date:** 28/May/19

Witness Name : Mr. Naresh Khemani, AGM, Finance.

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad - 382481, Gujarat, India

Institute:
KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar, Belagavi-590010,
Karnataka.

Sign: _____ **Date:** 11/June/2019
Dr M.V.Jali
MD & CEO
KLES Dr Prabhakar Kore Hospital & MRC

Signatory authority can be but not limited to HOD, Board of directors/designee/Financial head of the institute, as per site SOP.

Investigator:

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator:

Sign: _____ **Date:** 04 Jun 2019
Dr. Archana M. Uppin
KLES Dr. Prabhakar Kore Hospital and Medical
Research Centre, Nehru Nagar, Belagavi-590010,
Karnataka
Witness:

Sign: _____ **Date:** 04 Jun 2019

Witness Name : Maruti Patil

Witness Address : KLES Dr. Prabhakar Kore Hospital & MRC Belagavi

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Schedule A

Study Protocol

Protocol No: 0978-17

"A Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs ."

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Schedule B

Budget and Payment Agreement

(I) Budget

Payment Head	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Total for activity
	Screening visit (-9 days)	Randomization / Baseline visit (Day 1)	Day 14 (±2 days)	Day 28 (±2 days)	Day 56 (±2 days)	Day 84 (±2 days)	Day 112 (±2 days)	Day 142 (±2 days)	
Investigator Grant/Site payment	8000	4000	4000	6000	4000	4000	4000	6000	40000
CRC Grant	4000	2500	2500	3000	2500	2500	2500	4000	23500
Investigational cost	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	
Lab pass through cost	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	on an actual	
IOH 25 %	3000	1625	1625	2250	1625	1625	1625	2500	15875
Total Investigator Grant	15000	8125	8125	11250	8125	8125	8125	12500	79375
Subject wadges	1000	1000	1000	2000	1000	1000	1000	1000	9000
Total									**88,375**
1. PK sampling in blood samples will be kept in ice cold water bath in stored in temperature –55°C or colder									
2. LAMBDA will pay additonal Rs. 10,000/- per patient for PK patient hospitalization and other expenses.									
3. LAMBDA will pay Local Lab & Investigation Cost as per actuals. According to current hospital tarrif for all the tests the total lab cost would be INR 33,000/- per patient.									

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(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum **Rs. 88,375+33,000=121,375 (One Lakh Twenty One Thousand Three Hundred Seventy Five Only)** for every complete and evaluable patient as defined in the payment schedule.

b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately
- baseline evaluations done as per protocol

c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of visits completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

e) Any other parties designated by you (including Radiology, Local Laboratory & Cardiology, etc) will be managed and paid by you.

f) The **Ethics Committee fee** will be paid by the Sponsor, and it is separate from per patient grant as mentioned in budget.

g) Central Laboratory costs will be paid by Sponsor.

h) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before dosing on Day 1 will be paid for screening visit. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) subject(s) randomized. Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

i) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

j) **Patient conveyance/compensation** will be paid by Sponsor, and is included in budget as mentioned. TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **Service tax applicable as per union budget rules.**

k) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

l) The last amount payable will be considered as Final Payment. Final Payment will be paid during / after site close out visit. Sponsor will release payment within 40 days from the receipt of invoice.

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m) Payment reconciliation will be made before the final payment to site

n) Adhoc payments will be made as per actuals(subjected to the approval from management and sponsor)

Should the trial terminate prematurely, any payments made by Sponsor exceeding the amount actually earned will be promptly refunded to Sponsor (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment
Sponsor shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	**Dr Archana Khanagavi**
Address of Payee:	KLES Dr Prabhakar Kore Hospital & Medical Research Centre Nehrunagar Belagavi-590010 Karnataka India
PAN / TAN Number:	**CSTPK3409G**
Payment through wire transfer:	
Name of Beneficiary Account:	Dr Archana Khanagavi
Beneficiary's Account Number:	**8515101045846**
Bank Name:	Canara Bank
Bank Address:	KLES Dr Prabhakar Kore Hospital & MRC Nehrunagar Belagavi 590010 Karnataka India
IFSC:	CNRB0008515

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:
- all study related activities such as conduct of visits and CRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material

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Belagavi-590 010,Karnataka

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- all diagnostic tests and other investigations (like ECG, X-ray, etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- usage of internet while filling of eCRF
- miscellaneous (telephone, fax, courier, etc)
- All overhead or any incidental costs.

Not included are (which are separate and in addition to per patient payment):
- EC submission fee

2. In the event that the LAMBDA/Sponsor requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the Sponsor under this Agreement will be done within 30 days following receipt of the corresponding invoice (complete in all respects) from the Investigator to Sponsor through LAMBDA. All such payments will be made by A/C Payee Cheques to the Institution/Investigator. (Can also be paid through wire transfer under case to case basis)

4. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA/Sponsor. These additional tasks will be submitted to LAMBDA/Sponsor in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA/Sponsor and are subject to prior written approval by LAMBDA/Sponsor, which, in its turn, must obtain prior written approval from Sponsor.

5. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA/Sponsor will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, Sponsor has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to Sponsor any amount by which amounts advanced by the Sponsor exceed the adjusted Trial Cost.

6. The CRO/Sponsor may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

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LAMBDA Research Accelerated

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

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CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); Dr. Rohan Bhise, KLES Dr. Prabhakar Kore Hospital & MRC, Department of Medical Oncology, Nehru Nagar, Belagavi-590010, Karnataka, India ("**Principal Investigator**"); and in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 The parties agree that the section(s) in the Agreement below shall be amended and restated in its entirety as follows:

(i) Records. Site shall maintain all records required under Applicable Law and the Protocol for 10 years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records.

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20160372 entitled "Post-marketing Phase 4 Study to Evaluate Safety, Tolerability, and Efficacy of Kyprolis®(Carfilzomib) in Indian Patients With Relapsed or Refractory Multiple Myeloma: A Prospective, Open-label, Non-comparative, Multicenter Study", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that

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Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued. In addition, Principal Investigator or sub-investigator shall review data entered into EDC for accuracy and completeness, and apply electronic signature within 20 business days of Subject visit. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: Carfilzomib ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The parties agree that the section(s) in the Agreement below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Agreement, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless terminated earlier.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop (1). Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

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5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop (1).

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop (1).

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

First Payee

Payments payable to:	Dr Rohan Bhise "**Payee**"
Tax ID	AODPB2338D

75% of visit-wise cost mentioned in Schedule-A will be paid to this payee. 'Payment towards 'Non-Subject Fees' will be fully paid to this payee.

Second Payee

Payments payable to:	MD and CE KLE Hospital "**Payee**"
Tax ID	AAATK2644N

25% of visit-wise cost mentioned in Schedule-A will be paid to this payee.

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Personal Data. This section is applicable only where the Principal Investigator is an individual. Principal Investigator understands and agrees that "**Personal Information**" (as defined herein) including the name, contact details, curriculum vitae, areas of specialization of Principal Investigator and, where applicable, financial disclosure information will be Processed by Company, its affiliates and contractual partners. Personal Information will be used for the purpose to comply with this Agreement, Company's obligations imposed by law, regulatory authorities and good clinical practice, and may be used for other purposes including contacting Principal Investigator about future research or organizing safety reporting.

Personal Information may, if necessary, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that Company's use and disclosure of Personal Information may involve use and disclosure in countries other than that where Principal Investigator is located.

Company is a multi-national company that maintains datacenters around the world, including in the European Union and the United States (global headquarters of Amgen Inc.). Principal Investigator understands and agrees that Personal Information may be transferred to other Company's entities or to contractual partners providing services to Company located in countries that may not require the same level of data protection as the country in which Principal Investigator is located; however, Personal Information will only be transferred after ensuring that adequate safeguards (Standard Contractual Clauses in a form approved by the EU Commission) are in place to protect it.

Transfers of personal information among Company and its group entities follow applicable laws and Binding Corporate Rules (BCRs). More information on the BCRs, including the ability to file a complaint about any processing of personal information in violation of the BCRs can be found on http://www.amgen.com/bcr/.

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For any request to access, correct or delete personal information or to request portability of data, Principal Investigator can contact an Amgen Data Protection Officer at privacyoffice@amgen.com or lodge a complaint to the local data protection authority.

Company may process Personal Information for the duration required to fulfil the purposes described above and in any event as long as required by applicable law.

For the purposes of this Agreement, "Personal Information" shall mean information relating to Principal Investigator which is capable either directly or indirectly of identifying Principal Investigator, and "Process" and "Processed" shall mean any operation or set of operations performed on Personal Information, including the collection, use, modification, retrieval, transfer, storage, deletion, processing (both by computer and manually), and combination, of Personal Information.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that the section(s) in the Agreement below shall be amended and restated in its entirety as follows:

Publication. Site shall have the right, and shall exercise all reasonable efforts to publish or present the results of the Study in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement. Prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of the Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from the Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site and the principal investigator shall reference Company's support of the Study in any resulting manuscript, study report, presentation, poster, other publication, or abstract submission to a scientific or medical congress (including reference in the abstract itself where feasible). Subject to publisher's rights, Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(i) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. Manuscript or abstract development shall be consistent with Company's publication polices (see description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In the event that, as verified with Company, there is no multi-center publication within 18 months after completion or termination of the Study at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from the Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of the Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 The parties agree that the section(s) in the Agreement below shall be amended and restated in its entirety as follows:

(i) Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor

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and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors.

7.5 The parties agree that the Agreement shall be amended and supplemented by the following new provision:

(i) Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("**Anti-Corruption Laws**"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

(signature)

By: Mansi Malkan

Title: Senior Country Manager

Date: 8th Apr '19

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: DR M.V. Jali
(print or type name)

Title: MD and CE

Date: 30 Apr 2019

DR. ROHAN BHISE

(signature)

By: DR ROHAN BHISE
(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 18 APR 2019

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Protocol Number	20160372
Site Number	30019
Investigator	Dr. Rohan Bhise
Contract Number	
Number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 11,70,644	10	Subject(s)	INR 1,17,06,440
SCREEN FAILURES	INR 19,297	1	per Subject	INR 1,92,970
ADMINISTRATIVE FEES				INR 71,000
CONTRACT TOTAL				**INR 1,19,70,410**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs.*
Amgen has provided thermohygrometer for temprature reading.

SUBJECT FEES (Overheads 25%)

VISIT TABLE: STUDY	*PI*	*CRC*	*Institute*	Total Cost
	75% of total payment		*25% of total*	
Screening	INR 10,401	INR 4,072	INR 4,824	INR 19,297
Cycle 1 Day 1	INR 3,907	INR 4,335	INR 2,747	INR 10,989
Cycle 1 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 1 Day 8	INR 1,657	INR 3,210	INR 1,622	INR 6,489
Cycle 1 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 1 Day 15	INR 1,657	INR 3,210	INR 1,622	INR 6,489
Cycle 1 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 1 Day 22 (Arm 1 only)	INR 795	INR 0	INR 265	INR 1,060
Cycle 2 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 2 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 2 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 2 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 2 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 2 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 3 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 3 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 3 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 3 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 3 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 3 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 4 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 4 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 4 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 4 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 4 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 4 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 5 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489

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Cycle 5 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 5 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 5 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 5 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 5 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 6 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 6 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 6 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 6 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 6 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 6 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 7 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 7 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 7 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 7 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 7 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 7 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 8 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 8 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 8 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 8 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 8 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 8 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 9 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 9 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 9 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 9 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 9 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
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Cycle 10 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 10 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 10 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 11 Day 1	INR 3,907	INR 4,335	INR 2,747	INR 10,989
Cycle 11 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 11 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 11 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 11 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 11 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 12 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 12 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 12 Day 8	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 12 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 12 Day 15	INR 720	INR 3,075	INR 1,265	INR 5,060
Cycle 12 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 13 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 13 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 13 Day 8	INR 720	INR 937	INR 552	INR 2,209

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556

Cycle 13 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 13 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 13 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 13 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 13 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 14 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 14 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 14 Day 8	INR 720	INR 937	INR 552	INR 2,209
Cycle 14 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 14 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 14 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 14 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 14 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 15 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 15 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 15 Day 8	INR 720	INR 937	INR 552	INR 2,209
Cycle 15 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 15 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 15 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 15 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 15 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 16 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 16 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 16 Day 8	INR 720	INR 937	INR 552	INR 2,209
Cycle 16 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 16 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 16 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 16 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 16 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 17 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 17 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 17 Day 8	INR 720	INR 937	INR 552	INR 2,209
Cycle 17 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 17 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 17 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 17 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 17 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 18 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 18 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 18 Day 8	INR 720	INR 937	INR 552	INR 2,209
Cycle 18 Day 8 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 18 Day 9	INR 720	INR 937	INR 552	INR 2,209
Cycle 18 Day 9 Carfilzomib Dosing (Arm 2 only)	INR 0	INR 1,200	INR 400	INR 1,600
Cycle 18 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 18 Day 16	INR 720	INR 937	INR 552	INR 2,209
Cycle 19 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 19 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 19 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 19 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 19 Day 15	INR 720	INR 2,137	INR 952	INR 3,809

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Cycle 19 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 20 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 20 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 20 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 20 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 20 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 20 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 21 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 21 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 21 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 21 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 21 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 21 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 22 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 22 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 22 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 22 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 22 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 22 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 23 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 23 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 23 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 23 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 23 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 23 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 24 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 24 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 24 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 24 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 24 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 24 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 25 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 25 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 25 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 25 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 25 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 25 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 26 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 26 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 26 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 26 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 26 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 26 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 27 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 27 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 27 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 27 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 27 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 27 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 28 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489

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Cycle 28 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 28 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 28 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 28 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 28 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 29 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 29 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 29 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 29 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 29 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 29 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 30 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 30 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 30 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 30 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 30 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 30 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 31 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 31 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 31 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 31 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 31 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 31 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 32 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 32 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 32 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 32 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 32 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 32 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 33 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 33 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 33 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 33 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 33 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 33 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 34 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 34 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 34 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 34 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 34 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 34 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 35 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 35 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 35 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 35 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 35 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 35 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 36 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 36 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 36 Day 8	INR 720	INR 2,137	INR 952	INR 3,809

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Cycle 36 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 36 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 36 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 37 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 37 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 37 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 37 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 37 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 37 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 38 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 38 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 38 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 38 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 38 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 38 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 39 Day 1	INR 2,782	INR 4,335	INR 2,372	INR 9,489
Cycle 39 Day 2	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 39 Day 8	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 39 Day 9	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 39 Day 15	INR 720	INR 2,137	INR 952	INR 3,809
Cycle 39 Day 16	INR 720	INR 2,137	INR 952	INR 3,809
End of study visit	INR 3,982	INR 4,072	INR 2,685	INR 10,739
SUBJECT VISIT TABLE SUBTOTAL(S)	*PI*	*CRC*	*Institute 25%*	Total Cost
Arm 1 (KRd) - 18 cycles, EOS visit	INR 1,35,303	INR 2,79,686	INR 1,38,301	INR 5,53,290
Arm 2 (Kd) - 39 cycles, EOS visit	INR 2,68,530	INR 6,09,506	INR 2,92,608	INR 11,70,644
MAXIMUM PER SUBJECT FEE	**INR 2,68,530**	**INR 6,09,506**	**INR 2,92,608**	**INR 11,70,644**

**Screening costs are inclusive of costs associated with potential re-screens.*
C1D22 pregnancy test for KRd-treated FCBP only.
The Maximum Per Subject Fee includes Subject travel (960.00 INR) reimbursement for each protocol required in-clinic visits
CRC cost is inclusive of payment for data entry, infusion, administration, preparation and dispensation of IP and phlebotomy, apart from CRC payment and will be paid to PI

VISIT TABLE: SCREEN FAILURE	*PI*	*CRC*	*Institute 25%*	COST
Screen Failure	INR 10,401	INR 4,072	INR 4,824	INR 19,297
MAXIMUM SCREEN FAIL	**INR 10,401**	**INR 4,072**	**INR 4,824**	**INR 19,297**

Screen Failure costs are inclusive of costs associated with potential re-screens.
**One screen failure per subject.*

NON-SUBJECT FEES (Will be paid to PI)

ADMINISTRATIVE FEES (PI)	UNIT COST	UNIT(S)	TYPE	TOTAL
Document Storage, Archiving Total Cost for 15 years*	INR 41,000	1	per Site	INR 41,000
Initial Infrastructure Cost	INR 30,000	1	per Site	INR 30,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 71,000**

**Archival fee will be paid at the time of site close-out*
***Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure.*

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PAYMENT TERMS

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Dr Rohan Bhise' (Tax ID: AODPB2338D) First Payee & 'MD and CE KLE Hospital' (Tax ID: AAATK2644N) Second Payee

The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made in the favor of 'Registrar, KLE University, Belagavi'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."

2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

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Certificate No.	:	IN-DL72201118190447R
Certificate Issued Date	:	11-Apr-2019 04:24 PM
Account Reference	:	IMPACC (IV)/ dl988103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98810349504111574485R
Purchased by	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

PROTOCOL:

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date fully executed by the parties (the **"Effective Date"**) and entered into by and between

JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Faridabad, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or

Faridabad

Initials JSS India Initials INSTITUTION Initials SMO Initials INVESTIGATOR

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr Dnyanesh Morkar, the Principal Investigator presently employed at **KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi – 590010, Karnataka, India** (hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi – 590010, Karnataka, India (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

Genesis Research, (hereinafter referred to as the **"SMO"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

CRO, Principal Investigator, Institute and SMO is referred to herein individually as a "Party" and collectively as "Parties".

Whereas, **Mylan Laboratories limited** (hereinafter referred to as the **"Sponsor"**) through its CRO desires the Institution to study (add study drug in comparison with reference and/or placebo) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

A. Dolutegravir(the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No MYL-DTL-4001 and entitled " An Open-

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label, Multicenter, Prospective, Phase-IV, Interventional Study to Evaluate the Safety, Tolerability & Efficacy of Dolutegravir (50 mg once daily) in Treatment Naïve Adult Indian Subjects Infected with HIV-1, Eligible to Receive Dolutegravir with Tenofovir & Lamivudine" a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored by the CRO as per the Protocol.

B. The Principal Investigator represents and warrants that he is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of the curriculum vitae and other relevant documents requested by the Sponsor, the Ethics Committee, CRO and the Regulatory Authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled throughout the duration of the Study. The Principal Investigator should also ensure that he does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

C. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study services hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution and Principal Investigator. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study. In any event, if the Principal Investigator is unable to perform the obligations of Study or suspends or abandons or is unwilling to continue with the Study, CRO and Institution shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, in such case, the Study may be terminated at the option of the CRO for and on behalf of the Sponsor or by the Sponsor.

D. Conditions precedent. The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the Reference-listed Product with full prescribing information, and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Site under the supervision and direction of the Principal Investigator, who will be the Principal Investigator for the Study.

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E. The Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. CRO, Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board)

2. THE STUDY SCHEDULE

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest time after receiving the applicable regulatory / IEC / IRB approvals.

B. **Enrollment.** Principal Investigator shall be responsible for enrolling eligible Subjects to the Study. Principal Investigator shall use the best efforts to enroll the Subjects and ensure unbiased selection of suitable Subjects in accordance with the terms of Protocol. Principal Investigator will enroll minimum 05 Subjects (as per the randomization schedule) and not more than 10- 17 Subjects (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the CRO, or the Sponsor's designee, that, in the sole determination of the CRO:

i. the Complete Study enrollment has been achieved; or
ii. the CRO and Sponsor have placed the Study on hold, for any reason; or
iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under Applicable Laws and Requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the CRO and Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed

to Sponsor and CRO within **twentyfour (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals and applicable law.

Study Completion. The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit. In any event, Institution and Principal Investigator shall not publish or present interim or preliminary results of the Study at any time without the prior written approval of CRO and Sponsor.

3. PAYMENT

A. **Budget and Payment Schedule:** In consideration of the Services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque. Payment shall be made within sixty (60) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the CRO and sponsor's clinical and/or medical monitor identified in the Protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in

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the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

The further details for the payments should be provided as

1. **Cheque in the favor of: Genesis Research**
2. **PAN Number: CQJPP0528D**
3. **Name of Bank: SBI**
4. **Branch: Market yard Kolhapur**
5. **Account No: 36599680134**
6. **Branch Code:01887**
7. **IFS CODE: SBIN0001887**
8. **GST NO: 27CQJPP0528D1ZX**

Payee details for Institution overhead charges 25 %

1. **Cheque in the favor of: MD and CE**
2. **Pan No:** AAATK2644N
3. **GST No:** 29AAATK2644N6Z3

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 1:6 i.e. maximum one screen failure per six randomized Subjects.

G. **Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Goods and Service Tax will be paid, as applicable, on generation of valid invoice showing the amount of service tax not to be charged before any payment is made under this Agreement

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. **IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and CRO/Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the CRO or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notified by the Sponsor or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, , of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: Consolidated Guideline if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the CRO.

C. **Patient consent and entry into Trial**. As well as complying with the requirements of the Declaration of Helsinki, the principles of Good Clinical Practice [and other legislation appropriate to clinical trials, medical treatment, and the processing of personal and medical data], the Investigator shall, before entering a patient into the Trial:

i. exercise independent medical judgement as to the compatibility of each prospective Patient with the requirements of the Protocol;

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ii. advise the CRO of all instances in which, in the Investigator's judgement, there is any question as to any prospective Patient's suitability for participation in the Trial, and abide by the Sponsor's decision as to whether or not to enrol that Patient;

iii. ensure that, before their participation in the Trial, the Patients are duly informed about all aspects of the Trial that are relevant to them, including:

iv. the purpose, duration, nature, significance, implications, and risks of the Trial; and

v. the processing, auditing, and monitoring of data (including personal data) under this Agreement.

vi. ensure that, before his or her participation in the Trial, each Patient has given his or her Informed Consent on the basis of the information described in Clause 2.5(c) by signing a consent form in accordance with the Protocol;

vii. acknowledge that the use of the consent form does not release the Investigator from his or her legal and contractual obligations relating to Informed Consent, and that it remains the Investigator's responsibility to ensure that those obligations are complied with;

viii. comply with the procedures described in the Protocol in relation to that Patient; and

ix. provide details of the proposed Patient to the CRO.

D. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the CRO and/or Sponsor's designee and the CRO and/or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the CRO may terminate this Agreement as set forth in Clause 12(B) below.

E. **Sponsor Visits.** The Sponsor's representatives along with CRO as required may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four**

(24) **hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

a. The CRO or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

G. Study Records, Reports, and Data.

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all

Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of seven (7) years after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ Sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the Study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data. In no event, shall Institute and Principal Investigator remove any Study Records or destroy any Study Records without the prior written consent of CRO and Sponsor.

ii. *Case Report Forms.* The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.

iv. *Final Reports.* Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome (**"Final Report"**) to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of Study Records.

H. Reporting of Serious Adverse Event. The Institution and Principal Investigator shall notify CRO and Sponsor of any Serious Adverse Event encountered in the Study within **twenty four (24) hours** in accordance with the instructions set forth in the Protocol. Each

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such notice shall be given by fax / mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements. Institution and Principal Investigator shall indemnify and hold harmless the CRO and Sponsor for any failure to observe or non-compliance of any Laws, Institution and Principal Investigator shall bear all the resultant whatsoever liability (ies) arising thereof due to such failure.

I. Institute and Principal Investigator undertake to provide full and immediate access to, as well as to maintain, information and witnesses surrounding the occurrence of any Subject Injury as is sufficient for CRO and/or Sponsor to conduct an investigation concerning such injury.
In the event that:

i) the Subject Injury is caused due to failure in following the Protocol or by negligent and willful actions or omissions of Institute and/or Principal Investigator, its officers, directors, employees, or agents; and/or

(ii) Institute and/or Principal Investigator fails to promptly notify CRO and Sponsor of a Subject injury as required herein;

CRO shall treat such failure of Institute and/or Principal Investigator as amounting to material breach of this Agreement.

5. CONFIDENTIALITY

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution or the Principal Investigator as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party

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informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of stopping or preventing any existing or anticipated breach of the terms Confidentiality and of this Agreement.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party

Shire

AMENDMENT No. 1

Protocol Number: ***SHP-640-301***

THIS AMENDMENT NO. 1 (the "Amendment No. One) effective as of the 18th day of April, 2019 (the "Effective Date"), by and among **Shire Human Genetic Therapies, Inc.** having a place of business at 300 Shire Way, Lexington, MA 02421, USA ("Sponsor"), **GDD Experts India Pvt. Ltd.**, having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur- 440001, Maharashtra, India (as a limited party for payment purposes) ("Research Company"), **KLES Dr. Prabhakar Kore Hospital & Medical Research Centre** , having a place of business at Nehrunagar, Belagavi- 590010, Karnataka, India, ("Institution") and **Dr. Smitha K. S.** , (the "Investigator" and together with the Institution, the "Site") amends the terms of the Sponsored Clinical Trial Agreement dated as of the 24th day of May, 2018 and any subsequent amendment made by the parties to that Clinical Trial Agreement between the parties (the "Agreement"). For purposes of this Amendment No. 1, each of the Sponsor, Institution, and the Investigator may be referred to as a "Party" and together as the "Parties". Capitalized terms not defined herein shall have the same meaning as set forth in the Agreement.

WHEREAS, the Parties desire to amend the Agreement;

NOW THEREFORE, in consideration of the mutual covenants and agreements herein, the Parties, intending to be legally bound, have entered into this Amendment No. 1 and do specifically agree as follows:

1. Exhibit A (the "Budget & Payment Schedule") of the Agreement shall be amended as follows:

- **Screen Failure Reimbursement: Twenty Four Thousand Four Hundred Forty Eight Indian Rupees (24,448 INR),** upon receipt of CRF pages by DrugDev, with a cap of four (4) screen failure payments per Institution for every 1 Study subject(s) randomized.

The conditional payments table shall be amended to reflect the deletion of Informed consent/assent (for Screen Failure Subjects):

Conditional Procedure	**Amount (INR)**
Patient Stipend – Unscheduled Visit	1003
Pediatric consent form (in conjunction with Informed consent - signed by parent)	719
Inclusion/exclusion criteria (re-confirmation)	815
Urine pregnancy (for applicable female subjects)	271
Serum pregnancy (for applicable female subjects)	1,705

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Ocular Discomfort Scale	298
Best corrected visual acuity	431
Slit lamp biomiscroscopy	1,100
Fundus Examination	2,856
Red Reflex Assessment	1,686
Study Coordinator effort for Unscheduled Visit	2218
Physician effort for Unscheduled Visit	2945

a) All other terms and conditions of the Agreement,shall remain in full force and effect. In the event of any conflict between the terms of the Agreement and this Amendment No. 1, the terms of this Amendment No. 1 shall govern and control.

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound, have executed this Amendment No. 1 by their duly authorized representatives as of the Effective Date.

SHIRE HUMAN GENETIC THERAPIES, INC.

By: _____
(Signature)
Name: Emily Jochim
Title: Clinical Programs Team Lead

KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE

By: _____
(Signature)
Name: Dr. M. V. Jali
Title: Medical Director

DR. SMITHA K. S.

By: _____ 20 June 2019
(Signature)
Name: Dr. Smitha K. S.
Title: Principal Investigator

GDD EXPERTS INDIA PVT. LTD. :

By: _____ 21st June/2019
(Signature)
Name: Dr. Vinod Gyanchandani
Title: Director

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Authorised Signatory

NOVARTIS

THE DECCAN MERCHANT CO-OP BANK LTD. BHOJAR BR. JEEVANJILLA BUILDING, FIRST FLOOR RANKADE ROAD, DADAR(WEST) MUMBAI - 400 028

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CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of __ _____ *2019*_ ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at The Inspire – BKC, 7th Floor, G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai 400051 ("Novartis") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, located at /Nehru Nagar, Belagavi-590010, Karnataka, India ("**Institution**") registered Under Provisions Of Bombay Public Trust Act 1950 and which expression shall mean and include its successors and assigns of the SECOND PART;

AND DR PRASAD M. R., as clinical practitioner in the field of Consultant Cardiologist acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "Party" and jointly as the "**Parties**".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the prevelance of Lipoprotein (a) (hereafter the "Study") in accordance with a protocol entitled *TQJ230A12001- Multi-center cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein(a) levels among patients with established cardiovascular disease* and its amendments (hereinafter collectively the "Protocol") and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study to evaluate their interest in participating in the Study, wish to conduct the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(b) Good Clinical Practice;

ATTESTED

Dr. V.A.Kothiwale 576
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

(e) any "Applicable Law(s)" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.

(f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Anti-bribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

2. PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments thereto and the Annexes herein form an integral part of this Agreement.

2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

3. APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority has been obtained by Novartis *(wherever applicable as per Indian regulations)* and the competent ethics committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 6.3 provided by Novartis, has been approved by the Principal Investigator and/or the ethics committee.

4. DURATION OF THE STUDY

The Study shall commence on *25-April-2019*, subject to the compliance of Section 3 prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *23-September-2021* or as may be extended by a formal writing between the parties in that behalf. Provided that such extended study shall under no circumstances extend beyond the term of this Agreement.

5. TERM OF THIS AGREEMENT

5.1 This Agreement shall be effective upon 17-Apr-2019 ('Effective Date') and shall expire upon 16-Apr-2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

ATTESTED

ATTESTED

Dr.V.A.Kothiwale
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KLE Academy of Higher Education and Research,
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5.2 The following provisions shall survive the termination or expiry of this Agreement:

5.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis 30 (thirty) days prior to such termination. It is clarified that neither the Principal Investigator nor the Investigator shall be discharged of his/her or their obligations under this Agreement unless Novartis has been provided notice in terms of this clause.

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "**Sub-Investigators**") to assist in the conduct of the Study at his/her sole discretion, costs, risks and consequences including but not limited to such Sub-Investigators qualification, remuneration, work record, compliance with statutory obligations etc without recourse to Novartis. The Principal Investigator alone shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("**Study Subjects**") and undertake in particular to have it executed by competent resources.

6.2 **Study Site**

The Study shall be conducted at the premises of Institution at the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre: (hereinafter the "**Study Site**").

6.3 **Study Subject consent and entry into Study:** Before enrolling a Study Subject into the Study, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;

(c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, his/her legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be his/her legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.3 (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

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6.4 Study Subject Recruitment

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.5 Recordkeeping, Reporting, Access and Inspections

(a) Recordkeeping, Reporting

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely manner:

(i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").

(ii) Maintain a copy of all documents related to this Study for a period of a) fifteen (15) years following the Study completion or discontinuation by Novartis or b) as required by applicable laws and regulations.

(iii) Meet with a representative of Novartis to discuss the progress of the Study; and notify Novartis immediately upon discovering any significant violations of the Protocol.

(iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,

(v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

(vi) Maintain all documents and other Records generated in the Study in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Study; and obtain Novartis approval prior to disposing of any Record, provided that 'safe disposal' of any Record shall at all times be in compliance with 'Data Privacy and Protection' provisions set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis'

(viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;

(ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) Access and Inspection

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

(i) Examine and inspect the Institution's facilities required for performance of the Study; and

(ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Novartis will maintain the confidentiality of any subject-identifiable medical records.

(iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any of Novartis designated person within 24 hours, allow Novartis to be present at the inspection/action and/or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.

(iv) Grant access to Novartis or its representative to visit the Study Site periodically, as frequently as required for the proper performance and oversight of the Study, in order to proceed with any and all monitoring activities required for the Study.

(v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.

(vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.

(vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.6 Reporting: The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Study; and

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.7 Reporting of Safety Information:

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.7 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

(a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with analysed report of the Serious Adverse Event or Serious Adverse Reaction reported to Novartis and SUSARs LL in order to inform the ethics committees IRB/IEC, Head of Institution in accordance with the current Applicable Laws.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

(a) the Protocol,

(b) the CRF/e-CRF

6.9 The Principal Investigator, or sub-investigator for multicentre studies, shall sign the clinical Study reports.

ATTESTED

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manner provided under the Drugs and Cosmetics Act, 1940 and rules thereunder as may be applicable from time to time.

7.2 The Institution and Principal Investigator ("**Indemnifying Party**") jointly and severally shall indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "**Damages**") of whatever kind or nature arising from any third party demand, investigation, claim, action or suit based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

8. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place at the commencement of the Study.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees and the Institution confirms the Payment Schedule attached hereto as Annex 1.

9.2 Novartis reserves the right to terminate the Agreement immediately with notice if no subjects have been recruited at the Study Site by *90 days from site initiation*.

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator's control. Reimbursement for expenses related to patient travel will be made according to the Payment Schedule in Annex 1.

9.4 The Principal Investigator shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

Saumya Mathew/ Shumaila Qureshi

6 & 7 floor, Inspire BKC

G Block, BKC Main Road

Bandra Kurla Complex

Bandra (East), Mumbai - 400051

Maharashtra, India

ATTESTED

Dr. V.A.Kothiwale
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10. TERMINATION

10.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the ***Institution/Principal Investigator*** shall notify the relevant ethics committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

10.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

10.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement save and except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.

10.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.

11.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.

11.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to request amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

13.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

13.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "**Information**") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

ATTESTED

14.3 The confidentiality obligations set out above shall not apply to:

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(a) Information which is, at the time of disclosure, in the public domain or thereafter

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

GDO Trial Monitoring, India
Novartis Healthcare Private Limited

Murugananthan K,
The Inspire – BKC,
7th Floor, G-Block,
BKC Main Road,
Bandra Kurla Complex,
Bandra East, Mumbai 400051
Telephone: +91 -22 50243000
Fax: +91-22-50243005

or to such other address as may have notified to the other party in writing.

16. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

17. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

18. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

19. WAIVER

ATTESTED
Dr. V.A.Kothiwale
Registrar
585
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

20. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

21. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under the law including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drug and Cosmetics Act, 1940 as amended or under Applicable Law and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution becomes aware that the Principal Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Novartis at once.

22. CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23. TRANSPARENCY/DISCLOSURE

23.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

23.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.

23.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will

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24. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India for any disputes concerning or arising out of this Agreement.

25. DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data together with the general provisions regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

26. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY AND SPECIFICALLY in relation with trial procedures while in all other instances the Agreement shall prevail.

ATTESTED

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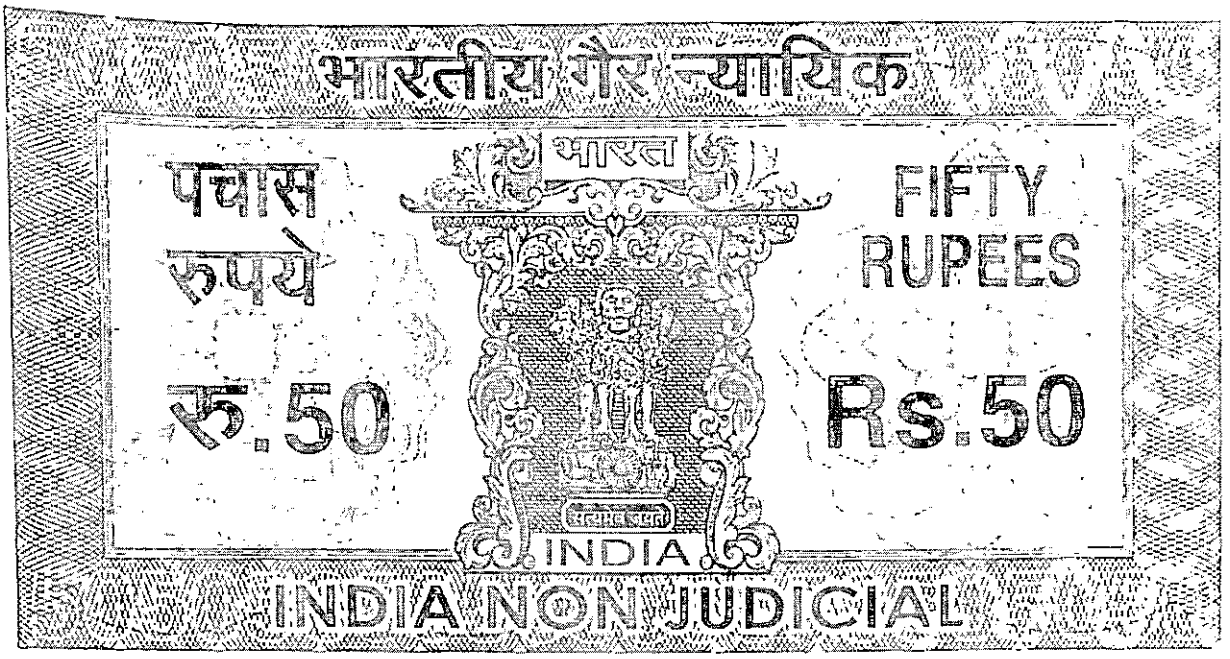

తెలంగాణ तेलंगाना TELANGANA

G 062116

S.No.17002 Date:10-05-2019
Sold to: M.Pandu Ranga Reddy
S/o Late M.Seetha Ram Reddy R/o Hyd
For Whom: M/s.BIOLOGICAL E. LIMITED, HYD

E.VENKATESH
LICENSED STAMP VENDOR
L.No.16-07-008/10,RL.NO.16-07-03/2019
5-3-856/17, G-17, NANDINI COMPLEX,
M.J.MARKET, HYD-12 PH:9866313526

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on 22nd day of May, 2019 ("**Effective Date**") by and between **Biological E. Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/1&3, Azamabad Hyderabad 500020, Telangana, India ("**Sponsor**"), of the First Part; and **Dr. N.S.Mahantshetti**, a registered medical practitioner holding MCI registration number **22164,** currently working as Professor in Department ofPediatrics ,KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum("**Principal Investigator**")of the Second Part; and **KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum**,a hospital established registered under the laws of India, having its place of business and **KLES JNMC Dr Prabhakar Kore Hospital & Medical Research Centre**, a hospital established registered under the laws of India, having its place of business at Nehru Nagar, Belgaum 590010, Karnataka represented by its Medical Director, ("**Institution**") Third Part

ATTESTED

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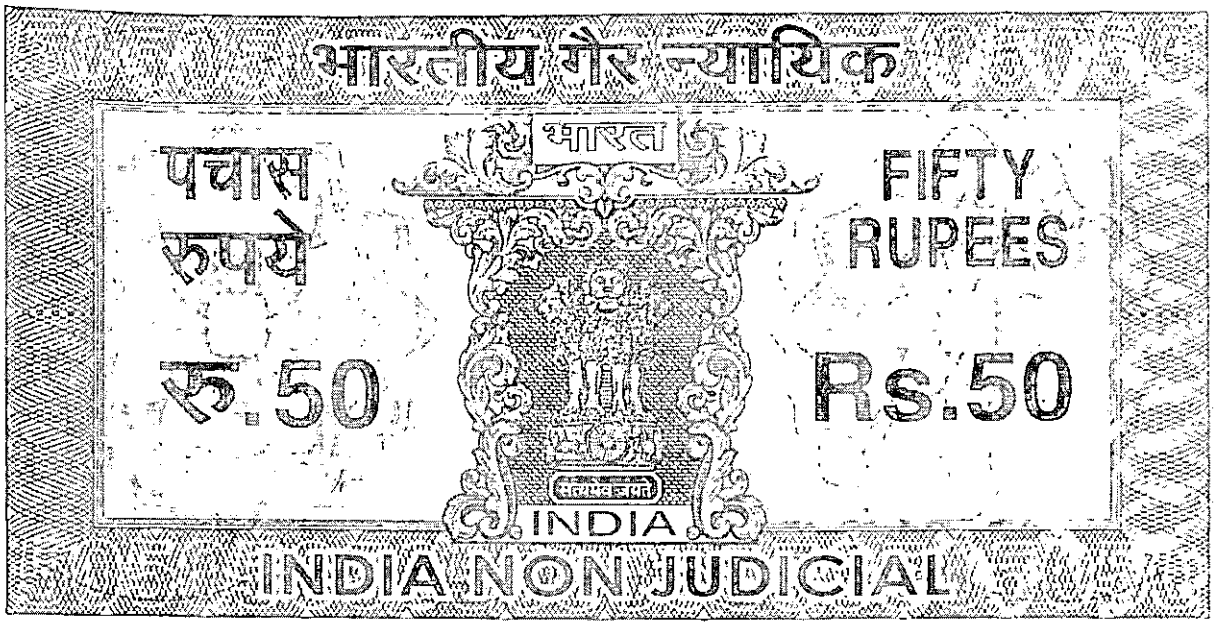
Belagavi-590 010,Karnataka



తెలంగాణ तेलंगाना TELANGANA

V7 G 062115

S.No.17001 Date:10-05-2019
Sold to: M.Pandu Ranga Reddy
S/o Late M.Seetha Ram Reddy R/o Hyd
For Whom: M/s.BIOLOGICAL E. LIMITED, HYD

E.VENKATESH
LICENSED STAMP VENDOR
L.No.16-07-006/10,RL.NO.16-07-03/2019
5-3-856/17, G-17, NANDINI COMPLEX,
M.J.MARKET, HYD-12 PH:9866313526

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited is planning to develop Hepatitis A vaccine (Adsorbed) product and is desirous of testing the same in humans through a phase III Clinical Trial to be conducted in ten study centers;

B. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

C. The Sponsor has already identified the Principal Investigator based on her experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

D. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed his willingness to the Sponsor to conduct the proposed Study;

E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and

F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. Definitions

1.1 **"Study"** or **"Clinical Trial"** shall mean study entitled:

"A single blind, parallel, randomised Phase-III comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-naïve children"and all the title amendments thereto as the Parties may from time to time agree in writing.

1.2 **"Protocol"** shall mean:

The description of the Study mentioned in the Study protocol number **BECT045/HepA-phase-III/CTP-02**and all amendments thereto as the Parties may from time to time agree in writing.

1.3 **"Study Drug"** or **"Investigational Drug"** shall mean:

Inactivated Hepatitis A Vaccine (Adsorbed)(Manufactured by Biological E. Ltd.).

1.4 **"Ethics Committee"** shall mean:

An independent bodyor an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

2. Responsibility of the Principal Investigator and the Institution

2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Pediatrics in the Institution, to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good

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Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws& Guidelines**"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and

(iii) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.

2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.

2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.

2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be

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made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. Conduct of Clinical Trial

3.1 The Sponsor shall appoint it's employee to monitor the Clinical Trial and also reserves it's right to nominate any other person as monitor.

3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.

3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.

3.4 Principal Investigator shall ensure that the Audio Visual recording of the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain audio visual informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio-visual recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the Sponsor, Principal Investigator shall handover a copy of such recording for regulatory compliance or any order.

3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

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3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.

3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. **Study Drug**

4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.

4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. **Visit and Inspection**

5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;

ii. inspect and copy all data and work products relating to the Study, and

iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. **Payment**

6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement,

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Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.

6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.

6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. <u>Indemnification and Insurance</u>

7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug <u>except</u> to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

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a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

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8. **Publication of Results**

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. **Publicity and Product Promoting Activity**

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. **Confidentiality**

10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and

(ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.

10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein.

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Principal Investigator and the Institution shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

(a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;

(b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;

(c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

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11. **Severability & Waiver and Assignment**

11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.

11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. **Validity & Termination**

12.1 This Agreement shall become effective on the date first set forth above and shall continue for a period of 1 year thereof or until this Agreement is terminated due to:-

a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the Sponsor that business or scientific considerations require termination;

d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;

e. At the request of either DCGIor Ethics Committee;

f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;

g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;

12.2 The Sponsor may terminate this Agreement:

a) At any time upon thirty (30) days written notice to the Principal Investigator /Institution.

b) Immediately for safety reasons relating to the use of the Study Drug.

12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

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13. **Effect of Termination**

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. **Miscellaneous**

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses:-

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India

(ii) **To Principal Investigator**: Dr. NS Mahantshetti
Title: Professor
Address: KLEs JNMC Prabhakar Kore Hospital,
Belgaum
Telephone No.: 0674 2304400
Mobile: +91-8312477201
Fax No: +0674 2725228
Email id: niranjanakle@gmail.com

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(iii) **To Institution:** Dr. M. V. Jali
Title: Medical Director
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar,
Belgaum 590010, Karnataka
Telephone No.: 0831 - 2473777
Email: drmvjali@gmail.com

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	Principal Investigator	For and on behalf of Institution
Signature & Date	Signature & Date 1/6/19	Signature & Date
Name: Mr. Sultan Baig Title: Vice President- Finance	Name: Dr N S Mahantshetti Title: Professor	Name: Dr M.V. Jali Title: Medical Director
Seal:	Seal: Dr. N. S. Mahantashetti Professor Consultant Pediatrics KMC Reg. No. 22164 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.	Seal: Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI
Witness: 1. N.Eswara Reddy 2.	Witness: 1. Vishal Jakati 2.	Witness: 1. Rvana S 2.

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Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

BEC045-HepA PHASE III STUDY BUDGET	
Cost Description	**Amount (INR)**
Investigator, co-investigator & study team fee(INR.16,000 per Subject x 52 subjects)	8,32,000
Study coordinator fee(INR.9,000 per month x 12 months)	1,08,000
Subject travel conveyance (Rs. 500 per subject x 4 visits x 52 subjects)	1,04,000
Audio Visual Consenting & Logistics	50,000
Study documents archival fee (for 15 years)	60,000
Sub Total	**11,54,000**
Institutional Overheads (25% on Investigator fees)	2,08,000
Total	**13,62,000**

Total Cost (in Words): Thirteen Lakhs sixty two thousand rupees only. (GST 18% extra as applicable by government laws, wherever applicable)

Budget Note:

- No charges will be paid for screen failure subjects
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	% of Total Cost
1	On Site Initiation	25%
2	On completion of 100% Subject Recruitment	25%
3	After Last Patient/subject Last Visit/Completion of all Data Query Resolutions and Database Lock	25%
4	After Site Close-out	25%

Based on the total agreed amount of Rs. 13,62,000/- for enrolling 52 subjects, the per subject cost would be Rs. 18,000/-(Investigator, co-investigator & study team fee + Subject travel conveyance).

All payments would be made based on actual number of subject's enrolled at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of:

- Payee Name: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- Bank Account Number: 910020034162231, IFSC code: UTIB0000048
- GST Registration Number: 27AADCG0363Q1ZA
- PAN of Payee: AADCG0363Q

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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CLINICAL TRIAL SITE AGREEMENT

This clinical trial site agreement ("**Agreement**"), having an effective date of 30 May 2019 ("**Effective Date**"), is between **Dr Rohan Bhise,** an individual, having an address at **Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India,** will serve as the principal investigator ("**Principal Investigator**"), the institution **Dr Prabhakar Kore Hospital & Medical Research Centre,** located at **Nehrunagar, Belagavi-590010, Karnataka, India** ("**Institution**") (collectively, Principal Investigator and Institution, with its personnel, officers, board members, affiliates and agents, "**SITE**"), and **Veeda Clinical Research Pvt. Ltd**, with a principal place of business at Shivalik Plaza–B. Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat.

CRO, Site, and Principal Investigator are hereinafter individually referred to as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, by separate agreement, Dr. Reddy's Laboratories, Limited (collectively, with its personnel, officers, board members, affiliates and agents, "**SPONSOR**"), with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, has engaged CRO, a contract research organization, acting as an independent contractor, to act on behalf of SPONSOR for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiation and execution of the Agreement and payment administration of grant amounts in coordination with the SPONSOR and;

WHEREAS, CRO, acting as an independent contractor on behalf of SPONSOR, desires to coordinate a clinical research study entitled "A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, crossover, single dose, bioequivalence study of Bortezomib for injection 3.5 mg/vial of Dr. Reddy's Laboratories Limited, India and VELCADE (bortezomib) for injection 3.5 mg/vial (Distributed and marketed by: Millenium Pharmaceuticals, Inc., 40 Landsdowne Street, Cambridge, MA 02139) in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patient." ("**the Study**"), which shall be conducted according to SPONSOR's Clinical Protocol Number 17-VIN-0772 ("**Protocol**") incorporated herein by this reference; and

WHEREAS, SPONSOR has developed an investigational product candidate designated as Bortezomib for injection 3.5 mg/vial ("**Investigational Product**"); and

WHEREAS, SITE has established and maintains a clinical trial study service, and has acquired expertise in conducting research evaluations, clinical trials, and laboratory test evaluations; and

WHEREAS, SPONSOR and CRO wish to engage the SITE to facilitate and carry out the Study; and

MUTUAL BALCHIK SAHAKARI BANK LTD.
NARANPURA BRANCH
AHMEDABAD-13

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WHEREAS, SITE has sufficient authority, competence and experience in conducting clinical trials and, having reviewed the Protocol, the investigator brochure, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement; and

WHEREAS, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth.

NOW THEREFORE THIS AGREEMENT WITNESSETH, that in consideration of the mutual covenants herein contained and other good and valuable consideration exchanged between the Parties, the receipt and sufficiency whereof is hereby acknowledged by the Parties hereto, the parties covenant and agree as follows:

ARTICLES

I. STATEMENT OF WORK

SITE will take appropriate direction and supervision from CRO in connection with monitoring, supervision, and carrying out of the Study.

II. PERIOD OF PERFORMANCE

The performance of this Agreement shall be from the Effective Date through termination of the Study by SPONSOR, unless earlier terminated in accordance with Article XI of this Agreement.

III. CONDUCT OF THE STUDY

1. The SITE agrees to conduct the Study in strict accordance with the Protocol as amended from time to time. SITE will conduct the Study in strict accordance with the terms and conditions of this Agreement, the Protocol and any amendments thereto, and all applicable federal, state and local laws and regulations applicable to the territory in which the Study is being including but not limited to (a) Good Laboratory Practice, the revised and applicable versions of the Declaration of Helsinki Directive 95/46/EC, as amended from time to time; (b) Schedule Y of the Drugs and Cosmetics Act, as revised from time to time; (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("ICH/GCP"); (c) all laws as applicable to clinical trials in [•], and shall include without limitation [•], and any regulations or laws as prescribed by [•], and / or the central government of [•], (e) the Prevention of Corruption Act, 1988, (f) the U.S. Foreign Corrupt Practices Act, UK Bribery Act 2010, the federal anti-kickback laws (42 U.S.C. Section 1320a-7b(b)), (h) the Standards for Privacy of Individually Identifiable Health Information, and (i) the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules,

2011 ("**Privacy Rule**") under the laws applicable for [•] (collectively, "**Applicable Law**").

2. The Study will be supervised by the Principal Investigator, who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the SITE, which the Principal Investigator and Institution represent and warrant are not inconsistent with (a) the terms of this Agreement, (b) the Protocol, (c) generally accepted standards of good clinical practice, and (d) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (a) – (b) of this Article III Clause 2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the Principal Investigator and otherwise adhere strictly to the Protocol. SITE shall ensure that Investigator shall not delegate his/her responsibility to personally supervise the Study without CRO's prior written approval. SITE further agrees to ensure that Investigator and/or any sub-investigators: (a) are fully informed of the Protocol, the Investigational Product; and (b) participates in all investigator meetings and telephone conferences as required for the conduct of the Study. SITE will further ensure that Investigator, sub-investigator, and any other personnel involved with the Study, participate in training sessions as necessary for the performance of the Study.

3. SITE will notify CRO immediately if Principal Investigator is unable to continue as principal investigator for the Study. Institution further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of CRO. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to SPONSOR is not available, this Agreement shall be terminated as provided for in Article XI Clause 2.

4. As required by Applicable Law, prior to initiation of the Study, SITE shall ensure that the Protocol has been reviewed and approved by the appropriate Institutional Review Board ("**IRB**") and shall provide CRO with evidence of such IRB approval pertaining to the: (a) the Protocol and/or any subsequent modifications thereof, and (b) the informed consent form and/or any subsequent modifications thereof.

5. As required by Applicable Law, SITE shall obtain the informed consent of patients to participate in the Study prior to said participation, and shall document the Study patients' informed consent by securing from each patient, his or her signature upon an informed consent form that complies with Applicable Law and is approved by an appropriate Institutional Review Board ("**IRB**"), a copy of which shall be retained by the SITE. The Study patient shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study

patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.

6. SITE shall ensure that Study patients have agreed to participate in the Study as defined by the Protocol to be conducted at the Institution's facilities in compliance with Applicable Law.

7. Enrollment in the Study is competitive: SITE will use its reasonable efforts to enroll the expected number of Study patients 6 in strict accordance with the requirements of the Protocol and within the enrollment period of 5 (five) months after Study initiation which is planned for Oct 2018. CRO on behalf of the SPONSOR, may change the enrollment period at its sole discretion, upon 7 (seven) days' notice to SITE. CRO will make its best efforts to monitor enrollment of Study patients, but does not guarantee that all eligible screened Study patients will be enrolled. In the event SITE screens and/or enrolls fewer than two [2] Study patients within 8 (eight) weeks after the Study's initiation at the site, through no fault of the SPONSOR or CRO, CRO may close enrollment at the Institution without liability therefore. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Study patients, the Institution shall immediately inform the CRO in writing. In each such event, the Parties shall discuss the consequences of the delay and if reasonable, as determined by CRO, each Party shall undertake reasonable endeavors to agree on measures to overcome such a delay.

8. SITE shall undertake to insure that all Study patients are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, CRO, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study.

9. Institution and Principal Investigator hereby represents that neither: (a) has a conflict of interest that would affect the conduct of the Study; (b) has received any offer by SPONSOR, CRO and/or their respective representatives or affiliates, of any extra benefit for participation in the Study, including offers to family members. Further, SITE agrees to promptly notify CRO if it becomes aware of any conflict of interest that arises during the term of this Agreement. SITE not enter into any financial security transaction based on the Study data or the Study results. Without limiting the foregoing, SITE acknowledges that as of the date of this Agreement, neither Institution nor Principal Investigator are parties to any oral or written contract or understanding with any third party which (a) is inconsistent with this Agreement nor SITE's performance hereunder or (b) will in any way limit or conflict with SITE's ability to fulfill its obligations under the terms of this Agreement. SITE further represents that it will not knowingly enter and will instruct its sub-investigators not to knowingly enter into any such conflicting agreements during the term of this Agreement

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10. SITE shall conduct the Study only at facilities that are determined to be adequate by CRO. SITE shall ensure that the facilities remain adequate for the duration of the Study (i.e. at a minimum, are safe, secure, hygienic, include adequately-maintained and calibrated equipment, and provide for secure and accessible storage of Study materials and records).

11. The Principal Investigator agrees to limit access to the Investigational Product to only qualified and delegated Study staff and shall personally ensure, administer, or supervise the administration of Investigational Product (whether active or placebo) to Study patients in accordance with the Protocol; shall not chemically, physically or otherwise modify Investigational Product, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Investigational Product with appropriate care and in compliance with manufacturer's instructions and all Applicable Laws, rules and regulations, including, but not limited to, those governing hazardous substances.

12. The Principal Investigator shall prepare a final report setting forth any accomplishments and significant research findings of the Study, and shall submit said final report to the IRB with a copy to CRO within 30 (thirty) days after the completion or termination of this Study.

13. CRO on behalf of SPONSOR and/or SPONSOR shall provide for the delivery to the SITE, the Investigational Product in sufficient quantities for use in the Study. Title to these materials provided by CRO and/or SPONSOR shall remain solely and exclusively with SPONSOR, and the materials shall be used solely and exclusively by SITE for purposes of carrying out the Study.

14. Adverse Events. SITE shall report to CRO and IRB with a copy to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than 24 (twenty-four) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events.

15. SITE shall rely upon the IRB for review, approval and continuing oversight of the Study including but not limited to, decisions surrounding all regulatory responsibility for scientific oversight and integrity of the Protocol from initial review to termination of the Study, review and approval of informed consent forms and recruiting materials prior to initiation of the Study. Institution may utilize a local IRB only where and Institution obtains certification from such local IRB that it operates within all Applicable Laws.

16. No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and the SITE, and reviewed and approved by the IRB in accordance with Applicable Law, or where deemed necessary by SITE to protect the safety, rights or welfare of any patients entered into the Study, in which case CRO.

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SPONSOR and the IRB will be immediately notified in writing of such action and necessity for deviation from the Protocol. If any changes in the Protocol affect the charge for research conducted in the Study, the SITE shall submit a written estimate of the charges for CRO's and SPONSOR's prior written approval.

IV. PAYMENT

1. In consideration of the work performed by SITE, payments shall be made to the SITE by CRO for evaluable Study patients in accordance with the terms of this Agreement, including those fees/expenses listed within Attachments A, B, and C, which is hereby incorporated herein by reference: subject however, to the following terms and conditions:

(a) Payment will be made per completed Study patient visit which is accompanied by a complete CRF for that visit. Payment will not be made for incomplete Study patient visits unless Study patient leaves the Study early, in which case payment is subject to proration per Article IV Clause 1 (c) below and the schedule of payments within Exhibit C.

(b) CRO shall not be obligated to compensate Institution for Study patients who are enrolled and/or treated in violation of the Protocol selection criteria.

(c) Payment for Study patients who withdraw prematurely will be prorated according to the terms presented in the schedule of payments within Exhibit C.

(d) In the event of early Study termination by SPONSOR, CRO, regulatory authority, or an IRB, as contemplated under Article XIII herein, the Institution will be reimbursed in full for completed Study patients except that Institution shall not be reimbursed in full or in part for any breach of this Agreement under Article XIII. CRO shall reimburse Institution on a prorated basis for enrolled Study Subjects that are terminated early due to Sponsor, CRO, regulatory authority, or IRB termination of the Study. CRO will compensate Institution for services provided up to the effective date of termination and for any services provided after termination that are necessary to safeguard subject safety or comply with Applicable Law, rules, regulations or CRO requirements.

(e) The Payment Schedule will be adjusted for cost increases due to Protocol amendments as necessary, subject to Article III Clause 16 hereinabove.

(f) CRO reserves the right to temporarily withhold payment to Institution if it is determined from a monitoring visit or audit that there are significant errors in the CRF's or where CRF's were not completed and/or provided to CRO in a timely manner.

2. The Institution shall not seek or accept compensation for any Investigational Product provided by or on behalf of Sponsor or for any test, treatment or other material/service

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provided or paid for by or on behalf of Sponsor (i.e. by CRO) from Study patient's or third-party payers.

3. The payment will be cleared within 45 days from the date of receipt of Invoice without any error.
4. The payment is subject to deduction of withholding tax as per Income Tax Act as amended from time to time.
5. From each payment 20% amount will be on hold and will be released as final payment after completion of study.
6. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.
7. Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, X-ray Chest. SAE or in case patient withdrew consent.
8. If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits. however screening visit can be paid. if performed according to protocol.
9. Details of Site is:
   Name of Site: KLES Dr Prabhakar Kore Hospital & Medical Research Centre
   PAN No. : AAATK2644N

V. RECORD KEEPING AND ACCESS

1. Institution and Principal Investigator shall prepare, maintain and retain complete, current, organized, and legible Study documents relating to its performance of the Study which are required to be retained under Applicable Law , and any other records pertaining to the Study patients who have participated in any way, in the Study including, without limitation, source documents monitoring Study patients' progress, medical and clinical records and complete case report forms ("**CRFs**") (collectively, "**Study Records**") for each Study patient no later than 10 (ten) days after a visit. SITE shall respond to all data queries within 7 (seven) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords. Study Records will be retained by SITE for 2 (two) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until 2 (two) years after the investigation is discontinued and FDA is notified, or any longer retention period mandated by Applicable Law.

2. The SITE shall maintain written adequate records of the disposition of the Investigational Product, including dates, quantity and use by Study patients according to Applicable Law, as amended from time to time, and any successor regulations), the

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Protocol, or as otherwise established by written notice from CRO, showing the receipt, administration, or other disposition of the Investigational Product.

3. The SITE is required to prepare and maintain adequate and accurate patient case histories recording all observations and other data pertinent to the clinical Study of each patient enrolled as a subject in the clinical investigation of the Investigational Product.

4. SITE shall retain the records and reports required by Applicable Law as amended from time to time, and any successor regulations), and the Protocol, and shall deliver copies of the same to CRO as required by the Protocol.

5. Authorized representative(s) of CRO and SPONSOR, after arranging in advance with the Principal Investigator and the SITE, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. In cases where the visits are required to respond to a deficiency query raised by any regulatory authority then only travelling / logistics cost will be charged at actuals as separate pass through cost. t.

6. To the extent applicable under Applicable Law, before permitting any clinical investigator to participate in the Study, SITE will provide CRO with financial disclosure information required under Applicable Law (as amended from time to time, and any successor regulations) from clinical investigators..

7. Subject to ownership of intellectual property under Article VIII and SITE's right to publish under Article VI, all results, data, reports, documents, information and the like generated in connection with the Study shall be the property of SPONSOR and shall be delivered promptly to SPONSOR. After the required retention period under applicable law for the Study, SPONSOR will have the option (a) to have the records returned to Sponsor, (b) to have the records destroyed, or (c) to continue having the documentation stored as set forth herein at mutually agreed price

8. SITE will comply with all Applicable Laws and regulations governing the privacy and security of Study patients' information. SITE will obtain written authorization from Study patients to use and disclose their information to the extent necessary to conduct the Study. Such authorizations will allow disclosures to CRO and/or SPONSOR, as applicable, to the extent necessary for CRO and/or SPONSOR to comply with this Agreement, Applicable Laws, regulations, and legal requirements. SPONSOR and CRO will not: (a) use Study patients' information except for purposes of the Study and as authorized in the informed consent documents signed by the Study patient; (b) disclose subject-identifying information or disclose Study patients' private information to any third party unless required to do so by Applicable Law, regulation, government order, or pursuant to a written request by the Study patient; (c) remove Study patient information from Institution; or (d) attempt to contact any Study patients (except as authorized by Study patient in accordance with Applicable Law).

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9. Regulatory Inspections and Audits: A governmental or regulatory authority (including but not limited to representatives of the FDA or other international health agency or regulatory body, having similar regulatory authority over the subject matter of the Study) may, at reasonable times, examine and inspect the facilities being used to conduct the Study. In the event SITE is notified of any such regulatory inspection of SITE's records, facilities, equipment, or procedures, or other materials (including CRFs and patient medical records to the extent allowed by the informed consent document or other legal disclosure authorization), or request for access to the Principal Investigator and/or any sub-investigators to discuss the Study, SITE shall promptly notify CRO and shall provide CRO with copies of any reports issued by any such regulatory authority, and allow CRO to review and comment on any SITE response to such authority. If Institution is found deficient in any manner and reasonable efforts to correct the deficiency are ineffectual, CRO, in its sole discretion, shall either terminate SITE's continued participation in the Study and/or take such corrective actions as may be agreed between SPONSOR and CRO. It is further agreed that if Institution is notified that the Study is to be the subject of an audit, SITE shall promptly inform CRO and SPONSOR. If a formal response to any audit is required, Institution agrees to permit representatives of SPONSOR to review and comment on such response.

VI. PUBLICATIONS

1. SPONSOR and/or CRO (on behalf of SPONSOR), shall be solely responsible for determination whether to submit the Study for listing in a publicly accessible clinical trial registry or any equivalent registry SPONSOR deems appropriate, prior to initiation of any Study patient enrolment and if so determined, CRO shall give the SITE notice of same. For greater certainty, neither Institution nor the Principal Investigator shall register the Study or Study results on any publicly accessible clinical trial registry. Where applicable, CRO shall ensure that a non-promotional summary of the results of the Study or a citation or link to a peer-reviewed article in a medical journal where one exists, will be posted on a free publicly accessible clinical trial results database within 1 (one) year after the Investigational Product is first approved and made commercially available in any country or, if the Study is under review by a peer-review journal that prohibits disclosure of results pre-publication, as soon as practicable after publication.

2. Institution and Principal Investigator hereby acknowledge and agrees that the SPONSOR has the right to use the Study results in any manner deemed appropriate to SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.

3. SITE acknowledges that the Study has been designed as a multicenter study and that the data generated from SITE's participation may not be sufficient to draw meaningful conclusions. For these reasons, SITE agrees not to individually publish the results of the Study, but rather, to participate in a joint, multicenter publication of the Study results coordinated by SPONSOR. If, however, such joint publication is not submitted

for publication within 1 (one) year or 12 (twelve) months of Study completion at all sites, SITE has the right to individually produce and submit a proposed publication, subject to the prior review and approval of SPONSOR as described in Article VI Clause 4 herein.

4. In the event Study is not part of a multi-center study or where no multi-site publication has occurred within 12 (twelve) months after completion and close out of the Study. SITE may freely publish and disseminate the site-specific results of the Study, or otherwise publish or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material containing or dealing with the site specific results of the Study (a "**Publication**") in accordance with the terms of this Agreement provided that, SITE shall: (a) obtain written consent of CRO and/or SPONSOR prior to any such Publication: (b) provide SPONSOR with a copy of any proposed Publication 60 (sixty) days prior to submission for Publication. If SPONSOR determines that the proposed Publication contains patentable subject matter which requires protection. SPONSOR may require the delay of publication for a further period of time not to exceed 180 (one hundred eighty) days for the purpose of filing patent applications.

5. Notwithstanding any other provision of this Article VI, and prior to any Publication. SITE shall preserve the right of SPONSOR to comment on the results and conclusions set forth in any proposed Publication upon SPONSOR's written request prior to the submission of any Publication. SITE agrees that all comments made by the SPONSOR in relation to a proposed Publication or presentation will be incorporated into the Publication or presentation. Reasonable comments for the purposes of this clause 6.5 shall mean such comments and suggestions that, with a view to the scientific interest or the treatment of Study patients, will clarify or improve the proposed Publication or presentation of the results of the Study or the conclusions drawn therefrom, or any other such comments that aim to avoid a Publication or presentation that will misrepresent the results. SITE shall delete any SPONSOR's confidential information in the proposed Publication where reasonably requested by SPONSOR.

6. The obligations described in this Article shall survive the expiration or termination of the Agreement.

VII. CONFIDENTIALITY AND USE RESTRICTIONS

1. CRO and/or SPONSOR will disclose to Principal Investigator and Institution, including its employees, agents, directors, and representatives, certain information furnished in any form, including written, verbal, visual, electronic or in any other media or manner, any information that a party would reasonably consider to be confidential or proprietary including, but not limited to, information concerning the Investigational Product, this Agreement, the Protocol, Study results, processes, know-how, discoveries, inventions, compilations, business or technical information, other materials prepared by either Party or their respective affiliates and representatives, containing or based in whole or in part, on any information furnished by the CRO and/or SPONSOR, and the

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procedures for carrying out the Study, (collectively, "**Confidential Information**"). SITE will keep, such Confidential Information in confidence and shall not use it for the benefit of nor disclose it to others, except as required by the Study or as defined in the Protocol and will at all times, refrain from any other acts or omissions that would reduce the value of SPONSOR's Confidential Information. SITE agrees to ensure that its employees, agents, contractors, representatives, or affiliates (including members of the Study team), who have access to Confidential Information are bound by an obligation of non-disclosure and shall procure non-disclosure agreements with such parties with the same breadth of coverage as provided for in this Article VII. SITE's obligations of confidentiality shall not apply to that part of the Confidential Information that SITE is able to demonstrate by documentary evidence: (a) already in the public domain prior to receipt of such information by SITE; or (b) that becomes lawfully part of the public domain through no act on the part of the SITE, and/or its employees, agents, and representatives; or (c) is obtained from a third party without an express obligation of confidence; or (d) where required by applicable law, regulation, legal process, or other applicable judicial or governmental order to disclose, provided that, should the SITE be required to make such disclosure, where legally permissible, SITE shall provide the SPONSOR and CRO with prompt written notice of such request or requirement so that SPONSOR and CRO may, at its sole expense, seek an appropriate protective order prior to such disclosure; and where SITE is compelled to disclose, SITE shall only disclose that portion of the Confidential Information that SITE is compelled to disclose and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to that portion of the Confidential Information disclosed; or (e) is approved by SPONSOR with written authorization for disclosure by the SITE.

2. SITE shall return all Confidential Information to CRO, except where retention of same is required by Applicable Law, at the earlier of: (a) the time at which SITE ends its participation in the Study; (b) as defined by the Protocol; or (c) immediately upon request of CRO.

VIII. INTELLECTUAL PROPERTY (IP)

1. Intellectual Property that either party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither party has any claims to, or rights in such intellectual property of the other party.

2. The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all intellectual property and Confidential Information provided to Institution and/or Principal

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Investigator relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Article VIII Clause 3 herein), Study data and CRFs produced by as a result of the Study, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, "**SPONSOR IP**"). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The parties further agree that neither party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of Institution and Principal Investigator to use such information for: (a) Institution's own internal, non-commercial research and for educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (b) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

3. Subject to the entirety of Article VII, and the provisions of this Article VIII Clauses 1 and 2, Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories involved in the Study in accordance with Applicable Law (collectively, "**Source Documents**") provided that such does not utilize any Sponsor IP and/or contain any Confidential Information of Sponsor. Institution may utilize any Source Documents in any manner deemed appropriate by Institution without jeopardizing SPONSOR's Intellectual Property Rights derived out of such documents. Sponsor shall have the right to access such Source Documents in accords with Applicable Law.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the ____ day of _____ 2019 between **1) Dr. Kumar Vinchurkar ("Investigator")**, Surgical Oncologist, at KLE's Dr. Prabhakar Kore Hospital Hospital & M.R.C and **2) KLE's Dr. Prabhakar Kore Hospital Hospital & M.R.C ("Institution")** both having its address at **NH 4, Nehru Nagar, Belagavi, Karnataka - 590010, India 3) Genesis Research**("Site Management Office-SMO") having its office at 4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, Indiaand **4) Reliance Life Sciences Pvt. Ltd.** ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	**RLS/ONC/2016/03**
PROTOCOL TITLE:	**Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Xgeva® for prevention of skeletal related events in patients with bone maetastases from solid tumours**
STUDY PRODUCT:	**Test Product: R-TPR-045 (120 mg/ml injection)** **Reference Product: Xgeva® (120 mg/ml injection)**
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Kumar Vinchurkar**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, NH 4, Nehru Nagar, Belagavi, Karnataka - 590010, India**

WHEREAS, Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/ONC/2016/03** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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WHEREAS the Institution has engaged **Genesis Research** as Site Management Organization of authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product. (a) Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

(b) The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

(c) Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not

destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 Adverse Events. The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 New findings. Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. Recruitment. Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **20 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. Enrolment; Notices; Informed Consent; Authorization:

Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects, including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws

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and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or

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discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

7. Publication. The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written

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authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. Subject Injury Reimbursement

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. Inspection and Debarment.

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and

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the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

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a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or
   iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;
   iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;
   v) It is proved that the dosage used for the Study no longer seems to be justified;
   vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;
   vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 Effect of Termination Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety,

Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii)any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

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Dr. V.A.Kothiwale
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Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its

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completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

13. Insurance: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. Shipping of Dangerous Goods and Infectious Materials. The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. Publicity.

15.1 Solicitation of subject: Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 Press Releases: Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 Enquiries from media and financial analysts: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 Use of Name: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 Additional Contractual Provisions.

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or

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Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. **RLS/ONC/2016/03** and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award

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rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate. The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

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By: _____

Name: Jamila Joseph

Title: Sr. Vice President, Head-Clinical Research

Date: _____

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Kumar Vinchurkar

Title: Surgical Oncologist

Date: _____

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: _____

Title: _____

Date: _____

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: _____

Title: _____

Date: _____

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (TAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Researchin** Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Shraddha , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. GST will be paid as per prevailing rates. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY
Protocol: **RLS/ONC/2016/03**
Investigational Product:
Test Product: R-TPR-045 manufactured by Reliance Life Sciences Pvt. Ltd., India
Reference Product: XGEVA®

SITE BUDGET SHEET			
Project Code:	**K070**		
Protocol Number	**RLS/ONC/2016/03**		
Investigational Product	**Xgeva® /R-TPR-045**		
No of patients in study	136		
No of patients	20		
No of visit per patient	12		
Site Related Costs (A)	**Unit Cost**	**Unit**	**Amount (INR)**
Principal Investigator	60000	20	1,200,000
Clinical Research Coordinator Fees	15000	20	300,000
Study Nurse	3000	20	60,000
Pharmacist	5000	20	100,000
Travel reimbursement	6000	20	120,000
#Travel reimbursement (First 52 patient PK)	3500	20	70,000
Hospital Admission	5000	20	100,000
$Travel reimbursement for PK Management week 28	3500	20	70,000
Concomittant medications (Calcium and Vit D)	1650	20	33,000
Sub-Total site related cost (A)			**2,053,000**
Local Laboratory Testing Charges (B)			
12 Lead ECG	1800	20	36,000
Chest X ray	550	20	11,000
CT Scan (whole body CT)	72000	20	1,440,000
Bone scan	22000	20	440,000
Bone mineral density (BMD) Assessment (L1 to L4)	22000	20	440,000
X-ray (Maxillofacial region jaw) (OPG Osteonecrosis of Jaw)	2200	20	44,000
Dental examination	1500	20	30,000
Sub Total Laboratory Testing Charges (B)			**2,441,000**
Total (A) + (B)			**4,494,000**
Per Subject without GST			**224,700**
Applicable GST (18%)			**808,920**
Total Site Budget			**5,302,920**
Per Subject Budget including GST 18%			**265,146**

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A.2 Per Visit Payment schedule:

Assessment	Screening	Randomization	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Total (INR)
PI Fees	2000	3000	6500	6500	6500	6500	6500	7500	3500	3500	3500	4500	60000
CRC Fees	1000	1500	1250	1250	1250	1250	1250	1250	1250	1250	1250	1250	15000
Study Nurse	250	250	250	250	250	250	250	250	250	250	250	250	3000
Pharmacist		500	500	500	500	500	500	500	500	500	500		5000
Travel Reimbursement	500	500	500	500	500	500	500	500	500	500	500	500	6000
#Travel Reimbursement (First 52 patient PK PD) for 7 visits @ INR 750 per visit			3500										3500
Hospital Admission for 24 Hrs only		2500							2500				5000
$Travel Reimbursement for PK Management after week 28 for 7 visits @ INR 500 per visit									3500				3500
12 Lead ECG	300	300			300			300			300	300	1800
Chest X ray	550												550
CT Scan (Whole body)	18000				18000			18000			18000		72000
Bone scan	5500				5500			5500			5500		22000
Bone mineral density (BMD) Assessment (L1 to L4)	5500				5500			5500			5500		22000
X-ray (Maxillofacial region jaw) OPG ; special interest to check Osteonecrosis of jaw	550				550			550			550		2200
Dental examination	300				300			300			300	300	1500
Conmeds (Calcium and Vit D)	150	150	150	150	150	150	150	150	150	150	150		1650
Per Visit Cost	34600	8700	12650	9150	39300	9150	9150	40300	12150	6150	36300	7100	224700
GST (18%)	6228	1566	2277	1647	7074	1647	1647	7254	2187	1107	6534	1278	40446
Per Visit Cost Including 18% GST	**40828**	**10266**	**14927**	**10797**	**46374**	**10797**	**10797**	**47554**	**14337**	**7257**	**42834**	**8378**	**265146**
												Per Subject Budget including GST 18%	**265146**

#Travel reimbursement cost INR 750 per visit will be paid on actual only to First 52 subjects who will be completing 07 visits of Single Dose PK sampling as follows:
07 Visits are: 72.00 (day 3), 120.00 (day 5), 168.00 (day 7), 216.00 (day 9), 264.00 (day 11), 360.00 (day 15), day 20

$Travel reimbursement cost INR 750 per visit will be paid on actual only to First 24 subjects who will be completing 07 visits of steady state PK sampling (will be done at week 28 dosing) as follows:
07 Visits are: 72.00 (day 3), 120.00 (day 5), 168.00 (day 7), 216.00 (day 9), 264.00 (day 11), 360.00 (day 15), day 20

Note:

*Payment will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit). X-ray (Skull, Spine, Chest, Pelvis, Shoulder to elbow, Hip to Knees) will be performed based on the patient requirement after discussion with the Medical Monitor and the Investigator.

In addition to the above Reliance shall make the following payments:

- The screen failure cost will be reimbursed on actual in the ratio of 2:1, i.e. for every 2 patients enrolled into the study. The laboratory and Investigation cost incurred for every screen failure would be reimbursed to the site. Additionally, Investigator Charges for Screen failure will be paid 50 % of the total screening of Investigator charges. However site need to send prescreen report to the sponsor before performing actual screening
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- The per visit activity cost will be paid on the completion of the corresponding activity and the completion of the corresponding CRF.
- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to reallocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- The archival of the study documents after the close out visit will be Reliance responsibility. The archival activity will be performed with the help of a third party vendor appointed by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted at applicable rate.

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Clinical Trial Agreement

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Engaged by:

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Maheshkumar Kalloli
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Investigator")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA")

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 **Investigator/Institution responsibilities**

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, New Drugs and Clinical Trials Rules, 2019, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

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this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambdaundertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 **CRO responsibilities**

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

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LAMBDA Research Accelerated

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6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

- Archival of study documents including source data as referred to in para 2.7 (i) and Section III/k on page # 24.
- Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
- Confidentiality as per para 11

7 **Data ownership / Intellectual property rights**

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

LAMBDA Research

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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11 **Confidentiality**

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

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14 **Termination**

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.
2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
5. The total number of patients required to be randomised is reached before the end of the recruitment period.
6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.

15 **Record retention**

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

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Belagavi-590 010,Karnataka

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Telephone : +918312470400
Fax : +918312493099

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 **Miscellaneous**

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

19.6 "All the Invoices raised to Lambda (CRO) should be GST compliant, according to the GST Invoice rules. Absence of necessary detail will result in delay /non-payment of Invoices till the time of rectification made."

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Principal Investigator:

Sign: _____ **Date:** 05/NOV/2019

Dr. Maheshkumar Kalloli
Principal Investigator
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Witness:

Sign: _____ **Date:** 05 Nov 2019

Witness Name : D Deepak

Witness Address : KLES Dr Prabhakar Kore Hospital & MRC

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Schedule B: Budget and Payment Agreement (I) Budget

Protocol Number: 0566-18		INVESTIGATOR GRANT (For Three Weekly Regimen)									
	Visit No.	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Total
	Cycle No.	NA	1	2	3	4	5	6	NA	NA	
	Weeks	Wk -2 to 0	0	3	6	9	12	15	18	24	
1	Investigator Grant	8500	8000	8000	9600	8000	9000	8000	10500	11000	80000
2	Co-ordinator Grant	3000	1500	1500	2000	1500	2000	1500	1500	3000	17500
3	Day Care Charges		3000	3000	3000	3000	3000	3000			18000
4.1	ECG (12 Lead)	400	400	400	400	400	400	400	400	400	3600
4.2	ECHO	2000					2000			2000	6000
4.3	CT/MRI scan (Whole Body) - Contrast / Bone Scan[5] (if applicable)	17000			17000		17000		17000		68000
4.4	Hepatitis (HCV and HepB) and HIV Screen	LTR Central Lab									0
4.5	Serum Pregnancy Test (For Female Subjects	LTR Central Lab							450	LTR Central Lab	450
4.6	Urine Pregnancy Test (For Female Subjects)		200	200	200	200	200	200			1200
4.7	Biochemistry and Urinalysis[1, 6]	LTR Central Lab			4000		4000			LTR Central Lab	8000
4.8	Hematology[4] - at Local Lab	500	500	500	500	500	500	500	500	500	4500
4.9	Biochemistry[2] - at Local Lab		800	800		800		800	800		4000
	Total	31400	14400	14400	36100	14400	38100	14400	31150	16900	211250
5	Institutional Overhead (25%) - Applicable on Investigator Grant and Coordinator Grant	2875	2375	2375	2750	2375	2750	2375	3000	3500	24375
	Total (with Institutional Overhead at 25%)	34275	16775	16775	38850	16775	40850	16775	34150	20400	235625
6	Patient Compensation (on actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grant/patient										240125

Note:

1	Hematology: Hemoglobin, hematocrit, WBC count with differential (as percentage for white blood cells and absolute for neutrophils & eosinophils only) RBC count and platelet count. BioChemistry: Total protein, albumin, alkaline phosphatase, GGT, AST, ALT, total bilirubin, triglycerides, cholesterol, glucose, calcium, phosphorous, potassium, sodium, urea, creatinine, eGFR and uric acid. Urinalysis: Specific gravity, pH, semi-quantitative evaluation of glucose, protein, bilirubin, ketones, leukocytes, blood. A microscopic examination including RBC, WBC, and casts
2	BioChemistry: ALT,AST, ALP, Total Bilirubin & Serum Creatinine
3	Patient compensation will be provided based on actual bills only (provided is upper limit)
4	Archival would happen at Lambda Clinical Services facility.
5	If Bone Scan will be performed as per PI discretion, only INR 5000/- per bone scan will be paid.
6	Biochemistry and Urinalysis at visit 4 and visit 6 will be performed at Local Lab

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LAMBDA will release payment within 30 days from the receipt of invoice.

k) Archival would happen at Lambda Clinical Services facility.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	**MG CLINICAL RESEARCH**
Address of Payee:	**sector no 12, Plot no 17, M M Nagar, Jain bhasti, Belgaum, Karnataka,590018**
PAN / TAN Number:	**ABFPG5340M**
Payment through wire transfer:	
Name of Beneficiary Account:	**MG CLINICAL RESEARCH**
Beneficiary's Account Number:	**50200044101301**
Bank Name:	**HDFC BANK**
Bank Address:	4830 / 28A, DrAmbedkar Rd, Belgaum, Karnataka,**590002**
IFSC:	**HDFC0000253**
GST Number:	**29ABFPG5340M1ZG**

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) **Per Patient Fee, Payment Schedule and Terms**

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and eCRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc.)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses for safety samples
- usage of internet while filling of eCRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc.)

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- All overhead costs.

Not included are (which are separate and in addition to per patient payment):
- EC submission fee

2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .

9. **Screen Failures:** All screen failure patients payments will be made post LPLV. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) Subject(s) randomized.Reimbursement for discontinued or early termination Subjects will be prorated based on the number of confirmed completed visits.

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

LAMBDA Research Private Limited ATTESTED

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LAMBDA will pay a sum **Rs. 2, 40, 125/- (Two Lakh Forty Thousand One Hundred Twenty Five Rupees Only) for Three Weekly regimen** for every complete and evaluable Subject as defined in the payment schedule.

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges

(l) **Payment Schedule**

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) A complete and evaluable patient is defined as follows:

- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately

b) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

c) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

d) Any other parties designated by you (including Radiology, Local Laboratory, Cardiology, etc.) will be managed and paid by you.

e) The **Ethics Committee fees** will be paid by LAMBDA on behalf of the Sponsor, and it is separate from per patient grant as mentioned in budget.

f) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, SAE, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before randomization will be paid for screening day.

g) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

h) Patient conveyance/compensation will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." GST applicable as per union budget rules.

i) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

j) Payment mentioned under "Final Payment" will be released at the time of site close out.

ATTESTED

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Belagavi-590 010,Karnataka

Schedule A

Study Protocol

Protocol No: 0566-18

"A MULTICENTRIC, OPEN LABLE, SINGLE ARM STUDY TO EVALUATE THE SAFETY AND EFFICACY OF INTP26 (TRASTUZUMAB BIOSIMILAR) IN PATIENTS WITH HER2 – OVEREXPRESSING BREAST (EARLY OR METASTATIC) CANCER OR METASTATIC GASTRIC CANCER".

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to be University)
Belagavi-590010 Karnataka

N WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ Date: 2/Nov/2019

Mr. Rajiv Bhattacharya / Mr. Gautam Vaghela
Clinical Trial Management,
Lambda Therapeutics Research Ltd.

Witness:

Sign: _____ Date: 02/Nov/19

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd.

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Institute: KLES Dr. Prabhakar Kore Hospital and MRC

Sign: _____ **Date:** 06/11/19

Name: Dr M.V. Jali
Designation: MD and CE
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Investigator: Dr Mahesh Kalloli

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

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15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than 30 days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 **Representation and Warranty**

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 **Laws and Jurisdiction**

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 **Notice**

18.1 All notices shall be delivered to the following addresses:

CRO	:	**Lambda Therapeutic Research Ltd**
Address:	:	Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Ahmedabad-382481, Gujarat. India.
Telephone	:	+91 79 4020 2020
Fax	:	+91 79 4020 2021
Contact Person	:	**Dr. Kiran Marthak**
Institution	:	KLES Dr. Prabhakar Kore Hospital and MRC
Address	:	KLES Dr. Prabhakar Kore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India
Telephone	:	+918312470400
Fax		+918312493099
Investigator	:	**Dr. Maheshkumar Kalloli**
Address	:	KLES Dr. PrabhakarKore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India

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d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12 **Privacy**

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13 **Independent Contractor**

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

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7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and thisagreement, irrespective of the PI presence in the institution. Institution will allowregulatory authorities, sponsor and CRO to perform inspections of study data. In casethe PI has to leave the institution, the PI should handover charge of the study to anyother designee in form of document and forward all future communications received toinstitute pertaining to trial. PI is responsible to update CRO and / or sponsor for thischange and all applicable communications, henceforth. Designee will execute all PIresponsibilities, henceforth. In case of change in institution management, the institutewill inform CRO and / or sponsor

8 **Publication**

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9 **Indemnity / Liability**

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10 **Compensation / Insurance**

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury. which are study and/or Compound related.

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3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 **Performance standards of the work to be conducted by the Investigator**

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **01-02 patient** within **1 months;** minimum expected recruitment rate from the site is **01-02 patients** per month on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be **6** months as per study design; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within 3 working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 **Payment terms**

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. Lambda will have oversight on patient reimbursement records maintain at the site.

6 **Period of validity of the Agreement**

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2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);

b) progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure.

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol.

i) Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in

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KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Maheshkumar Kalloli
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Investigator")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.

Intas Pharmaceuticals Limited has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric cancer."** ("Clinical Trial") to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	INTP26 – Trastuzumab Biosimilar 150mg/vial and 440mg/vial of Intas Pharmaceuticals Limited, India
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization
"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA34503809943664R
Certificate Issued Date	:	07-Nov-2019 11:52 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM30/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0887322695371133R
Purchased by	:	DR MAHESH KALLOLI
Description of Document	:	Article 5(J) Agreement (In any other cases)
Property Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KLES DR PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
Second Party	:	DR MAHESH KALLOLI
Stamp Duty Paid By	:	DR MAHESH KALLOLI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

Issued by
The Judicial Employees
Co-operative Credit Society Ltd.
Dist. Court Complex, Belagavi
Pooja
Authorised Signatory

Please write or type below this line

TO,

THE MD & CE,

KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,

NEHRU NAGAR, BELAGAVI-590010

SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE CLINICAL TRIALS AND RESEARCH PROJECT BY DR. MAHESH KALLOLI

Statutory Alert:

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Sir,

I **Dr. Mahesh Kalloli** the undersign is Principal investigator for the clinical trial "A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)." I have no co-investigator and Research Coordinator is Mr. Prakash Patil.

I hereby give an undertaking that I will conduct the investigations/clinical trials as per the agreed terms and deposit 25% of the total funds (as and when received from time to time) to the second party (Medical Director & CE KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi) to the institution as mentioned in the Judicial agreement made. The payment due will be paid within 3 to 4 working days on receipt of the payment from the sponsors.

I will maintain records of all the receipts from the third party as well as payments to the second party throughout the trial period and submit a final report about the finances including institutional charges, when I conclude the trial.

Date: 8/Nov/2019

Place: Belagavi

Signature of PI

Dr. Mahesh Kalloli
MS, Mch (Surgical Oncology)
Consultant Surgical Oncologist
KMC Reg. No. 71586
KLES Dr. Prabhakar Kore Hospital &
MRC, Belagavi - 590010.

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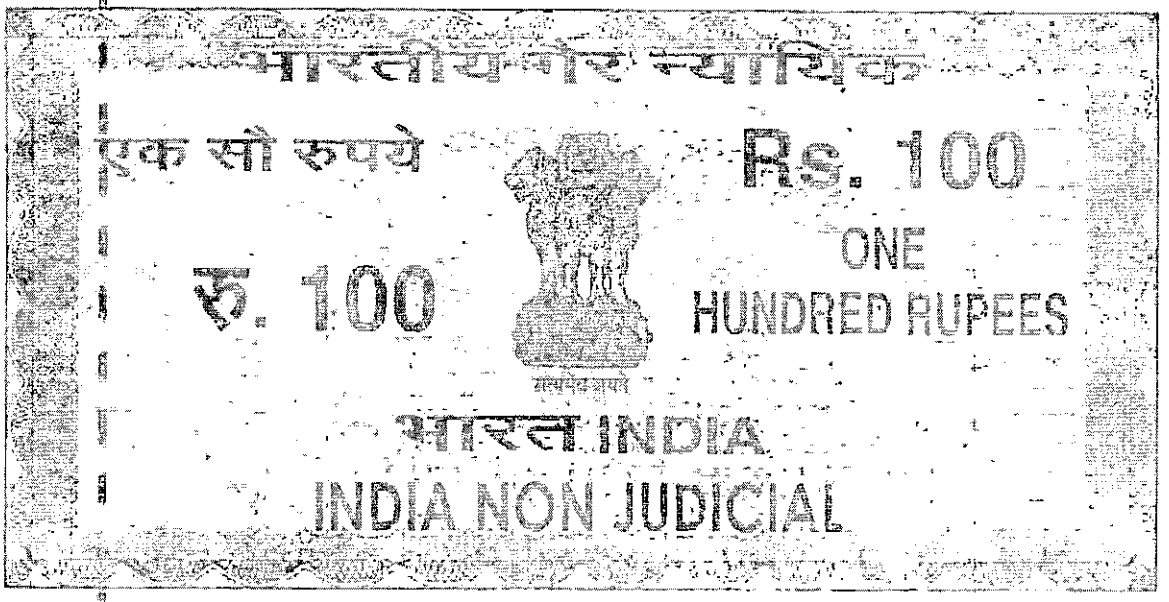

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- 6 SEP 2019

CLINICAL TRIAL AGREEMENT

This contract (hereinafter "**the Contract**") is made as of the **16-10-2019** (hereinafter "**the Effective Date**"). by and among:

Dr.Mahesh Kalloli, Consultant Surgical Oncologist at **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590 010, Karnataka.**

Hereinafter "the **INVESTIGATOR**",

AND

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590 010.

Hereinafter "the **INSTITUTION**" study site

AND

MG Clinical Research , having working office address at **Sector No. 12, Plot No. 17, M M Nagar, Jain bhasti, Belagavi (Belgaum), Karnataka, 590 018.**

Hereinafter "the **SITE MANAGEMENT ORGANISATION/SMO**"

AND

ALKEM LABORATORIES LIMITED, having its registered office at Alkem House, Senapati Bapat Marg, Lower Parel. Mumbai 400013, India.

Hereinafter "the **SPONSOR**"

Initials	Initials	Initials	Initials
INVESTIGATOR	INSTITUTION	SMO	SPONSOR

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Annexure - A

Only for Affidavit

17 SEP 2019

17 SEP 2019

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The INVESTIGATOR, the INSTITUTION, the SITE MANAGEMENT ORGANISATION and the SPONSOR are hereinafter individually referred to as a "**Party**" or collectively referred to as the "**Parties**".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial (hereinafter the "**STUDY**") to evaluate its product **CETUXIMAB** (hereafter the "Investigational Product") in accordance with a protocol of SPONSOR entitled **A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN).**

[**ALK18/ENZ124-CET1**] and its amendments (hereinafter collectively the "Protocol"),

WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study.

AND WHEREAS, the SITE MANAGEMENT ORGANISATION shall initiate, facilitate and make required arrangements for conducting the Study and related activities as mentioned in the Contract on behalf of the Institution.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol, a copy of which has been provided and signed by the INVESTIGATOR, INSTITUTION and SPONSOR. Such Protocol shall be submitted to the registered Institutional Ethic Committee (**"IEC/IRB"**) by the INVESTIGATOR for favorable opinion/ approval which may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified by the INVESTIGATOR to the relevant IEC/IRB according to regulation & guidelines mentioned in section 3.1. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE

The Study shall be performed at the INSTITUTION (hereinafter the "**Study Site**"). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract shall be paid as a compensation for the performance of the Study carried out at the Study Site. Such amount paid to the INVESTIGATOR/INSTITUTION/SITE MANAGEMENT ORGANISATION shall be further distributed between the INVESTIGATOR and/or INSTITUTION and/or SITE MANAGEMENT ORGANISATION as per the mutual terms and conditions agreed between the SITE MANAGEMENT ORGANISATION, INVESTIGATOR and/or INSTITUTION. SPONSOR shall not be responsible for any further payment to INVESTIGATOR, and/or INSTITUTION, and/or SITE MANAGEMENT ORGANISATION, for the

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ARTICLE 3. COMPLIANCE

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines, (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the "**ICH–GCP**"), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF)/electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/e-CRFs to the SPONSOR.

ARTICLE 4. TERM

This Contract is being entered into force from the Effective Date and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately TWENTY FOUR months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR

5.1 The SPONSOR shall provide the INVESTIGATOR and/or the INSTITUTION and/or SITE MANAGEMENT ORGANISATION with all necessary information, documents and materials, including but not limited to :

- the Investigator's Brochure (IB)
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall use the information, documents and Investigational Product provided by the SPONSOR, solely for the purpose of the Study or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

For the purpose of the Contract, the term "Collaborator(s)" shall mean any person involved in the Study including but not limited to research associates, sub-investigators, biologists, assistants and nurses.

Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Product shall be returned or made available to the SPONSOR upon completion of the Study.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

The Investigational Product will not be released until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB and DCGI for the study.

5.3 The INVESTIGATOR / INSTITUTION / SITE MANAGEMENT ORGANISATION or its designee shall ensure that an accurate record of the quantity of Investigational Product received and dispensed to each patient is maintained. The INVESTIGATOR/INSTITUTION/SITE MANAGEMENT

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5.4 The INVESTIGATOR/INSTITUTION/ SITE MANAGEMENT ORGANISATION agrees to take responsibility for the safeguarding of such materials and to notify SPONSOR promptly in case of any loss damage, or failure of these materials.

5.5 The INVESTIGATOR/SITE MANAGEMENT ORGANISATION shall be responsible for management of the medicinal products and blood samples collected from the patient at the Study Site.

5.6 SITE MANAGEMENT ORGANISATION shall be responsible for appointment of clinical research coordinator at the Study Site.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS' RECRUITMENT

6.1 The INVESTIGATOR has estimated that he/she may require to recruit a maximum of 30 (Thirty) Subjects (the "**Subjects**"), within SIX months of commencement of the Study. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g, x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of THREE patients must be enrolled within TWO months of initiating the Study at the STUDY SITE. If no subjects are enrolled over a period of THREE months, the SPONSOR may decide at its discretion to discontinue the Study at the STUDY SITE.

6.3 The SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed informed consent. The INVESTIGATOR shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

6.4 The SITE MANAGEMENT ORGANISATION shall facilitate patient recruitment, and follow up.

ARTICLE 7. CONSENT OF THE SUBJECTS

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1).

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and/or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

7.3 The INVESTIGATOR &/ INSTITUTION shall ensure that the entire informed consent process referred to in Article 7.2 above be video recorded, if the same is applicable as per local regulations and/or made applicable by Institutional Ethics Committee. The INVESTIGATOR &/ INSTITUTION should ensure that the confidentiality of the recorded files is appropriately maintained.

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8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

8.3 SITE MANAGEMENT ORGANISATION shall assist, advise and alert the INVESTIGATOR with respect to any potential Protocol and ICH-GCP violations.

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATOR and/or the INSTITUTION and/or SITE MANAGEMENT ORGANISATION shall immediately inform the SPONSOR, CRO, IRB/IEC, Licensing Authority & Ethics Committee of any serious adverse event ("SAE") or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS

10.1 In consideration for the proper performance by the INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION of their obligations under the Contract, the SPONSOR shall pay the SITE MANAGEMENT ORGANISATION, who shall compensate the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the "**Confidential Information**"), is confidential. The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION agree to keep the information confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall use the Confidential Information solely for the purposes of the Study.

11.2 Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects. the INVESTIGATOR, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

11.3 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or INSTITUTION or the SITE MANAGEMENT ORGANISATION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION or to the SITE MANAGEMENT ORGANISATION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION or to the SITE MANAGEMENT ORGANISATION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's or the SITE MANAGEMENT ORGANISATION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION or the SITE MANAGEMENT ORGANISATION give the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.4 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination or expiry whichever is later.

ARTICLE 12. RECORD RETENTION

The INVESTIGATOR, SITE MANAGEMENT ORGANISATION ...

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for 5 years from the date of closeout visit of SPONSOR to the Study Site after the Study is completed ("**Retention Period**").

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be mutually agreed , or destroy the records, and send the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. DATA PROTECTION

13.1 The Subject data, the INVESTIGATOR's data, the INSTITUTION's data, the SITE MANAGEMENT ORGANISATION's data and Collaborators' data, which may be included in the SPONSOR's databases, shall be treated by the Parties in compliance with all applicable laws and regulations.

13.2 The SPONSOR also collects specific data regarding the INVESTIGATOR and the Collaborators which may be included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations.

13.3 When archiving or processing data pertaining to the INVESTIGATOR, the Collabborators, the INSTITUTION and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

14.2 The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS

15.1 All Confidential Information, documents, materials, Investigational Product and equipment provided by the SPONSOR (hereinafter collectively "**Information**") are and shall remain the sole and exclusive property of the SPONSOR.

The INVESTIGATOR and INSTITUTION shall not and shall cause the Collaborators not to mention any Information in any application for a patent or any other intellectual property rights whatsoever.

15.2 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators, INSTITUTION and the SITE MANAGEMENT ORGANISATION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
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ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE

16.1 The SPONSOR agrees that it has subscribed to a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION and/or the SITE MANAGEMENT ORGANISATION with a certificate of insurance.

16.2 The insurance subscribed to by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION or the SITE MANAGEMENT ORGANISATION from their obligation to maintain their own liability insurance policies.

16.3 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, the SITE MANAGEMENT ORGANISATION and the Collaborators (**"Indemnitees"**) from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Product or the performance of any procedure required under the Protocol as per Indian laws, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Product or the performance of any required procedure;

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or wilful malfeasance of the Indemnitees.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnitees cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnitees without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION or the SITE MANAGEMENT ORGANISATION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate to this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or INSTITUTION and/or SITE MANAGEMENT ORGANISATION to the SPONSOR.

17.4 The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION and/or SITE MANAGEMENT ORGANISATION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the

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17.6 The rights and obligations under this Article shall remain in effect for a period of five (5) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT

This Contract may be terminated: (1) by a mutual written consent of the SPONSOR, INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION on immediate basis; or (2) by the SPONSOR upon serving thirty (30) days prior written notice to the INVESTIGATOR,INSTITUTION and the SITE MANAGEMENT ORGANISATION.

In the event this Contract is terminated, the SPONSOR will be responsible for compensating INVESTIGATOR and/or the INSTITUTION and/or the SITE MANAGEMENT ORGANISATION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 11, 13, 14, 15, 19 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE

The INVESTIGATOR, SITE MANAGEMENT ORGANISATION and the INSTITUTION represent and warrants that neither he/she nor any Collaborators /INSTITUTION involved in conducting the Study nor any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct.

The INVESTIGATOR and the SITE MANAGEMENT ORGANISATION shall immediately notify the SPONSOR should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve months following the expiration or termination of the Contract.

ARTICLE 20. CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE

The INVESTIGATOR shall ensure that he/she and the Collaborators involved in this Study at the INVESTIGATOR's Study Site provide the SPONSOR with the appropriate financial disclosures required for compliance with DCGI, on such forms as the SPONSOR may supply or approve.

ARTICLE 21. MISCELLANEOUS

21.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

21.2 Any work performed by the INVESTIGATOR, SITE MANAGEMENT ORGANISATION and the Collaborators and/or the INSTITUTION under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

[illegible] shall be made by mail or fax

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for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

21.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

21.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

21.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR , INSTITUTION and the SITE MANAGEMENT ORGANISATION shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, INSTITUTION and the SITE MANAGEMENT ORGANISATION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract.

21.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

21.9 This Contract shall be governed by the laws of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and they waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

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IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

ALKEM LABORATORIES LIMITED

Name: Dr Akhilesh Sharma
Designation: President & Chief Medical Officer

In presence of:

INVESTIGATOR

Name: Dr Mahesh Kumar Kalloli
Designation: M.B.B.S, M.S., M.ch (Surgical Oncology)

In presence of: Avinash. I

INSTITUTION

Name: Dr M.V Jali
Designation: MD & CE

In presence of: Revana S.Devanth - Asst coordinator - SMO

SITE MANAGEMENT ORGANISATION

For M.G. Clinical Research

Name: PR MALLIKARJUN J GADGI
Designation: Proprietor
MBBS.

In presence of: Prakash. Patil

ATTESTED

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The SPONSOR will pay Rs. 1,99,175/- **(One Lakh Ninty Nine Thousand One Hundred and Seventy Five only)** per subject included in accordance with the Protocol and who has completed the Study and does not participate in PK study.This sum includes investigator fees, patient travel and meals. Such amount is divided as follows:

Cetuximab Non-PK STUDY Site Budget		
Sr. No	**Particulars**	**Rate per visit**
1	Screening	6,000
2	Cycle 1_Week 0	6,000
3	Cycle 2_Week 1	5,000
4	Cycle 3_Week 2	5,000
5	Cycle 4_Week 3	6,000
6	Cycle 5_Week 4	5,000
7	Cycle 6_Week 5	5,000
8	Cycle 7_Week 6	6,000
9	Cycle 8_Week 7	5,000
10	Cycle 9_Week 8	5,000
11	Cycle 10_Week 9	6,000
12	Cycle 11_Week 10	5,000
13	Cycle 12_Week 11	5,000
14	Cycle 13_Week 12	6,000
15	Cycle 14_Week 13	5,000
16	Cycle 15_Week 14	5,000
17	Cycle 16_Week 15	6,000
18	Cycle 17_Week 16	5,000
19	Cycle 18_Week 17	5,000
20	EOS_Week 18	5,500
Per Patient Grant (A)		**107,500**
Additional Grant (B)		
1	Lab Cost including CT scan, ECG	Actuals
2	Pre and Post Chemo Medication	Actuals
3	Hospitalization charges/Day care charges	64,800
4	Instituitional Overheads (25%)	26,875
Subtotal (B)		**91,675**
TOTAL PAYABLE (A+B)		**199,175**

2) Ethics Committee fees will be based on actuals.

3) Charges of protocol specific local laboratory test, including repeated local laboratory test done in case of adverse event will be reimbursed as per the lab rate list attached with the agreement.

4) Institutional overheads will be 25 % on patient visit fees listed in clause 1 and clause 2.

5) A subject is considered as having completed the study when he/she has completed the specified study period, and is evaluated as per the Protocol.

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EXHIBIT 1

1) The SPONSOR will pay **Rs. 2,19,575/- (Two Lakh Ninteen Thousand Five Hundred and Seventy Five only)** per subject included in accordance with the Protocol and who has completed the Study and participated in Pharmacokinetic study.This sum includes investigator fees, patient travel and meals. Such amount is divided as follows:

Cetuximab PK STUDY Site Budget		
Sr. No	**Particulars**	**Rate per visit**
1	Screening	6,000
2	Cycle 1_Week 0-PK	11,000
3	Cycle 2_Week 1	5,000
4	Cycle 3_Week 2-PK	6,000
5	Cycle 4_Week 3-PK	6,000
6	Cycle 5_Week 4-PK	11,000
7	Cycle 6_Week 5	5,000
8	Cycle 7_Week 6	6,000
9	Cycle 8_Week 7	5,000
10	Cycle 9_Week 8	5,000
11	Cycle 10_Week 9	6,000
12	Cycle 11_Week 10	5,000
13	Cycle 12_Week 11	5,000
14	Cycle 13_Week 12	6,000
15	Cycle 14_Week 13	5,000
16	Cycle 15_Week 14	5,000
17	Cycle 16_Week 15	6,000
18	Cycle 17_Week 16	5,000
19	Cycle 18_Week 17	5,000
20	EOS_Week 18	5,500
Per Patient Grant (A)		**119,500**
Additional Grant (B)		
1	Lab Cost including CT scan	Actuals
2	Pre and Post Chemo Medication	Actuals
3	Hospitalization charges/Day care charges	70,200
4	Instituitional Overheads (25%)	29,875
Subtotal (B)		**100,075**
TOTAL PAYABLE (A+B)		**219,575**

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7) A sum of Rs. 6,000/- (Six thousand only) per subject will be paid as investigator fees for maximum 20% of screen failure subjects at site, this sum includes investigator fees, patient travel and meals. Lab investigations of screening visit for all screen failure subjects will be paid as per actuals.

8) The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION upon presentation of the invoices within 45 days.

NAME OF PAYEE	
Payment through NEFT/ Cheque:	
Name of Payee:	MG CLINICAL RESEARCH
Address of Payee:	sector no 12, Plot no 17, M M Nagar, Jain bhasti, Belagavi (Belgaum), Karnataka, 590018
PAN / TAN Number:	ABFPG5340M
Payment through wire transfer:	
Name of Beneficiary Account:	MG CLINICAL RESEARCH
Beneficiary's Account Number:	**50200044101301**
Bank Name:	**HDFC BANK**
Bank Address:	**4830 / 28A, Dr Ambedkar Rd, Belgaum, Karnataka**
IFSC:	**HDFC0000253**

9) GST shall be added to invoiced amount as per indian tax regulations.

10) All payments made shall be subject to tax deducted at source.

11) The final payment will occur only after:

- The delivery and review of the final data of the study, provided that they shall be ready for statistical analysis;
- The completion of all CRF, including resolution of all DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- Receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- The INVESTIGATOR has returned all remaining Investigational Product and applicable study material, if any.

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KLES
DR. PRABHAKAR KORE HOSPITAL
&
MEDICAL RESEARCH CENTRE
NEHRU NAGAR, BELAGAVI-590 010
KARNATAKA INDIA

Dr. MAHESH KALLOLI
M.S., Mch (Surgical Oncology)
Consultant Surgical Oncologist
KLES Dr. Prabhakar Kore Hospital & MRC
Nehru Nagar Belagavi-590010
Tel : 0831 - 2551669 M : 9945014996
Email : mahesh.kalloli@gmail.com

SL.NO	TESTS	RATE	10% TDS	TOTAL AMOUNT
1	CBC	370	37	407
2	Hb	130	13	143
3	Platelet Count	140	14	154
4	RBC	130	13	143
5	WBC With differential Count	130	13	143
6	ANC	180	18	198
7	ALT	140	14	154
8	AST	150	15	165
9	Alkaline Phosphate	150	15	165
10	Total Bilirubin	150	15	165
11	Serum Creatinine	130	13	143
12	Sodium	100	10	110
13	Potassium	100	10	110
14	Calcium	140	14	154
15	Magnesium	140	14	154
16	INR	350	35	385
17	APTT	400	40	440
18	Urinalysis :Routine & Microscopic Examination	200	20	220
19	HIV	420	42	462
20	HBV	370	37	407
21	HCV	610	61	671
22	Urine Pregnancy Test (UPT)	220	22	242
23	CT Scan of Head (Including Brain)	2400	240	2640
24	CT Scan of Neck	3000	300	3300
25	CT Scan of Chest	3000	300	3300
26	CT Scan of Abdomen+Contrast	5700	570	6270
27	CT Scan of Pelvis	3000	300	3300
28	Bone Scan	4500	450	4950
29	12-LEAD-ECG	200	20	220
30	2-D ECHO	1700	170	1870

Dr. Mahesh Kalloli
M.S., Mch (Surgical Oncology)
Consultant Surgical Oncologist
KMC Reg. No. 71566
KLES Dr. Prabhakar Kore Hospital &
MRC, Belagavi - 590010.

ATTESTED

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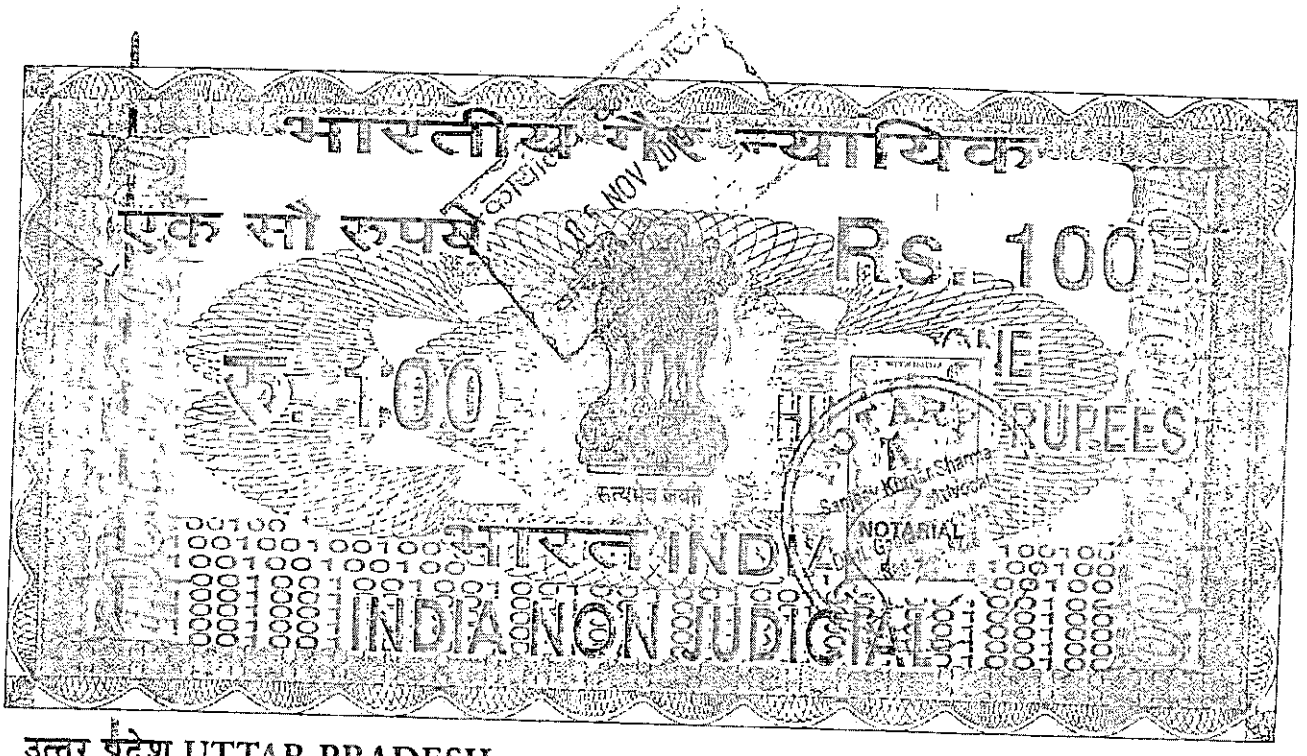

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CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)
And
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi (Institution)
And
Dr. Saroja A.O. (Principal Investigator)

FOR THE STUDY

Title of Study:	A Prospective, Multicentric, Randomized, Double-blind, Parallel, Phase III Clinical study to assess efficacy of PMZ-1620 along with standard treatment in patients of acute ischemic stroke.
Protocol Number:	PMZ-1620/CT-3.1/2019
Version Number /Dated:	Version 1.0/29 APRIL 2019

ATTESTED

Sanjeev Kumar Sharma
Advocate Notary
Dist. Ghaziabad (U.P.)

Dr. Saroja A.O.
M.D (Med) DM (Neuro
Consultant

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on 22 Nov 2019 ("**Effective Date**") at Gautam Buddha Nagar **BY AND BETWEEN:**

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Registered Office at B-4, Sarita Vihar, New Delhi-110076 & its corporate office at H-6, Site C Surajpur Industrial Area, Greater Noida-201307(hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Department of Neurology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, having its office at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010. (hereinafter referred to as "**KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Dr. Saroja A.O. a registered medical practitioner holding MCI registration number-26496 is the D.M/M.Ch Neurology at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010 (hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

Pharmazz, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi and **Principal Investigator** shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

RECITALS

1. WHERE **(KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi)** is a pioneering institution of world-class investigator site in India, having an exclusive set up for conducting clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial and is associated with an Ethics Committee registered with the Licensing authority. **(Exhibit -G)**
2. Pharmazz has rights to Intellectual Property related to PMZ-1620 is a lyophilized IRL-1620 Injection (Sovateltide), proposed to act as a Treatment agent in Acute Ischemic Stroke for which Phase III Clinical Trial NOC has been issued by DCGI **(Exhibit F)**
3. Principal Investigator **Dr. Saroja A.O (D.M Neurology** is a registered medical practitioner

Dr. Saroja A. O.

ATTESTED

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and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement **Dr. Saroja A.O** for conducting Clinical Trial Phase III study titled "**A Prospective, Multicentric, Randomized, Double-blind, Parallel, Phase III Clinical study to assess efficacy of PMZ-1620 along with standard treatment in patients of acute ischemic stroke** at **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi .**

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to conduct the proposed Study at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) "**AGREEMENT**" shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipment's, samples, services, customer lists, marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) **"EFFECTIVE DATE"** shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items, and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and

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Belagavi-590 010,Karnataka

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supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled "**A prospective, multicentric, randomized, double-blind, parallel, phase III clinical study to assess efficacy of PMZ-1620 along with standard treatment in patients of acute ischemic stroke.**"As defined in the Protocol.

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocolnumber-1620/CT-3.1/2019 (a copy of which is attached as **Exhibit A** and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"INVESTIGATIONAL DRUG"** shall mean: PMZ-1620 or IRL-1620 (Sovateltide) For Injection 30 µg/vial.

i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act 1940 and Rules 1945 and New Drugs and Clinical Trials 2019 and amendments.

j) **"DCGI"** Drug Controller General of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) Wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) Unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period

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commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) Unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) The terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi and Principal Investigator to complete the following

Responsibility of the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi & Principal Investigator

The **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** agrees to provide full support to the Principal Investigator at **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** to conduct the Clinical Trial in **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** premises and to make all reasonable endeavors to retain the Principal Investigator and utilize reasonably the facilities available in the **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The **Principal Investigator** and **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** shall be jointly and severally responsible

a) To conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol, **Case Report Form (Exhibit-I)** shall also be provided by the sponsor to record all the data mentioned in protocol.

b) To comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (ICH E6 (R2) 2016 (OMB Control No. 0910-0843, 2018)), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**") and New Drugs and Clinical Trials Rules 2019 issued by Central Licensing Authority;

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c) To fulfills all other terms and conditions stipulated herein and, in the Exhibits, hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) To provides Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.2 The Principal Investigator shall personally review all Case Report Forms duly filled in to assure its completeness and accuracy. A case report form is deemed complete when:

a) The case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) It relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) It can be used in all analysis of the Study results.

d) The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

e) Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements and also ensure the retention of subject till the completion of the study.

f) Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty-four (24) hours of knowledge of event in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments and New Drugs and Clinical Trials Rules, 2019 and its subsequent amendments, if any.

g) The **Principal Investigator** and **Pharmazz** shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of knowledge of such deviation and/or serious adverse events of death, as the case may be.

h) The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of knowledge of such serious adverse events other than death.

i) The Principal Investigator shall provide detailed report of serious adverse event along with duly filled CRF to Pharmazz within (4) calendar days of such serious adverse event.

j) In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the **Principal Investigator/ KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the KLES, Belagavi.

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The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after signing the necessary revised CTA with the sponsor's consent & completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethics Committee or the regulatory agency if required. **The study shall only be initiated at site after getting clean approval from concerned Ethics Committee (Exhibit -H).**The Study of the Pharmazz is being entrusted to the **Principal Investigator** and **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi throughout the period of the Clinical Trial and then with third party vendor assigned by sponsor for a period of fifteen (15) years after the Study completion or such longer period as required with the consent of Sponsor by Applicable Laws & Guidelines. At the end of such period mentioned above, the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Dr. Saroj

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2.6 **Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.7 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.8 **Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained to be conducted at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. The Pharmazz will provide the Study Drug to the Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the efficacy of PMZ-1620 along with Standard Treatment in patients of Acute Ischemic Stroke.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. Examine and inspect the **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 's** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study and audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol;

Dr. Sanjay A. K...
Registrar
Co-ordinating Secretary
KLE's Reg. No. 27...

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Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 **Pharmazz** agrees that in consideration of the **Principal Investigator's** and **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in **Exhibit-B**, to the **Saroja Onkarappa Aralikatte** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related costs including institutional overhead etc.

5.2 The Parties agree that the payment of the amount set forth in **Exhibit B** will be paid by the Pharmazz to the **Saroja Onkarappa Aralikatte** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the institute nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in **Exhibit B** is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in **Exhibit B** to be paid **to Saroja Onkarappa Aralikatte** shall be paid by Pharmazz. This amount is based on the estimated number of subjects in the time duration as agreed by Principal Investigator as per site feasibility report **Exhibit D**. Any change in the estimated number of subjects will proportionally affect the amount of payment.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi under this Agreement.

5.5 **Saroja Onkarappa Aralikatte** will raise GST invoices (if applicable) subject wise after sharing the subject's complete data as per the specific study Protocol with Pharmazz. After reviewing the receipt of data Pharmazz shall release the payments within 15days of completeness of data. In cases where there is loss to follow-up the proportionate amount will be paid till the last visit data is received of that particular subject, however in case of any SAE full payment shall be made after all formalities and reporting's are done as per the latest applicable regulatory guidelines. If there is any consent withdrawal case, no payment shall be

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made as the data cannot be used for the study.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** and **Principal Investigator** shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect).

The Second Party i.e. **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** shall be solely liable to pay all costs of such compliance.

In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement. KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi and Principal Investigator are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

The Second Party and Principal Investigator will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement.

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8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90-days written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, KLES, Belagavi and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** and **Principal Investigator**

b) **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters of enrollment and as per his undertaking and site feasibility report provided **(Exhibit D)**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the **Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** to Provide Access by the Pharmazz's Representatives all original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and Principal Investigator's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be affected by written notice to the Second Party and Principal Investigator, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phasedown costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and Principal Investigator, whichever is later. The Second Party and Principal Investigator shall be given reasonable opportunity to present

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to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and Principal Investigator will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and Principal Investigator to meet the deadline of (30) days for corrective measures, then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the **Principal Investigator** and **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator ,KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) The failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

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INVESTIGATOR CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "Agreement"), effective as of the later of the dates appearing on the signature page, is entered into by and among, Dr Navin Mallikarjun Mulimani, Consultant Interventional Radiologist. ("Principal Investigator) KLES Dr. Prabhakar Kore Hospital, Nehru Nagar, Belgaum-590010, Karnataka, India ("INSTITUTION"), **SIRO Clinpharm Pvt. Ltd.,** a company incorporated under the laws of India whose principal place of business is located at Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra,, INDIA (hereinafter referred to as "SIRO")

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to vascular anomalies is consultant at KLES Dr. Prabhakar Kore Hospital, Nehru Nagar, Belgaum-590010, Karnataka, India.

WHEREAS, the SMO is engaged in site management Ardent Clinical Research Services, Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune-411001 (SMO) and providing CRC support throughout the study.

WHEREAS, the INSTITUTION is a Private Multispeciality Hospital

WHEREAS, SPONSOR is engaged in the research and development of human pharmaceutical products;

WHEREAS, SPONSOR is the Sponsor of the clinical study of "Safety and Efficacy of Lipiodol ultra fluid in association with surgical glues during vascular embolization. A phase IV study." (the "Clinical Study")

WHEREAS, SIRO is the Clinical Research Organization acting on behalf of SPONSOR to administer the clinical study;

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to vascular anomalies and

WHEREAS, the Principal Investigator wishes to participate in the Clinical Study and SPONSOR wishes to have the participation of the Principal Investigator.

NOW THEREFORE, the parties agree as follows:

1. **Protocol**

1.1 **Title.** The Clinical Research protocol LUF-44-001, titled a "Safety and Efficacy of Lipiodol ultra fluid in association with surgical glues during vascular embolization. A phase IV study" which will guide the performance of the Clinical Study, has been prepared by SPONSOR and accepted by the Principal Investigator (the protocol, together with any of its subsequent amendments, shall be referred to in this Agreement as the "Protocol").

1.2 **Conflicts.** In the event of a conflict between the terms and conditions set forth in this Agreement and the Protocol, this Agreement will govern.

1.3 **GCP.** If generally accepted standards of Good Clinical Practice ("GCP") relating to the safety of subjects participating in the Clinical Study require a deviation from the Protocol, these standards shall be followed. Any party who becomes aware of the deviation from the Protocol will immediately inform the other parties to this Agreement of the facts causing the deviation as soon as the facts are known to the

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party. In addition, the Principal Investigator will promptly inform the Institution's institutional review board ("IRB") of the deviation.

1.4 **Amendments.** SIRO on behalf of SPONSOR, may also, from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

2. Principal Investigator

2.1 The Principal Investigator shall carry out the Clinical Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement. The Principal Investigator will also be responsible for the direction of the Clinical Study in accordance with any applicable Institution policies. The Principal Investigator shall ensure that all staff of site and SMO are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator or the INSTITUTION or SMO should inform SIRO and SPONSOR in the event of a discrepancy between the terms of the Protocol, this Agreement and its own INSTITUTION policies within twenty-one (21) days of the Effective Date of this Agreement. In the absence of any such intimation by the Principal Investigator or the INSTITUTION, the terms of the Protocol and this Agreement shall prevail The Principal Investigator shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement.

3. Study Initiation and Subjects

3.1 It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed on or 31 December 2019 and that the Clinical Study will be completed on or about July 2020 unless otherwise terminated in accordance with the provisions of Para 17 of this Agreement.

3.2 If however, the Clinical Study obligations have not been completed by December 2019, the Principal Investigator shall continue with, and complete all obligations under this Agreement. All payments shall correspond with the appropriate milestone, as listed in Schedule A.

3.3 The Clinical Study will involve the competitive enrollment of a maximum of 125 subjects (provided there may be an increase in enrollment upon SIRO or SPONSOR request) meeting all Protocol eligibility requirements ("Subjects"). SIRO shall not be obligated to pay any sums for tests performed on subjects who do not meet all Protocol eligibility criteria or for additional subjects who are enrolled in the Clinical Study without SIRO's prior written approval.

4. Patient Information and Consent

4.1 It is the Principal Investigator's responsibility to explain the Study to each potential patient and obtain written informed consent before any Study procedures are performed. This is an unconditional prerequisite for participation of a patient in the Study. The Investigator shall inform the subject or his/her nominee(s) for their rights to contact the sponsor or SIRO (whosoever has obtained permission from the licensing authority for the conduct of clinical trial) for the purpose of lodging claims in case of any trial related injury/death. The explanation shall at least include all points listed in the Guideline for Good Clinical Practice, section 4.8.10 including but not limited to applicable regulations, and it must be given both verbally and in writing in compliance with Indian GCP, ethical principles based on the Declaration of Helsinki in its current version and national requirements. Patients shall be given sufficient time to consider their participation in the Study. Consent must be documented by the patient's dated signature on the trial informed consent form. A copy of the signed and dated information and consent form must be provided to the patient. In the event the Patient is not able to give informed consent, the same may be obtained from a legally acceptable representative. For the purpose of this section, a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the Patient as provided by the

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applicable law(s) of India. In the event the Patient and where required his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the trial informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the trial informed consent form.

4.2 Provision of consent will be confirmed in the CRF as well as by the Principal Investigator's signature on the consent form. The signed and dated declaration of informed consent will remain at the INSTITUTION and must be safely archived by the Principal Investigator, so that the forms can be retrieved at any time for monitoring, auditing and inspection purposes.

5. Insurance Coverage

5.1 SPONSOR shall adequately insure each and every participating patient covering any injury or illness suffered as a direct result of their participation in this Clinical Study. Provided that the SPONSOR shall not be responsible to provide for insurance coverage with respect to any injury (including death) or illness arising as a result of (i) negligent acts of Principal Investigator, and/or INSTITUTION and/or SMO with respect to activities or services undertaken pursuant to this Agreement; (ii) improper or negligent administration or use of the Clinical Study Drug during the course of the Clinical Study by the Principal Investigator,; or (iii) in violation of any and all applicable Central, State or Local laws rules and regulations in India and in France by Principal Investigator, INSTITUTION, SMO and SIRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

5.2 Both, the INSTITUTION and the Principal Investigator, shall have adequate insurance coverage for any claims arising from their negligence, willful misconduct and other actions or omissions. The Institution and the Investigator will provide a copy of their insurance certificate to SIRO and the SPONSOR upon signature of this Agreement.

6. Ethics Committee Approval

6.1 The Study will only be started, when full written approval of/ favorable opinion on the Protocol has been obtained from the concerned Investigational Review Board (IRB). It is the Principal Investigator's responsibility to obtain EC/IRB approval/opinion for the Protocol and all subsequent amendments, in compliance with the national regulatory requirements and laws.

7. Study Management

7.1 **Case Report Form handling.** The Principal Investigator shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

7.1.1 The main objective of the CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

7.1.2 The data recorded in the course of the Study shall be documented in the CRFs and, as necessary, on the SAE report. They will then be forwarded to SIRO/SPONSOR for data management and biometric analysis.

7.1.3 The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to SIRO/SPONSOR.

7.1.4 Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the CRFs and considered as source data will be identified as such. All data in the CRFs must correspond exactly with data recorded in the source documents.

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7.1.5 If CRFs are not complete the Principal Investigator shall be obliged to complete them on request of SIRO/SPONSOR.

7.2 **Source Data.** The Principal Investigator shall be responsible for providing the Source Data according to the following regulations.

Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically they comprise:

- Signed informed consent form.
- Patient hospital file and individual clinical notes.
- Laboratory reports.
- Pharmacy records.
- Study specific source documents (e.g. angiograms).
- Appropriate sections of the CRF, where data are recorded directly onto specific forms.
- Other reports and records of any procedure performed in accordance with the Protocol.

The Principal Investigator shall safely maintain the original Study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 15 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify SIRO/SPONSOR. If the duration of archival by the Institution is less than 15 years, SIRO will transfer the records at Guerbet cost to a different archival center at the time of termination of the INSTITUTION archival period.

7.3 **Investigator Study File and Archiving.** The INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with Indian GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study, including without limitation:

- Signed protocol and amendments.
- Investigator's Brochure and updates.
- EC composition, approval(s)/opinion correspondence/reporting.
- Notifications of regulatory authorities.
- CVs and signature sheet for key study personnel (e.g. investigators, study nurses).
- Signed study agreements including financial agreement.
- Trial initiation report.
- Approved and signed informed consent forms.
- Study insurance certificate.
- CRFs (investigator's copy).
- SAE documentation and related correspondence/reporting.
- Shipping/accountability/destruction records for investigational product and material.
- Certificate of analysis
- Instructions for handling of investigational product and material.
- Laboratory accreditation/certification and up-to-date reference ranges of normal values.
- Screening, enrollment and monitoring logs and subject identification code list.
- Appointment diaries.
- Study related correspondence with SPONSOR or SIRO.

7.4. **Documentation and Material (Supplies).** All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of Investigational Product and any other material for the Study, supplied by SIRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to SIRO/SPONSOR or destroyed at site, alternatively. In the latter case

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the identification and quantity of each unit of study medication, the method of destruction, and the person in charge must be documented.

7.5. **Monitoring, Quality Assurance, and Inspection by Authorities.** The Study will be monitored by SIRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information.

SIRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor comprise the following, included without limitation:

- to ensure protocol adherence,
- to verify the data in the CRFs against source documents (SDV),
- to check progress of the study and to motivate, if necessary,
- to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
- to check all data for possible SAEs and AEs,
- to review signed informed consent forms for signatures and date of consent,
- to ensure accurate record of drug accountability,
- to ensure adequate storage of study supplies,
- to collect completed CRFs,
- to discuss and help resolve any problems,
- to verify adequate insurance coverage undertaken by PI,
- to verify the ICF(s) as per the applicable regulatory guidelines.

Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation, and drug accountability.

The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time will be allowed for monitoring visits. Follow-up correspondence between the site and SIRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both SIRO and the site.

This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the SIRO.

For monitoring visits and in case of audits and inspections by authorities the Principal Investigator must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additionally required background data. Furthermore, access to Study related facilities must be ensured.

7.6 **Confidentiality of Patient Records.** The INSTITUTION, Principal Investigator and SMO must assure that study patients' anonymity will be maintained, and that their identities are protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full names and dates of birth together with the corresponding patient identification numbers to allow revealing identity of any subject.

The Principal Investigator agrees that representatives of SPONSOR, SIRO, of the responsible EC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and SIRO guarantee for their representatives that patient data will be treated confidentially. Monitors and auditors are bound to secrecy.

8. **Budget**

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Cost and payment terms are set forth in Schedule "A" attached to this Agreement and incorporated by reference. All the payment obligations of the Sponsor shall be routed through SIRO. All the payment obligations of the Site shall be routed through SMO.

9. Data and Information

9.1 **Confidential Information.** During the term of this Agreement, and for a period of ten (10) years after termination of this Agreement, the Principal Investigator and Institution shall not disclose or use for any purpose other than performance of the Clinical Study, information including but not limited to any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and non-technical, disclosed to the Principal Investigator and Institution by SIRO or SPONSOR ("Information"). The obligation of non-disclosure shall not apply to the following:

9.1.1 Information at or after such time that it is or becomes publicly available through no fault of the Principal Investigator/Institution;

9.1.2 Information that is already independently known to the Principal Investigator/Institution as evidenced by their prior written records;

9.1.3 Information at or after such time that it is disclosed to the Principal Investigator/Institution on a non-confidential basis by a third party with the legal right to do so;

9.1.4 Information developed by the Principal Investigator/Institution without the use of SIRO's or SPONSOR's Information as evidenced by their written records; or

9.1.5 Information required to be disclosed by law.

9.2 **Medical Records.** In the event that either SIRO or SPONSOR come into contact with Subjects' medical records, such party shall hold in confidence the identity of the Subject and shall comply with the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 made under the Information Technology Act, 2000 (and all other applicable law(s) with respect to the confidentiality of such records.

9.3 **Trading in Securities.** Securities and Exchange Board of India (SEBI) interalia, prohibits any person either on his own behalf or on behalf of any other person, deal in securities of a company listed on any stock exchange when in possession of or is likely to have access to or has received any unpublished price sensitive information. The Principal Investigator, by virtue of their participation in the Clinical Study, has access to data and information arising out of the conduct of the Clinical Study, which is material non-public information that belongs to SPONSOR. The Principal Investigator agrees not to use, or cause any other person to use, the data and information arising out of the Clinical Study to purchase or sell securities in SPONSOR Company.

9.4 **Proprietary Rights.** All information resulting from the Clinical Study conducted under this Agreement, including all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not ("Data") shall be fully disclosed by the Principal Investigator to SPONSOR. All Data shall be the sole property of SPONSOR and SPONSOR shall have the unrestricted right to freely utilize all such Data in whatever manner it desires. Principal Investigator and/or the INSTITUTION agree to undertake such actions reasonably requested by SPONSOR to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.
INSTITUTION and Principal Investigator hereby assigns to SPONSOR all inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefore, and appoints any officer of SIRO as his duly authorized agent to execute, file, prosecute and protect the same before any government agency, court or authority

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9.5 **Resignation etc. of the Principal Investigator:** The INSTITUTION shall inform SIRO in case the Principal Investigator ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the Principal Investigator in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

9.6 **Change of SMO**: The INSTITUTION and/or Principal Investigator shall inform SIRO in case the SMO ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the SMO in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

10. Drug Safety

10.1 The recording of adverse events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR/SIRO's medical monitor concerning any AEs.

10.2 According to the Protocol, the Principal Investigator will assess whether any adverse event (AE) including abnormal laboratory values or worsening of pre-existing diseases has occurred during the course of the study. The details of all AEs, whether reported by the patient or observed by the Principal Investigator /Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship. All AEs must be followed until complete resolution or sequelae stabilization.

10.3 The Principal Investigator must immediately report all Serious Adverse Events (SAE) (as defined in protocol) and **within at most 24 hours of occurrence of SAE**, which occur during the course of the Study and up to the date of the patient's last visit, to the sponsor (Guerbet HQ Pharmacovigilance), to the Health Authority and to the Ethics Committees (addressee given below). The study specific SAE Report form will be used for documentation and reporting.
In addition, a due analysis report has to be submitted to the following addressee within 14 calendar days of occurrence to the DCGI (Licensing Authority), Ethics Committee Chairman and Head of the Institution for all the Initial and Follow-up information until stabilization/ resolution of the event.

The SAEs must be reported within 24 hours to:

- Licensing authority: all initial SAE forms only are to be e-mailed and faxed at :
  - Email ID: dci@nic.nic.in
  - Fax no.: 011-23236973

- Guerbet HQ Pharmacovigilance: all Initial and follow up SAE reports are to be sent on the following:
  - Email ID: pharmacovigilance.headquarters@guerbet.com
  - or faxed to the number: 0033 1 45916770.

- Ethics Committee: all initial and follow up SAE reports are to be sent via e-mail klecliniclresearch@gmail.com to Ethics committee.

The SAE must be reported within 14 Days to:

- Licensing authority: For all SAEs as hard copy via courier at DCGI address by Guerbet or its representative

The Drugs Controller General (India)
FDA Bhavan, CHEB Campus
Kotla Road,
(Adjacent to Mata Sundari Girls College)
New Delhi – 110 002.
Fax: 011-23236973

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- Chairman of Ethics Committee by the principal investigator: For all SAEs as hard copy via courier at Institutional Ethics Committee, KLE University, JNMC Campus, Nehru Nagar, Belgaum-590010, Karnataka India.
- Head of the Institution by the principal investigator: For all SAEs as hard copy via courier at, Institutional Ethics Committee, KLE University, JNMC Campus, Nehru Nagar, Belgaum-590010, Karnataka India.

10.4 The Principal Investigator will inform the local Ethics Committee of any findings that could adversely affect the patients' safety could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

10.5 Guerbet and/or its representative will be responsible to notify on time the DCGI any findings that could adversely affect the patients' safety, could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

11. Study Drug and Study Materials

11.1 **Study Drug.** SIRO, on behalf of SPONSOR, will provide Clinical Study Drug for the Clinical Study. The use of the Clinical Study Drug for any purpose outside of the Clinical Study is prohibited by this Agreement. While SIRO in no way condones the use of the Clinical Study Drug for any purpose outside of the Clinical Study if such work is performed, all data, results, conclusions, observations, discoveries, inventions, ideas know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Data in accordance with this Agreement. INSTITUTION and Principal Investigator shall assure that the Clinical Study Drug will be dispensed or administered to Subjects only under the supervision of authorized investigator/personnel responsible for this activity,

11.2 **Materials.** Access to Study Materials shall be limited to only those persons who under the Principal Investigator's direct control will be using Study Materials for the Clinical Study. The term "Study Materials" shall include the Clinical Study Drug, reagents and materials derived from Subjects enrolled in the Clinical Study, including, but not limited to, blood, bone marrow, sera, and other biological materials. At no time shall any Study Materials be used for any purpose other than as described in the Protocol or transferred to any third party without SPONSOR's prior written consent. Upon termination or completion of the Clinical Study, all unused Study Materials shall be returned to SPONSOR or at SPONSOR's sole option, destroyed.

12. Publications

12.1 The Principal Investigator /INSTITUTION/SMO shall not publish any article or paper nor make any presentations, nor assist any other person in publishing any articles or papers or in making any presentations, relating or referring to:

(a) the Study or any results data or insights therefrom;
(b) the Services performed hereunder; or
(c) any data, information or materials obtained or generated in the performance of its obligations hereunder, in whole or in part without the prior written consent of SIRO and SPONSOR , which consent may be granted or withheld depending on the Study Sponsor's sole discretion.

13. Use of Name and Advertising

13.1 **Use of Name.** The INSTITUTION / Principal Investigator / SMO and SIRO, on behalf of SPONSOR, shall each obtain prior written consent from the other before using the name, symbols or marks of the other in any form of publicity in connection with the Clinical Study. If the INSTITUTION or SIRO is legally required to make any disclosure that identifies the existence or terms of this Agreement, then either may do so with prior written consent from the other,

13.2 **Advertising.** In the event that the Principal Investigator elects to advertise to recruit Subjects for enrollment in the Clinical Study Principal Investigator will provide a copy of any such advertisement to SIRO / SPONSOR for prior approval. In addition, Principal Investigator will obtain Institutional Review

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Board and Ethics Committee approval of all advertisement prior to use. Any promotional representation or suggestion that an investigational drug is safe or effective for the purposes for which it is under investigation is not permissible / a violation of the United States Code of Federal Regulation 21 CFR 312.7(a).(Strike out if not applicable depending upon the country of the sponsor)

14. Compliance with Law: Financial

14.1 The Principal Investigator, the INSTITUTION and the SMO shall perform the Clinical Study in compliance with generally accepted standards of Indian Good Clinical Practice as defined by Central Drugs Standard Control Organisation (CDSCO), the Protocol, instructions provided by SIRO and SPONSOR and all applicable local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the Indian Drugs and Cosmetics Act, 1940 and the Rules thereunder, World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, June 1964, and amended in October 2013 (Fortaleza), DCGI Order F. No. GCT/20/SC/Clin./2013 of November 19, 2013, Appendix XII of Schedule Y- "Compensation in case of injury or death during Clinical Trial" of Drugs and Cosmetics (Amendment) January 30th 2013, Drugs and Cosmetics (Sixth Amendment) Rules, December 12th 2014, Guideline on good pharmacovigilance practices (GVP), Module VIII – Post-authorization safety studies, Directive 2010/84/EU from 15 December 2010 amending, as regards pharmacovigilance. The Principal Investigator shall retain any records mutually agreed to by SIRO, resulting from the Clinical Study for the time required by applicable local and federal regulations, and to allow for inspection of all such records including the Subjects' medical records. The informed consent form signed by the Subjects shall provide for access to the Subjects' medical records by SIRO, SPONSOR and by regulatory agencies.

15. Debarment

15.1 The Principal Investigator certifies that neither the Principal Investigator nor any person employed by the Principal Investigator or SMO or any other subcontractor to perform any services in connection with the Agreement has been subject to any legal or regulatory discipline, nor ever been suspended, debarred, or is under any medical license limitation or condition, or otherwise disqualified from providing medical services by any governmental, regulatory or administrative body or organization within their jurisdiction.

16. Indemnification

16.1 SPONSOR warrants that they shall defend, indemnify and hold harmless SIRO, PRINCIPAL INVESTIGATOR, INSTITUTION and any of their agents and employees ("indemnitees of Sponsor") from any and all liabilities, claims actions or suits for personal injury or death directly arising out of the administration or use of the Clinical Study Drug during the course of the Clinical Study in accordance with the Study Protocol.

16.2 The indemnity granted in this Article 16 shall NOT apply in the event such liability, damage, loss, or expense is caused by the failure of an Indemnitee to:

16.2.1 adhere materially to the terms of the Protocol;

16.2.2 comply with government regulations or requirements; or

16.2.3 conduct the Clinical Trial in accordance with generally accepted medical standards including avoidance of negligence and willful misconduct.

16.3 SIRO warrants that it shall indemnify, defend and hold harmless SPONSOR, INSTITUTION and Principal Investigator, including their agents and employees (the "Indemnitees of SIRO") from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of negligent or deliberate wrongful acts of SIRO or its employees during the term of this Agreement; except to the extent that the same is caused as a result of the Project Materials provided by the Sponsor or adhering to the instructions of the Sponsor or Applicable Laws while rendering the Services or due to reasons attributable to the SPONSOR, INSTITUTION or Principal Investigator and their agents and employees.

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16.4 The indemnity granted in Article 16 shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

16.5 Each party warrants that it shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. The indemnifying Party shall have the right to settle claims at its sole expense.

16.6 The Principal Investigator' INSTITUTION/SMO shall promptly notify SIRO and SPONSOR of any claim for which indemnity may be sought. The Principal Investigator / INSTITUTION/SMO shall fully cooperate with SPONSOR / SIRO and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. If the claim or action is asserted, the Principal Investigator shall have the right to select and obtain representation by separate legal counsel, as long as the Principal Investigator pays for all costs and expenses incurred by it for the separate counsel.

16.7 SPONSOR warrants that it maintains policies or programs of insurance or self insurance at levels sufficient or have SIRO to maintain such programs of insurance at the cost of SPONSOR to support the indemnification obligations assumed under this Agreement. Upon request, SPONSOR will provide evidence of their insurance or self-insurance.

16.8 The SMO,Principal Investigator and INSTITUTION each shall indemnify, defend and hold harmless the Sponsor, including its agents and employees, and SIRO, including its agents and employees, against any losses suffered and from all liabilities, claims, actions or suits for personal injury or death, directly arising out of the negligence, willful misconduct or any other act or omission by the Principal Investigator or the INSTITUTION, or by their agents and employees, during the course of the Clinical Study.

16.9 The SMO, Principal Investigator and the INSTITUTION each shall also indemnify, defend, and hold harmless the Sponsor and SIRO against:

(i) any and all loss, costs, claims, actions, liability and/or suits (including without limitation, interest, penalties and reasonable attorneys' fees) on the Sponsor or SIRO due to negligence, gross negligence or intentional misconduct of Principal Investigator and/or SMO and/or INSTITUTION in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(ii) SMO, Principal Investigator's and/or INSTITUTION's violation of any and all applicable Central, State or Local laws rules and regulations of India;

(iii) Principal Investigator's and/or INSTITUTION's and/or SMO's breach or default in performance of its obligations in connection with a Study;

(iv) Principal Investigator's and/or INSTITUTION's and/or SMO's material deviation from the Protocol or other written recommendation or instructions furnished by SPONSOR through SIRO to Principal Investigator and the INSTITUTION for the Study;

(v) Principal Investigator's and/or INSTITUTION's and/or SMO's failure to complete the Study and any such delay attributable solely to Principal Investigator's and/ or INSTITUTION's willful misconduct, negligence or mistakes and/or or failure to comply with its obligations under this Agreement.

Without prejudice to any other Section, the reference to SMO, Principal Investigator and INSTIUTION above includes reference to its agents and employees.

17. <u>Independent Contractor</u>

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17.1 The parties to this Agreement hereby agree that the Principal Investigator, SMO and Institution are independent contractors hereunder and are not employees or agents of the SPONSOR or SIRO. The Principal Investigator, SMO and INSTITUTION further agree that neither they nor their employees or agents shall make any claim against the SPONSOR or SIRO for compensation, vacation pay, sick leave, retirement benefits social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind. Further, their agents and employee shall not be considered to be employees of the Sponsor or SIRO under any circumstance.

18. Termination

18.1 This Agreement may be terminated:

18.1.1 by the Principal Investigator upon thirty (30) days' prior written notice;

18.1.2 by SIRO on behalf of SPONSOR immediately upon thirty (30) days written notice;

18.1.3 by SIRO immediately if the Principal Investigator is unable to continue to serve and his/her successor as acceptable to SIRO is not available; or

18.1.4 upon the occurrence of an event qualifying as a termination event as described in the Protocol

18.1.5 upon thirty (30) days prior written notice to the other party if the authorization and approval to perform the Clinical Study is withdrawn by the applicable regulatory agency having jurisdiction over the Clinical Study. However, the Principal Investigator shall immediately upon receipt of such notice, cease entering new subjects onto the Clinical Study, cease conducting procedures to the extent medically permissible on the existing subjects already entered into the Protocol and shall initiate the process of their safe withdrawal from the Clinical Study as per the prevailing medical standard and Principal Investigator's medical judgment.

18.2 Upon the effective date of termination, the Principal investigator shall conduct an accounting review, which is subject to verification by SIRO. If SIRO objects to any charges, the parties shall use reasonable efforts to resolve expeditiously any disagreement. Within thirty (30) days upon receipt of adequate documentation therefor, SIRO will make payment to the Institution for:

18.2.1 all services properly rendered and monies properly expended by the Principal Investigator prior to the date of termination and not yet paid for; and

18.2.2 reasonable non-cancelable obligations properly incurred for the Clinical Study by the Principal Investigator prior to the effective date of termination.

18.3 The Principal Investigator will credit or return to SIRO any funds not expended or obligated by the Principal Investigator in connection with the Clinical Study prior to the effective termination date.

18.4 Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Clinical Study and shall cease conducting procedures on Subjects already enrolled in the Protocol as directed by SIRO to the extent medically permissible and appropriate.

18.5 Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Sections 4.2, 7.2, 8, 9, 11.2 and 16 survive the termination or expiration of this Agreement.

19. Miscellaneous

19.1 **Applicable Law And Arbitration.** This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. Notwithstanding the foregoing, SPONSOR may seek injunctive or equitable relief, in addition to damages, for a breach of any of the confidentiality provisions contained herein in any court of competent jurisdiction.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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19.2 All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be referred to and settled by sole arbitrator. The proceedings will be governed by the Indian (Arbitration & Conciliation) Act, 1996. The place of the arbitration shall be Mumbai and the language of the arbitration proceedings shall be English. Any judgment, decision or award of the arbitrators shall be final and binding on both the Parties, and shall be enforceable in any court of competent jurisdiction.

19.3 Subject to 19.2 above the courts of Mumbai will have exclusive jurisdiction to try and entertain any dispute arising out of this Agreement.

19.4 The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.

19.5 **Amendments.** This Agreement may only be amended by the mutual written consent of the parties hereto.

19.6 **Entire Agreement.** This Agreement represents the entire understanding of the parties with respect to the subject matter of this Agreement and supercedes all prior agreements, undertakings, negotiations and discussions whether oral or written between the parties and there are no warranties, condition, representations or other Agreements between the parties in connection with the subject matter of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all the parties even though each of the parties may have signed different counterparts. This Agreement shall also be considered executed by the parties upon receipt by SIRO by facsimile transmission of the counterparts signed by all the parties.

19.7 **Severability.** Should one or more provisions in this Agreement be or become invalid or unenforceable, the Parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

19.8 **Assignment.** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of SIRO. SIRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

19.9 **Waiver.** Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every provision of this Agreement.

19.10 **Notice.** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Principal Investigator:

Dr. Navin Mallikarjun Mulimani
Consultant Interventional Radiologist
KLES Dr. Prabhakar Kore Hospital , Nehru Nagar,
Belgaum-590010, Karnataka India

If to INSTITUTION:

Dr. M. V. Jali
(Medical Director and Chief Executive)
KLES Dr. Prabhakar Kore Hospital , Nehru Nagar, Belgaum-590010, Karnataka, India

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka

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If to SIRO:

Partha Chatterjee
Head Clinical Research and CTSM.
SIRO Clinpharm Pvt. Ltd
Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra, India

If to SMO

Mr. Chandu Devanpally
Managing Director
Ardent Clinical Research Services, Office No. 318, 3rd Floor, Next to Frankfin Institute, Connaught Place, Bund Garden Road, Pune-411001 (SMO)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement Triplicate by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

Signature:_____

Name: Partha Chatterjee

Designation: Head Clinical Research and CTSM

Date: 06 DEC 2018

INSTITUTION

Signature:_____

Name: Dr. M. V. Jali

Designation: Medical Director and Chief Executive

Date: 24/Dec/2018

INVESTIGATOR

Signature:_____

Name: Dr. Navin Mallikarjun Mulimani

Designation: Principal Investigator

Date: 12/DEC/2018

SMO

Signature:_____

Name: Mr. Chandu Devanpally

Designation: Managing Director

Date: 13/Dec/2018

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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SCHEDULE A
BUDGET AND PAYMENT SCHEDULE

Type of visit	Professional fees	Procedural fees	Patient Travel Reimbursement
	(INR)	(INR)	(INR)
Screening	3000	2,000.00	500
First Study Procedure	33,000.00	16000	500
Second study procedure (Optional as per PI discretion)	10000	5,000.00	500
Final Follow Up Visit	5,000.00	2,000.00	500
Total (A)	51,000.00	25000	2000
Institutional Overhead (B=25% of A)	12,750.00	NA	NA
Total (A+B=C)	63,750.00	25000	2000
GST (D=18%)	11,475.00	4500	360
Total	75,225.00	**29,500.00**	**2360**
Total per subject	**₹ 1,07,085.00**		

1. **PAYMENT TERMS**

1.1 Payments by CRO to Payee will be made in accordance with the Budget and the following principles:

(a) Payments of professional fees are made on a quarterly basis

(b) Payments are made only for every completed visit for the properly enrolled subject according to the Protocol

(c) Payments shall be based on prior quarter enrollment data confirmed by subject Case Report Forms ("CRFs").

1.1 Actual payments shall be limited to ninety percent (90%) of each payment due.

1.2 Payee Details (for all study related payments) :

- Cheque in favor of : **Ardent Clinical Research Services**
- Bank Name : HDFC
- Account Number : 50200007013912

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

697

- IFSC : HDFC0003708
- Category : the Research And Experimental Development Services In Medical Sciences And Pharmacy
- HSN/SAC Code : 998113
- PAN Number : APQPD7081M, (Ghorpadi, Pune Branch)
- GSTIN No. : 27APQPD7081M1Z9

All the payment obligations of the Site shall be routed through SMO; the Principal Investigator and the Institution have no objections for this arrangement.

1.3 Ten percent (10%) of the compensation earned by Site in accordance with the Budget will be reserved by CRO, and will be paid by CRO to the Payee upon completion of the following ("Final Deliverables"):

(a) final acceptance by Sponsor of all CRFs pages;

(b) final acceptance by Sponsor of all data clarifications issued;

(c) receipt and approval by Sponsor of any outstanding regulatory documents as required by CRO and/or Sponsor;

(d) return of all unused supplies of the Investigational Product and comparator product to CRO and/or Sponsor; and

(e) approval by Sponsor of Site's satisfaction of all other applicable conditions set forth in the Agreement.

1.4 Material violations of the Protocol constituting disqualifications shall not be payable under the Agreement.

1.5 Any expense or cost incurred by Site in performing the Study under this Agreement not specifically designated as reimbursable by Sponsor shall not be payable. Such expense or cost shall be Site's sole responsibility.

2. **SCREENING FAILURE PAYMENTS.**

Procedure costs of Screening failures will be reimbursed in accordance with the following principles:

2.1 Only visit which a subject has undergone for the study with properly obtained informed consent will be reimbursed upon receipt of invoice.

2.2 Payments require submission of completed screening CRF pages to CRO and any additional information requested by CRO for proper documentation of subject screening procedures.

3. **DISCONTINUED OR EARLY TERMINATION PAYMENTS.** Discontinued or early termination subject will be reimbursed based on the number of confirmed completed visits.

4. **ORIGINAL INVOICES AND RECEIPTS.**

4.1 Original Invoices preferably in English and/or receipts pertaining to the Study shall be submitted to CRO for reimbursement at the following address:

CRO Name	SIRO Clinpharm Pvt. Ltd
Attention	Project Manager

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Address	SIRO Clinpharm Pvt Ltd Kalpataru Prime, 1st Floor, Unit Nos. 3 and 4, Plot No. D-3, Road No. 16, Wagle Industrial Estate, Thane (West) – 400604
Telephone	+91 (022) 6108 8000

4.2 To properly process invoices, (a) Sponsor name, (b) Protocol number,(c) invoice number, (d) Investigator name, (e) Site number, (f) invoice date, (g) date and description of services provided, (h) CRO project number, (i) total amount payable, (k) exchange rate used where applicable, and (l) CRO Address listed above must be specified in the invoice. After receipt and verification, reimbursement for invoices will be included in the next regularly scheduled payment for subject activity.

4.3 Payment Instructions: For professional fees, the Payee shall send invoice to CRO, via e-mail transmission followed by couriering the original. Payments shall be made by CRO on behalf of Sponsor and shall be paid within Forty Five (45) days of receipt of original invoice, review and approval of an original invoice submitted to the CRO's address.

For subject procedural reimbursement, payments shall be made by CRO on behalf of Sponsor and shall be paid within Fifteen (15) days of receipt, review and approval of original invoice and bills, submitted to the CRO's address.

5. Additional Expenses

5.1 Any additional expenses connected to the Study and specified in this Section shall be reimbursed to Payee only if such expenses were previously approved by CRO and Sponsor and actually incurred. Such expenses shall be reimbursed to Payee on the pass-through basis upon acceptance by CRO of invoices and/or receipts or other documentations. CRO shall not reimburse any additional expenses which were incurred by Site or Site Personnel without prior written approval by CRO or Sponsor.

(a) Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments

- IRB/IEC costs shall be reimbursed upon receipt of original invoices and shall not be included in the Budget, and
- Any costs for subsequent re-submissions or renewals of IRB/IEC shall be reimbursed upon receipt of appropriate documentation subject to approval by CRO and Sponsor.

(b) Archiving Fee: a one time, non-refundable payment will be paid on actual basis as per hospital policy;

- Payment shall be used for archiving and storage of Study files by Site for a period of fifteen (15) years,
- In accordance with Sponsor's Protocol requirements, Institution shall maintain all Study records in a safe and secure location to allow easy and timely retrieval, when needed.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka

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- Payment shall be used for archiving and storage of Study files by Institution for a period of fifteen years,

- Payment shall be made upon completion and receipt by CRO of all original contractual and regulatory documentation, and receipt by CRO of original invoice.

(c) Subject Expenses: A maximum of 500 INR per visit exclusive of overhead fee will be paid for the Subject travel expenses reimbursement only for the 4 visits of the study. This amount needs to be reflected in the informed consent form as it will be provided to the subject. The Subject travel expenses will be paid upon receipt of the corresponding support documentation.

(d) Start Up fees: A non refundable payment of 25000 INR for start-up related activities will be made upon execution of the Agreement, and IRB/EC approval, and prior to site initiation. This payment shall not be recovered from subsequent payments done to the site

(e) Equipment: The Site will be provided with the following Study-dedicated infrastructure

- External Hard disk
- Set of CD's
- Thermo hygrometer
- Camera

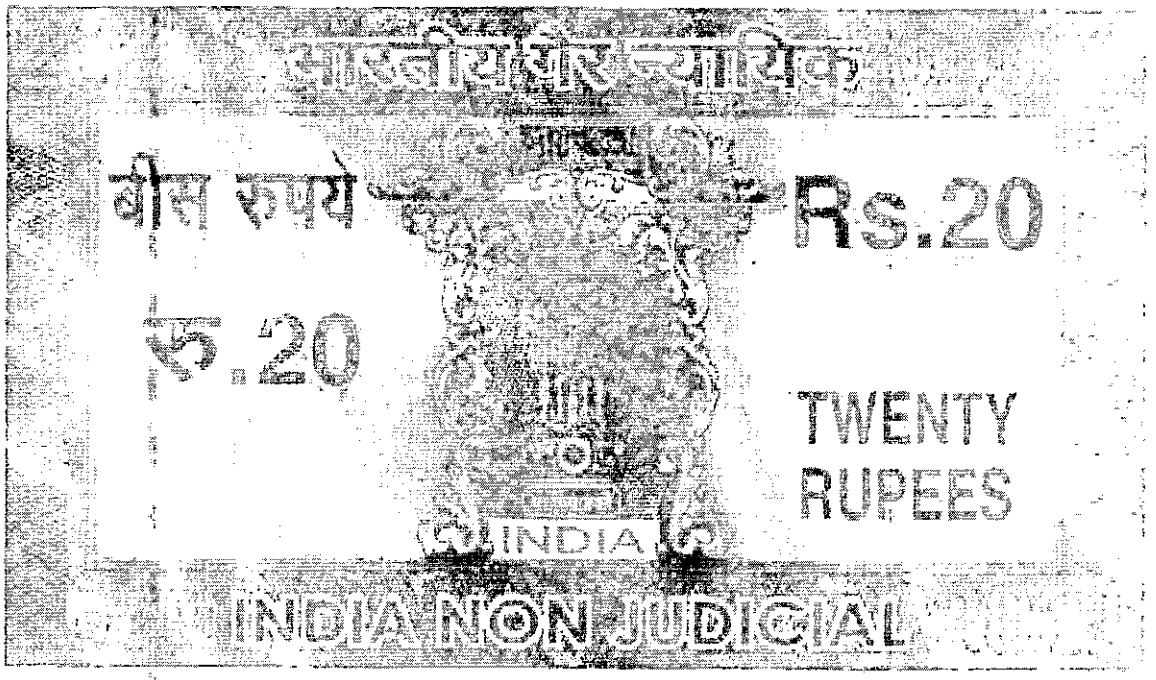
All equipment needed for the conduct of the Study (and Sub-Study, if applicable) will be supplied to the Site by CRO for its strict and sole use in performing the Study. Sponsor retains ownership of such equipment at all times. Site must use reasonable efforts to protect the equipment from damage or loss. Such equipment must be returned to CRO following the closure of the Study at the Site and CRO shall coordinate its return with the Site, to ensure that all equipment is returned within 30 calendar days after site closure at Site.

(f) NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Institute's Co



GUJARAT

43AA 431601

12 JUN 2015

VASU RESEARCH CENTRE
(A Division of Vasu Healthcare Pvt. Ltd.)
295/A, G.I.D.C., Makarpura,
Vadodara-390010.

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MEMORANDUM OF UNDERSTANDING

This memorandum of understanding is entered into on this *18th day of month September, 2015*

BETWEEN

M/s Vasu Research Center (A Division of Vasu Healthcare Pvt. Ltd.), Vadodara a company incorporated under the Indian Companies Act having its registered office at 295/A, GIDC, Makarpura, Vadodara - 390 010, Gujarat India, through its authorized signatory Shri Haribhai B. Patel, Managing Director authorized by the Board Resolution dated 02.06.2015, hereinafter referred to as the company, which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the one Part

AND

KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya - Vidya Nagar, Belagavi - 590 010, India, through its Principal Dr. B. S. Siddapur hereinafter referred to as the Institute which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

Page 1 of 4

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010,Karnataka

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WHEREAS the company is engaged inter alia in research and development of various [illegible]

AND WHEREAS the Institute has fully established good research facilities and hospital [illegible] studies in the field of Ayurved and Ayurvedic Drugs.

WHEREAS the company has developed a drug in collaboration with the Institute, name of which is [illegible] for its efficacy and safety as Standardized Ayurvedic Dry extract of the [illegible] herbs which the Institute has agreed

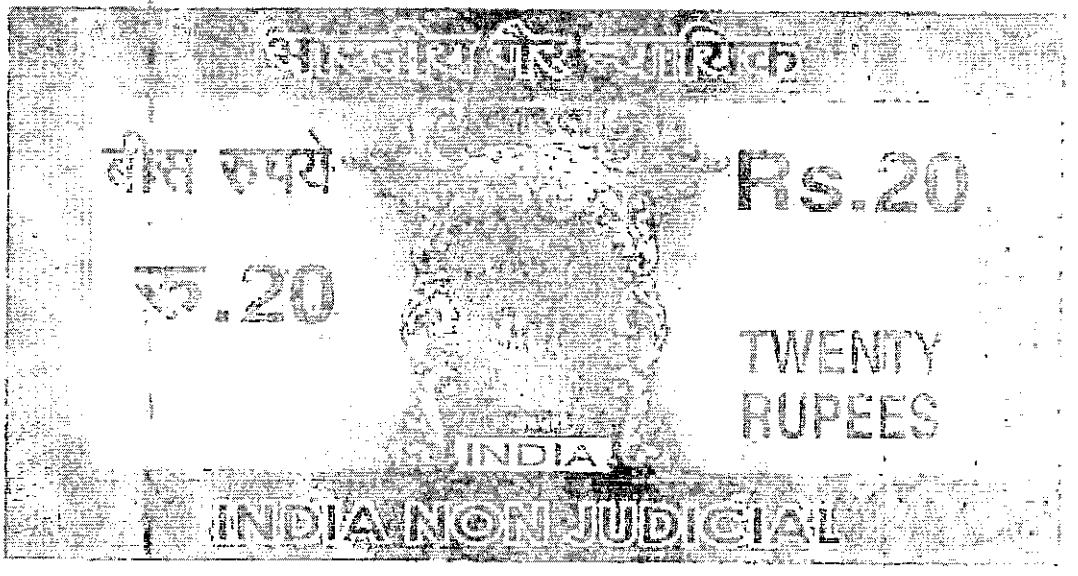
NOW, THEREFORE, in consideration of the representations warranties, covenants and agreements set forth herein and other valuable considerations and subject to the terms and conditions set forth herein, the parties hereto hereby agree as follows:

1. That the Institute has agreed to conduct a clinical assessment of the *above* herbal *agents* developed by the company.
2. That the company has agreed to provide to the Institute detail ingredients of the [illegible] of investigation required in the clinical trial, brief detail of the product, copy of certificate of analysis of used raw material and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible / liable for any legal or other requirements arising out of the application of the result of the project.
4. That the clinical study would require certain amount of expenditure as per details attached hereto as the project proposal including, financials to which both the parties have agreed. The amount of project is Rs. 1,74,230/- (one lakh seventy four thousand two hundred thirty only) [illegible] Amount of the IEC will be Rs. 1,20,000/- each (Rupees one lakh twenty thousand only) [illegible] expenses only.

   That out of the proposed fixed expenditure of Rs. 1,26,700/- the company has already paid to the Institute amount (Rs. 42,670/- vide cheque no. 735697 dated 13.05.2011 of [illegible] expenses which will be a fixture, as total project cost. [illegible] of the project, [illegible] at the time of grant of project initiation, and [illegible] of the project, when [illegible] 50% of sample size is reached. Remaining [illegible] Rs. 1,67,560/- of the project cost will be [illegible] after the completion of the project.
5. That the said trial shall be completed in a period of *24 months*.
6. That the Institute is served to provide bimonthly basis progress report of the [illegible] The company has agreed to provide all details of work, case diaries, [illegible] examination or consultation in order to complete the research activities of the [illegible]
7. That in case of [illegible] the parties that all rights arising out of research [illegible] Institute / Research Centre shall vest with the company and the Institute [illegible] shall not have any claim on future.
8. *Important research findings arising out of the activities carried under this MOU, [illegible] the written consent of National Innovation Foundation [illegible] without [illegible] of both the parties.*
9. All notices and other communications required to be served on parties under the terms [illegible] shall be considered duly served if the same have been delivered or dispatched by registered [illegible] in case of Vasu Research Centre:

   Manager – R&D
   Vasu Research Centre
   (A Division of Vasu Healthcare Pvt. Ltd.)
   596-A, GIDC, Makarpura, Vadodara-390010, Gujarat, India
   Tel.: 91-265-2635710 Fax: 91-265-2641134
   Web: www.vasuresearch.com www.vasuhealthcare.com

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010,Karnataka



Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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i) The [illegible] undertakes to keep confidential all information [illegible]
[illegible]
iii) [illegible] confidential [illegible]
[illegible]

3. [illegible] Parties to this MOU shall [illegible] any [illegible] disclosure [illegible] without the prior written consent of the other party, provided the party [illegible] to [illegible] to Government agencies [illegible] the party [illegible] applicable law, rule or regulation of the Government [illegible] in this MOU.

This MOU [illegible] be terminated by either of the party by giving [illegible] notice [illegible]

(i) Any material breach of terms of the agreement

The termination [illegible] not affect the parties' [illegible] for the [illegible] prior to the date of termination [illegible] the parties [illegible] till the date of termination.

The Parties to the MOU agree that the [illegible] MOU [illegible]

[illegible]

[illegible] Arbitration Act [illegible]

[illegible]

[illegible] the parties [illegible] have signed this [illegible] on the day [illegible]

PARTIES

[illegible]
[illegible] Research Center
(A Division of [illegible] Healthcare Pvt. Ltd.)

Mr. Harshad B. Patel

[illegible]
KLE University's [illegible]
[illegible]

Dr. H. Sheshagiri Prasad

WITNESSES

Mr. Vikram Trivedi

Dr. Hardik Soni

Dr. [illegible] Tubaki

Dr. [illegible]

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL52945729502204P
Certificate Issued Date	:	28-Feb-2017 02:23 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306393239347782P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

.....Please write or type below this line.....

For MB Lifesciences Pvt. Ltd.,

Jitender Kumar

Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Dr. V. A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at54/8, DeshBandhu Gupta Road, Karol Bagh, New Delhi, 110005, through its authorized signatory Mr. Jitender Kumar(Director)

Managing Director authorized by the Board Resolution dated- 28th February 2017, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs. successors of the one part.

AND

KLE.University'sShri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India through its Principal Dr.B.Sreenivas Prasad hereinafter referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, interalia, in research and development of various Ayurveda Drugs.

AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of Male Impotency and wants a clinical assessment for its efficacy and safety in Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute has agreed.

NOW, THERERFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and condition s set for the herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of the drug Contrapain-Lep&Contrapain Oil, development by the company.
2. That the company has agreed to provide to the Institute detail ingredients of the drugs, type of investigation required in the clinical trial, brief details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs.4,05,600/- Only(Four Lakhs Five Thousand and six Hundred Only)in words.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Put of the above proposed fixed expenditure of Rs.4,05,600/- the company has agreed to make 10% non- refundable amount (Rs.40,560/-) along with application which will be adjustable in total project cost. 50% (Rs.2,02,800/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,21,680/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.40,560/-) of project cost should be paid after the completion of the project.

5. That the said trial shall be completed in the period of 12 months.
6. The Institute has agreed to provide trimonthlybasis progress report of the clinical trial of the said drug,
7. The company has agreed to provide all detail of work, raw drugs, finished drugs and all other necessary co-operation in order to complete the research activities of the drugs.
8. It has agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.
9. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
10. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

    In case of M/S. M.B.Life Sciences Pvt. Ltd., New Delhi.
    Mr. Jitender Kumar,
    Director,
    M/S. M.B.Life Sciences Pvt. Ltd., New Delhi

    In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

    Coordinator,
    Medical Research Centre,
    KLE University's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
    Shahapur-Belagavi-590003, Karnataka, India
    Fax:0831-2424157, Tel: 0831- 2486286
    Website: www.klebmk@gmail.edu.in,
    Email:mrcklebmk@gmail.com.

11. That the company shall provide various trade secrets and proprietary information of the company to the Institute. The Institute acknowledges that the company's information is valuable, special and unique to its business and the company has exclusive right to the use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:
    - I. All rights to the proprietary information to the development product shall remain the sole property of the company.
    - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
    - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

12. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Government Reviews or approvals of the proposed business agreement disclosed on this MOU.
13. This MOU can be terminated by either of the party by giving 30 days of notice to the other party for the reasons stated below:
    I. Any material breach of terms of the agreement.
    The termination shall not affect the parties liability for its unperformed obligations which have accrued prior to the date of termination and hence the parties shall fulfill its obligation under the agreement till the date termination.
14. The parties to the MOU agree that the present MOU can be modified, varied, changed or otherwise in whole or in part only with mutual consent, in writing and executed by or on behalf of the parties.
15. This is the essence of this agreement.
16. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settledwithin fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.
17. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:

PARTIES

For and on behalf of
M/s. M.B.Life Sciences Pvt. Ltd
54/8, DeshBandhu Gupta Road,
New Delhi - 110005

Mr. Jitender Kumar
Director, M.B.Life Sciences Pvt. Ltd

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

For and on behalf of
KLE.University's,Shri.B.M.Kankanawadi
Ayurveda Mahavidyalaya

Dr.B.S. PRINCIPAL sad
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

(1) Dr. Pradeep L.G.

(2) Dr. Vedantam Girindhar
Girindhar
28/02/17

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/17/PLG/01

Protocol Title: Evaluation of analgesic and anti-inflammatory activities of CONTRAPAIN – LEPA& OIL topical application in Musculoskeletal Disorders – CLINICAL STUDY
Principal Investigators/Co-investigators: Dr. Pradeep L Gramapurohit Dr.VedantamGiridhar
Name & Address of Institution: KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&KLE Ayurved Hospital, Shahapur, Belagavi
[√] New Review [ ] Revised Review [ ] Expedited Review
Date of Review (DD/MM/YY):25/03/2017 **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. Pradeep Shinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,
Decision of the the Ethics Committee: **Recommended** [ ] **Recommended with suggestions** [√] **Revision** [ ] **Rejected** [ ]

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Suggestions/ Clarifications / Reasons/ Remarks:

Following are the suggestions/clarifications of the EC

1. Replace the word 'subjects' with 'patients'
2. Replace the twice '0' Day with '-7' Day
3. More assessment of joint pain viz. inflammation, joint pain can be added
4. CRP can be used as efficacy parameter

Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr.SupriyaBhalerao
(Chairperson)

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No	:	IN-DL52946211730541P
Certificate Issued Date	:	28-Feb-2017 02:23 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306394265287215P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

For MB Lifesciences Pvt. Ltd.,

Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Statutory Alert

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

MEMORANDUM OF UNDERSTANDING

The memorandum understanding [illegible] to this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian [illegible] Act, having its Registered Office at54/8, DeshBandhu Gupta Road Karol Bagh New Delhi [illegible] through its authorized signatory Mr. Jitender Kumar

Managing Director authorized by the Board Resolution dated- 28th February 2017 [illegible] to as the company, which expression shall unless repugnant to the context and meaning [illegible] include its heirs successors of the one part

AND

KLE University'sShri B M Kankanawadi Ayurved Mahavidyalaya Medical Research [illegible] Shivaji Belagavi, Karnataka-590003, India through its Principal Dr B Sreenivas Prasad [illegible] elected as the Institute which expression shall unless repugnant to the context and meaning [illegible] its heirs, successors and assignees of the Second Part

WHERE AS the company is engaged interalia in research and development of [illegible] Ayurvedic

AND WHERE AS the institute has fully established good research facilities [illegible] clinical studies in the field of Ayurveda and Ayurvedic Drugs

WHERE AS the company has developed Proprietary Ayurveda Preparation [illegible] management of Male Impotency and wants a clinical assessment for its effect [illegible] Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute

NOW, THEREFORE, in consideration of the representations, warranties [illegible] set forth herein and other valuable consideration and subject to the terms and [illegible] herein, the Lessor and the Lessee hereby agree as follows

1. That the Institute has agreed to conduct a clinical assessment [illegible] PLUSPower Capsule, developed by the company
2. That the company has agreed to provide to the Institute detail [illegible] investigation reported in the clinical trial, brief details of the product [illegible] analysis of used raw materials and moreover pharmacology of used [illegible]
3. That the company has also agreed to indemnify [illegible] of the [illegible] patents and other [illegible] requirements in connection with the [illegible]
4. That the clinical study would require certain amount of expenditure [illegible] hereunto in the project proposal the Institute [illegible] amount of project is Rs. 5,93,800/- (Only Five Lakhs Eighty [illegible] Hundred Only) [illegible]

For MB Lifesciences Pvt. Ltd.
Director

ATTESTED

PRINCIPAL
K.L.E. University's
[illegible] Belagavi

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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[illegible] the above proposed fixed expenditure [illegible] the contract [illegible] agreed to [illegible] of refundable amount (Rs 58,280/- [illegible] all applications [illegible] be made [illegible] which will cover 50% (Rs 2,91,000/-) [illegible] will be made after [illegible] of project institution, and 30% (Rs 1,75,140/-) [illegible] agreement will be made [illegible] after receipt of [illegible] as audited. Remaining 10% (Rs 58,380/-) [illegible] will be paid [illegible] at the project

3 The [illegible] shall be completed [illegible] months.

4 The [illegible] has agreed to provide [illegible] Rs. [illegible] per [illegible] basis.

5 The [illegible] has agreed to provide [illegible] necessary co-operation in order to complete the [illegible] activities of the [illegible]

6 It has agreed between the parties that all rights arising out of research [illegible] said drugs including patent right shall vest with the company and the institute shall not have any right over the drugs time in future

7 Important research findings arising out of the activities covered under [illegible] MOU will be published or presented at National/International Journals, Conference [illegible] with the prior consent of both of parties

8 All notices and other communication required to be served on parties under the terms of this agreement shall be considered duly served if the same have been delivered to the parties by registered mail to

In case of M/S. M B Life Sciences Pvt. Ltd., New Delhi

Mr. Jitender Kumar

Director

M/S. M B Life Sciences Pvt. Ltd., New Delhi

In case of KLE's Shri B M Kankanawadi Ayurveda Mahavidyalaya

Coordinator,
Medical Research Centre,
KLE University's Shri B M Kankanawadi Ayurveda Mahavidyalaya
Shahapur-Belagavi-590003 Karnataka India
Fax 0831-2424137, Tel 0831- 2486782
Website www.klebmk@gmail.edu.in
E-mail mrcklebmk@gmail.com

11 That the company shall provide various trade secrets and proprietary [illegible] at the time of [illegible] to the Institute. The Institute acknowledges that the company's [illegible] valuable [illegible] and unique to its business and the company has exclusive right [illegible] Hence in order to save the proprietary information trade secrets [illegible] as follows:

i [illegible] to the [illegible] information by the [illegible] its sole property [illegible]

ii The Institute [illegible] company in the [illegible] of the drugs [illegible]

iii The Institute [illegible] Agreement under [illegible]

For MB Lifesciences Pvt. Ltd.

Jitender Kumar

Director

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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PRINCIPAL
K. L. E. University's
Shri B. M. Kankanawadi
Ayurved Mahavidyalaya

KLE | BMK | MRC | 448 | 18

KLES AYURVED HOSPITAL

INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/SN/01

Protocol Title: Evaluation of Vatsyayan plus (capsule) in the management of Male Impotency – Double Blind Placebo control clinical study

Principal Investigators/Co-investigators: Dr. Sukumar Nandigoudar

Name & Address of Institution:

KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi

☐ New Review ☐ Revised Review ☑ Expedited Review

Date of Review (DD/MM/YY): 20.03.2018

Date of previous review, if revised application: 25.03.2017

Name of the Reviewers who attended the meeting:

Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. PradeepShinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,

Decision of the the Ethics Committee:

Recommended	☑	**Recommended with suggestions**	☐
Revision	☐	**Rejected**	☐

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:
Recommended for a period of :One Year

Please note *

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Dr. Basavaraj R Tubaki
(Member Secretary)

Dr. Supriya Bhalerao
(Chairperson)

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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