भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

ગુજરાત ગુજરાત GUJARAT

BU 943836

નંબર : 14539 રૂ.૧૦૦

તારીખ : ૧૫ માર્ચ ૦૫ ૨૦૧૯

નામ : LAMBDA THERAPEUTIC RESEARCH LTD.
Plot No. 38, Near Silver Oak Club,

ઠેકાણું : S.G. Highway, Gota,
Ahmedabad-380061

કે. જી. ફોતરીયા

લા. નં. એસ.બી. ૪૨૮, ૪૨૯/૧૯૯૯

બે-૪, સ્નેહા કોમ્પ્લેક્ષ, મેમનગર, અમદાવાદ ના સાર્વભૌમી

લેનારની સહી.....

Clinical Trial Agreement

BETWEEN

Lambda Therapeutic Research Ltd.
Lambda House, 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
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.

Dr. Santosh Hajare, 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. Santosh Dhananjay Hajare
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

AND

Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Lambda House, 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
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND

Dr. Santosh Dhananjay Hajare
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

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

Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of **Intas Pharmaceuticals Ltd.;**

Intas Pharmaceuticals Ltd. 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, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment."** and, The Principal Investigator, having reviewed the Protocol for the Clinical Trial, the Investigator brochure 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"	Tacrolimus Lipid Suspension for enema 4 mg/vial **(Test Product)**
"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

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

"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and 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.
"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, analyzed and accurately reported according to the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the applicable regulatory requirements.
Clinical Trial	means the investigation to be conducted at the Trial Site in accordance with the Protocol
Clinical Trial Subject	means a person enrolled to participate in the Clinical Trial

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

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

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 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.

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

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

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.

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 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 LAMBDA, 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.

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

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 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 **2-3** Eligible Patients within **1** month; minimum expected recruitment rate from the site is **2-3 patients per month** 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 **10** 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.

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.

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

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 and 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

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.

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

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.

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

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 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

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

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.

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.

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

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.

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

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 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 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 endeavours 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 endeavours 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

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

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.

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

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

17.1 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

Address:	Lambda Therapeutic Research Ltd Lambda House, 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 2021/22
Contact person:	**Dr. Kiran Marthak**

Investigator	:	Dr. Santosh Dhananjay Hajare
Address	:	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone	:	0831-2470400
Fax	:	0831-2493099

Institution Contact Person:	:	Dr. M.V.Jali
Address	:	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone	:	
Fax	:	NA

SMO Name	:	Doclin Clinical Research Services
Address	:	445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
Telephone	:	+91-9164256468
Contact Person	:	Mr. Maruti Patil

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.

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

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 If SMO is involved in any study related activities, PI / Institution needs to provide the copy of MOU/Agreement to CRO during / before the time of execution of CTA. The MOU provided should have the clarity on the responsibilities of Investigator /Institute and SMO.

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:** 3 Jul. 2019

Mr. Rajiv Bhattacharya/ Mr. Gautam Vaghela
Clinical Trial Management
Lambda Therapeutic Research Ltd.

Witness:

Sign: _____ **Date:** 03/Jul/19

Witness Name : Mr. Naresh Khemani, AGM, Finance
Witness Address : Lambda Therapeutic Research Ltd.,
Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481, Gujarat, 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

Institute: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India

Sign: _____ **Date:** 19.07.2019

Dr. M.V.Jali – MD & CEO

Witness:

Sign: _____ Date: 19-07-2019

Witness Name: Revanna Sperandi

Designation: Assistne-coordinator

Department/Work Unit:

Institute Name: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India.

SMO: Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008

Sign: _____ Date: 12 Jul 2019

Mr. Maruti Patil – Managing Director

Witness:

Sign: _____ Date: 12 Jul 2019

Witness Name: Akshay Thombare

Witness Address:

Investigator: Dr. Santosh Dhananjay Hajare

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: Dr. Santosh Dhananjay Hajare

Sign: _____ **Date:** 15-Jul-2019

Witness:

Sign: _____ **Date:** 15-Jul-2019

Witness Name : Dr. Arvind Jadhav

Witness Address : KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-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

Schedule A

Study Protocol

Protocol No: 0979-17

A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment."

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

Schedule B
Budget and Payment Agreement

(I) Budget

S.No		Screening washout	Treatment Period					Follow up period		Total
	Visit Number	1	2	3	4	5	6	7	8	
	Week Number	W-1	W-0 Baseline	W-1	W-2	W-3	W-4/EOT	W-6(2 Week post treatment follow up	W-8(EOS 4 week post treatment follow up	
	Days	D-7 TILL D-1	D-0	D-7(+_2)	D-14(+_2)	D-21(+_2)	D-28(+_2)	D-42(+_2)	D-56(+_2)	
	Activity									
1	PI Grant	7000	4000	4000	4000	4000	5000	5000	5000	38000
2	CRC Grant	5000	3500	3500	3000	3000	3000	3000	3500	27500
3	ECG-12 lead	600					600			1200
4	Serum pregnancy test	650					650		650	1950
5	Urine pregnancy test		250							250
6	Drug urine scan	200								200
7	Urine analysis	500					500		500	1500
8	Stool test for CD toxins	600								600
9	Hematology	800					800		800	2400
10	Blood/serum Biochemistry(Including S.electrolytes)	1800					1800		1800	5400
11	X-ray (Chest PA view)	500								500
12	Immunology (S.anti HIV antibodies, Hbsag, and antibodies against HCV)	2000								2000
13	UCDAI Score(including colonoscopy)		10000				10000			20000
14	PK assessment		800	800	800	800	800		800	4800
15	Histopathology (Biopsy) [Optional]		1000							1000
16	Institutional OverHeads (25%)	3000	1875	1875	1750	1750	2000	2000	2125	16375
17	Patient Conveyance	1000	1000	1000	1000	1000	1000	1000	1000	8000
	Total	23650	22425	11175	10550	10550	26150	11000	16175	131675

Note:

Archival Fees: LAMBDA will pay the Institute / Investigator/Payee towards archival fees INR 1,50,000/- for 15 yrs. on behalf of sponsor.

Screen Failures: LAMBDA will pay the Institute/Investigator towards screen failure payment of INR 10,000/- for each screen failure up to the maximum of 20% of total patients screened at the site. All screen failure patients payments will be made post LPLV.

PK Sample will be collected only from the patients randomized in test arm.

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. Santosh Hajare, Belagavi

LAMBDA
Research Accelerated

(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum Rs. **One Lakh Thirty One thousand Six hundred and Seventy Five** (in words) 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." **GST applicable as per union budget rules.**

k) All Services provided by the site under this Agreement are taxable under the laws related to Goods & Service tax in India (GST) and it is required to be charged at the rate of 18%, as may be amended from time to time. The Sponsor / CRO (applicable word as per agreement should be used) undertake to provide Patient Visit Tracker on monthly basis (on last day of the month) to CRCs for the trial and on the basis of the tracker site shall raise invoice for the month. The invoice shall be in accordance with the terms of Rule 5 of the Tax Invoice, Debit and Credit Notes Rules of Goods & Service Rules 2017.

LAMBDA Research Accelerated

TESTED

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

l) Payment for the final invoice raised by the site will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

m) LAMBDA will pay the Institute / Investigator/Payee towards archival fees **INR 1, 50,000/-** for 15 yrs. on behalf of sponsor.

n) LAMBDA will pay the Institute/Investigator towards screen failure payment of **INR 10,000/-** for each screen failure up to the maximum of **20%** of total patients screened at the site.

o) All medical and hospital bills related to SAE management for the SAEs related to IMP to be paid by the Sponsor/Lambda.

p) 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.

q) Payment reconciliation will be made before the final payment to sites.

r) 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:	**Doclin Clinical Research Services**
Address of Payee:	445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
PAN / TAN Number:	**AZXPP8818R**
GST Number:	**29AZXPP8818R1ZP**

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:

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

- 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
- all diagnostic tests and other investigations (like ECG, X-ray, Slit lamp examination etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses
- 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.

TESTED
LAMBDA
Research Accelerated

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 DECCAN MERCHANT CO-OP BANK LTD.
DADAR (W), JESHELLA BUILDING, FIRST FLOOR
RANADE ROAD, DADAR (WEST)
MUMBAI - 400 028

Authorised Signatory

भारत 62179 144283 SPECIAL ADHESIVE महाराष्ट्र JUL 18 2019 10:37
Rs.0000200/- PB6584
INDIA STAMP DUTY MAHARASHTRA

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("**Agreement**") is entered into as of 19th July 2019 ("Effective Date") between **Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956** and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400018 ("**Novartis**") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar kore hospital and MRC, , located at *Nehru Nagar Belagavi* ("**Institution**") registered under the provisions of Bombay Public Trust Act, 1950 and having its address at *Nehru Nagar, Belagavi, Karnataka, 590010* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Shivakumar Patil* as clinical practitioner in the field of *Dermatology*, 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 following drug: QGE031 (hereafter the "Study Drug") in accordance with a protocol entitled A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines, CQGE031C2302 and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct 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,

WHEREAS, the Parties wish to set forth certain the 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

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

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(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 Antibribery 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.

PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes 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 may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis 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 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

DURATION OF THE STUDY

The Study shall commence on ***1 Dec 2018,*** subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by ***27 July 2021*** or as may be extended by a formal writing between the parties in that behalf

TERM OF THIS AGREEMENT

1 This Agreement shall be effective upon 9 May 2019 ('Effective Date') and shall expire upon 8 May 2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

3 In the event that the Principal Investigator [illegible] no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and [illegible] within 30 days prior to such departure. It is clarified that Principal Investigator shall

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

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. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator 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 MRC*, located at *Nehru Nagar, Belagavi* : (hereinafter the "**Study Site**").

6.3 **Use of Study Drug:**

Novartis shall provide QGE031 (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study:** Before entering 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, her/his 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;

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) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (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. An example ICF is attached hereto as Annex 3;

(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;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

6.5 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.

6.6 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 fashion:

(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 the receipt and disposition of the Study Drug 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 the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) 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

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

(vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.

(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). Sponsor 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 designated person within 24 hours, allow Novartis to be present at the inspection/action 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 periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site 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.

6.7 **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

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

(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 **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 6.6 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 Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. 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 safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

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.

6.9 **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 Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure 1

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

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

8.2 In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

8.3 The Institution and Principal Investigator ("**Indemnifying Party**") will 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 (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the 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 a Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have bee recruited at the Study Site by *16 Feb 2020.*

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the numbe of completed visits. All payment will be made for subject visits according to the above Paymer Schedule attached as Annex 1. No payment will be made for any Study Subject excluded fro analysis because of Protocol violations that were within the Institution or Principal Investigator control. Reimbursement for expenses related to screening failures, patient travel, and local la test 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

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the accou indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novar may provide equipment (the "**Equipment**") to the Institution and/or Investigator strictly o returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclus property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: T Equipment shall only be used for the conduct of the Study in accordance with the Protoc Novartis instructions and until the Study is completed or discontinued.

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

purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 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 ***KLES Dr. Prabhakar kore hospital and MRC/Dr. Shivkumar Patel*** 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

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement 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.

11.4 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.

12. INTELLECTUAL PROPERTY

12.1 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.

12.2 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.

12.3 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.

12.4 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.

13. 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.

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

PUBLICATION

14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to 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 require 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.

14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

14.3 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.

14.4 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.

14.5 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.

15. CONFIDENTIALITY

15.1 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.

15.2 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.

15.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(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;

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

NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, writing and shall be delivered personally, or sent by registered mail or facsimile to the ac given in this Agreement

Mr. K. Murugananthan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road, Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: murugananthan.k@novartis.com

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Pa prior written consent, except that Novartis may (a) assign its rights and obligations under Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement i entirety to a successor to all or substantially all of its business or assets to which this Agree relates. Any permitted assignee will assume all obligations of its assignor under this Agree (or related to the assigned portion in case of a partial assignment). Any attempted assignme contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agree will be binding upon and inure to the benefit of the Parties and their respective successors permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform an its obligations under this Agreement without the prior written consent of Novartis. Any consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunc

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or other in any one or more instances shall be deemed to be or construed as a further or continuing wa of any such term, provision or condition, or of any other term, provision or condition of Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the par with respect to the subject matter hereof. No amendment to this Agreement will be effective binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor collaborator who is involved in the performance of the Study has been debarred under the l including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, D and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by Institution in connection with any work to be performed for or on behalf of Novartis. If at time after the execution of this Agreement

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

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.

TRANSPARENCY/DISCLOSURE

4.1 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.

4.2 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.

4.3 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 provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. 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 without restricting any right of appeal.

26. 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.

27. 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.

28. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

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

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

NOVARTIS HEALTHCARE PRIVATE LIMITED

By: _____

Name: Saluja Singh

Title: Head CTO

Date: 19th July 2019

KLES Dr. Prabhakar kore hospital and MRC

By: _____

Name: Dr. M V Jali

Title: MD & CE KLES Dr. Prabhakar Kor Hospital and MRC

Date: 26/07/2019

Dr. Shivakumar Patil

By: _____

Name: Dr. Shivakumar Patil

Title: Associate Professor/Consultant Dermatologist

Date: 25/07/2019

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

ANNEX I PAYMENT SCHEDULE

[redacted]

[redacted]

Investigator's Name: Dr. Shivakumar Patil

Institute Name: KLES Dr. Prabhakar kore hospital and MRC

Sponsor Name: Dr. Shivakumar Kalagouda Patil

Sponsor Card Number: BJJPP7382P

[redacted]: NA

Approximated Number of Study Subjects: 5 randomized patients

Description of Equipment provided to Institution / Principal Investigator:

- Thermo-hygrometer
- ERT Log Pads - It would be retrieved from site post database lock is achieved.
- ERT Machine - It would be retrieved from site post database lock is achieved

Payment Schedule:

	Screening		Double blind treatment												
Visit	1	20	110	120	130	140	150	160	170	180	190	200	210	220	
Week	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44	
[redacted] diluents	16800	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500	3
[redacted]igator	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3
[redacted]rator	2000	2000	3000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2
[redacted]ded [redacted]	[redacted]		1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	15
[redacted]ional [redacted]	5700	1950	3750	2750	2750	2750	2375	2375	2750	2375	2375	2375	2375	2375	23
	28500	9750	19250	14250	14250	14250	12375	12375	14250	12375	12375	12375	12375	12375	123

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

	post treatment follow up			
Visit	240/EoT/TD	310	320	1999/EOS? PSD
Week	52	56	60	64
Protocol Procedures	6200	5000	5000	5700
Investigator Fees	4000	3000	3000	4000
Coordinator Fees	2000	2000	2000	2000
Unblinded Pharmacist fee	1500	1500	1500	1500
Institutional Overhead @ 25%	3300	2750	2750	3175
TOTAL (INR)	17000	14250	14250	16375
TOTAL COST 1 PT	275375			

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit will be upto 1000 INR for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice

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

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: Belagavi/25/07/2019

Name: Dr. Shivakumar Patil

Principal Investigator

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

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"**Personal Information or Data**" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"**Sensitive Personal Information or Data**" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"**Data Subject**" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"**Processing**" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"**Institution Third Parties**" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

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

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Part that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreer to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply wit applicable Laws governing the privacy and security of Personal Information that Institu shall create, acquire, access or receive as a result of this Agreement, to the extent that Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measure protect Personal Information, from (i) unauthorised or accidental destruction, (ii) tl forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthor alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of data processing, (ii) nature and extent of the processing, (iii) assessment of possible risk the data subject; and (iv)current industry best practices and state of the art technolog including but not limited to encryption of information at rest and in transit. Secu measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related informati should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutio email Ids), if any must be discussed with Novartis and a secure communication solution, mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior writt notification to Novartis. In the event that any Institution Subcontractor shall have acce to Personal Information, such access shall be permitted under a need-to-know basis an only to the extent required for the due performance of Institution's obligations. Institutio shall enter into Agreements with its' subcontractors that contain privacy and securit provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novarti Personal Information, including that by Institution's Third Party (if any) have appropriat skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

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

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

I / We, the undersigned Institution and Principal Investigator for study number CQGE031C2302 decl that I have received a copy of;

(a) Novartis global Antibribery Policy

(b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

KLES Dr. Prabhakar kore hospital and MRC	Dr. Shivakumar Patil
By: _____	By: _____
Name: Dr. M. V Jali	Name: Dr. Shivkumar Patil
Title: MD & CEO	Title: Consultant Dermatologist / PI
Date: 26/07/2019	Date: 25/07/2019

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

THE DECCAN MERCHANT CO-OP BANK LTD.
DADAR (W), KESHELLA BUILDING, FIRST FLOOR
RANADE ROAD, DADAR(WEST)
MUMBAI - 400 028

D-5/SB(V)/C.R.1893/01/16/765-69/18

Authorised Signatory

भारत 62179 SPECIAL ADHESIVE महाराष्ट्र
144283 JUL 18 2019
10:37
Rs.0000200/- PB6584
INDIA STAMP DUTY MAHARASHTRA

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("**Agreement**") is entered into as of 19th July *2019* ("Effective Date") between **Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956** and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400018 ("**Novartis**") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar kore hospital and MRC, , located at *Nehru Nagar Belagavi* ("**Institution**") registered under the provisions of Bombay Public Trust Act, 1950 and having its address at *Nehru Nagar, Belagavi, Karnataka, 590010* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Shivakumar Patil* as clinical practitioner in the field of *Dermatology*, 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 following drug: QGE031 (hereafter the "Study Drug") in accordance with a protocol entitled A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines, CQGE031C2302 and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct 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,

WHEREAS, the Parties wish to set forth certain the 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

ATTESTED

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

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) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(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 Antibribery 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.

PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes 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 may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis 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 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

DURATION OF THE STUDY

The Study shall commence on *1 Dec 2018*, subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *27 July 2021* or as may be extended by a formal writing between the parties in that behalf

TERM OF THIS AGREEMENT

1 This Agreement shall be effective upon 9 May 2019 ('Effective Date') and shall expire upon 8 May 2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

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 as soon as possible, and [illegible] within 30 days prior to such departure. It is clarified that Principal Investigator shall

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

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. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator 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 MRC*, located at *Nehru Nagar, Belagavi* : (hereinafter the "**Study Site**").

6.3 **Use of Study Drug:**

Novartis shall provide QGE031 (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study:** Before entering 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, her/his 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;

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) ensure that, before his/her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (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. An example ICF is attached hereto as Annex 3;

(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;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

6.5 **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.

6.6 **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 fashion:

(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 the receipt and disposition of the Study Drug 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 the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) 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

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

(vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.

(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). Sponsor 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 designated person within 24 hours, allow Novartis to be present at the inspection/action 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 periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site 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.

6.7 **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

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

(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 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 6.6 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 Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. 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 safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

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.

6.9 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 Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure I

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

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

In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

The Institution and Principal Investigator ("**Indemnifying Party**") will 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 (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the 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 a Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have bee recruited at the Study Site by *16 Feb 2020.*

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the numbe of completed visits. All payment will be made for subject visits according to the above Paymer Schedule attached as Annex 1. No payment will be made for any Study Subject excluded fro analysis because of Protocol violations that were within the Institution or Principal Investigator control. Reimbursement for expenses related to screening failures, patient travel, and local la test 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

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the accou indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novar may provide equipment (the "**Equipment**") to the Institution and/or Investigator strictly o returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclus property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: T Equipment shall only be used for the conduct of the Study in accordance with the Protoc Novartis instructions and until the Study is completed or discontinued.

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

purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 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 *KLES Dr. Prabhakar kore hospital and MRC/Dr. Shivkumar Patel* 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

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement 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.

11.4 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.

12. INTELLECTUAL PROPERTY

12.1 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.

12.2 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.

12.3 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.

12.4 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.

13. 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.

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

PUBLICATION

14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to 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 require 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.

14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

14.3 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.

14.4 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.

14.5 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.

15. CONFIDENTIALITY

15.1 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.

15.2 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.

15.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(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;

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

NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, writing and shall be delivered personally, or sent by registered mail or facsimile to the ac given in this Agreement

Mr. K. Murugananthan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road, Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: murugananthan.k@novartis.com

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Pa prior written consent, except that Novartis may (a) assign its rights and obligations under Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement i entirety to a successor to all or substantially all of its business or assets to which this Agreei relates. Any permitted assignee will assume all obligations of its assignor under this Agreei (or related to the assigned portion in case of a partial assignment). Any attempted assignme contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreei will be binding upon and inure to the benefit of the Parties and their respective successors permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform an its obligations under this Agreement without the prior written consent of Novartis. Any consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunc

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or other in any one or more instances shall be deemed to be or construed as a further or continuing wa of any such term, provision or condition, or of any other term, provision or condition of Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the par with respect to the subject matter hereof. No amendment to this Agreement will be effective binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor a collaborator who is involved in the performance of the Study has been debarred under the l including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, D and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by Institution in connection with any work to be performed for or on behalf of Novartis. If at a time after the execution of this Agreement the Institution

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

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.

TRANSPARENCY/DISCLOSURE

4.1 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.

4.2 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.

4.3 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 provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. 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 without restricting any right of appeal.

26. 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.

27. 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.

28. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

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

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE PRIVATE LIMITED

By: _____

Name: Saluja Singh

Title: Head CTO

Date: 19th July 2019

KLES Dr. Prabhakar kore hospital and MRC

By: _____

Name: Dr. M V Jali

Title: MD & CE KLES Dr. Prabhakar Kor Hospital and MRC

Date: 26/07/2019

Dr. Shivakumar Patil

By: _____

Name: Dr. Shivakumar Patil

Title: Associate Professor/Consultant Dermatologist

Date: 25/07/2019

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

ANNEX II: PAYMENT SCHEDULE

[redacted] NUMBER: CDCEBSICL002

[redacted] NAME: PEARL - I

Investigator's Name: Dr. Shivakumar Patil

Institute Name: KLES Dr. Prabhakar kore hospital and MRC

Center Name: Dr. Shivakumar Kalagouda Patil

Pan Card Number: BJJPP7382P

GSTIN: NA

Estimated Number of Study Subjects: 5 randomized patients

List of Equipment provided to Institution / Principal Investigator:

* Thermo-hygrometer
* ERT Log Pads - It would be retrieved from site post database lock is achieved.
* ERT Machine - It would be retrieved from site post database lock is achieved

Payment Schedule:

	Screening		Double blind treatment												
[redacted]	1	20	110	120	130	140	150	160	170	180	190	200	210	220	
[redacted]	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44	
[redacted] durres	16800	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500	3
[redacted]igator	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3
[redacted]nalior	2000	2000	3000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2
[redacted]ated vaccine	[redacted]	[redacted]	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	15
[redacted]tomat[redacted]	5700	1950	3750	2750	2750	2750	2375	2375	2750	2375	2375	2375	2375	2375	23
[redacted]	28500	9750	19250	14250	14250	14250	12375	12375	14250	12375	12375	12375	12375	12375	123

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

	post treatment follow up			
Visit	240/EoT/TD	310	320	1999/EOS? PSD
Week	52	56	60	64
Protocol Procedures	6200	5000	5000	5700
Investigator Fees	4000	3000	3000	4000
Coordinator Fees	2000	2000	2000	2000
Unblinded Pharmacist fee	1500	1500	1500	1500
Institutional Overhead @ 25%	3300	2750	2750	3175
TOTAL (INR)	17000	14250	14250	16375
TOTAL COST 1 PT	275375			

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit will be upto 1000 INR for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice

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

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: Belagavi/25/07/2019

Name: Dr. Shivakumar Patil

Principal Investigator

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

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"Personal Information or Data" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"Sensitive Personal Information or Data" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"Data Subject" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"Processing" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"Institution Third Parties" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

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

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Part that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreer to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply wit applicable Laws governing the privacy and security of Personal Information that Institu shall create, acquire, access or receive as a result of this Agreement, to the extent that Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measure protect Personal Information, from (i) unauthorised or accidental destruction, (ii) tl forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthor alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of data processing, (ii) nature and extent of the processing, (iii) assessment of possible risk the data subject; and (iv)current industry best practices and state of the art technolog including but not limited to encryption of information at rest and in transit. Secu measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related informati should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutio email Ids), if any must be discussed with Novartis and a secure communication solution, mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior writt notification to Novartis. In the event that any Institution Subcontractor shall have acce to Personal Information, such access shall be permitted under a need-to-know basis an only to the extent required for the due performance of Institution's obligations. Institutio shall enter into Agreements with its' subcontractors that contain privacy and securit provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novarti Personal Information, including that by Institution's Third Party (if any) have appropriat skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

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

I / We, the undersigned Institution and Principal Investigator for study number CQGE031C2302 decl that I have received a copy of;

(a) Novartis global Antibribery Policy

(b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

KLES Dr. Prabhakar kore hospital and MRC	Dr. Shivakumar Patil
By:	By:
Name: Dr. M. V Jali	Name: Dr. Shivkumar Patil
Title: MD & CEO	Title: Consultant Dermatologist / PI
Date: 26/07/2019	Date: 25/07/2019

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

తెలంగాణ तेलंगाना TELANGANA
S.No:434 Date:08/07/2019 Rs.50/-
To :-MADHAVA RAO MOLABANTI
S/o :- LATE M VENKATESWARLU
FOR WHOM:-M/S.BIOLOGICAL E.LIMITED.
R/o:-HYDERABAD.

G 668219
The Advocates' Co-op Society
Sri/Sri G.VIJAY KUMAR YADAV, Licence-4 Stamp Vendor
Lic No 16-08-08/2015
...by Legal Court Premises, Nampally, Hyderabad
District Phone No 040-24418387

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on 19th July, 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 of Pediatrics, KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum, Karnataka, India ("**Principal Investigator**") of the Second Part; and **KLEs JNMC Dr Prabhakar Kore Hospital,** Belgaum, Karnataka, India a hospital established registered under the laws of India, having its place of business at Nehru Nagar, Belgaum - 590010, Karnataka, India represented by its Medical Director ("**Institution**") Third Part

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

తెలంగాణ तेलंगाना TELANGANA

B 900218

S.No: 7697 DATE:08/07/2019 RS: 50/-
SOLD TO : MADHAVA RAO MOLABANTI
S/O LATE M.VENKATESWARLU
FOR WHOM :- M/S BIOLOGICAL E. LIMITED R/O HYD

The Advocates' Co-op Society
Rep.By.N Madhusudhan ,Licenced stamp Vendor,
Lic.No.16-10-10/2015, Ren.No.16-10-17/2018.
Metropolitan criminal courts, Nampally,
Telangana State Phone.No:040-23313246.

Page : 2 :

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited has developed the live attenuated Measles and Rubella vaccine developed by Biological E. and received marketing authorization by DCG(I), the present study is a phase IV Clinical Trial for obtaining additional safety data and to be conducted in twelve study centres;

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 his experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

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;

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

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 multicenter single arm non-comparative Phase-IV post marketing study to Evaluate the safety and tolerability of Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) in 9-12 month old Healthy Infants" 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 **BECT048/MRV-PIV/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:

Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) (Manufactured by Biological E. Ltd.).

1.4 "**Ethics Committee**" shall mean:

An independent body or 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 Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services,

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

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

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

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 &

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

Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

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

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

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, 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. Indemnification and Insurance

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 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.

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

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 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 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

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

an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

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

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

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 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

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

limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

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 DCGI or 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.

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

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.

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

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

(ii) **To Principal Investigator**: Dr. NS Mahantshetti
Title: Professor
Address: KLEs JNMC Prabhakar Kore Hospital,
Belgaum, Nehru Nagar, Belagavi, KARNATAKA
Telephone No.: 0674 2304400
Mobile: +91-8312477201
Email id: nsmahantasheeti@gmail.com

(iii) **To Institution**: : Dr. M. V. Jali
Title: Medical Director
Address: KLEs Dr. Prabhakar Kore Hospital &
Medical Research Centre, Nehru Nagar,
Belgaum 590010, Karnataka
Telephone No.: 0831 – 2473777
Fax No: 0831-2470732
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 Name: Mr. Sultan Baig Title: Vice President- Finance Seal: Witness: N.ESWARAREDDY Sr.Vice President - Legal	Signature & Date 29/7/19 Name: Dr.N.S. Mahantshetti Title: Professor Dr. N. S. Mahantashetti Professor Consultant Pediatrics KMC Reg. No. 22164 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi Seal: Witness: Vishal Jakati 29/7/19	Signature & Date 30/07/2019 Name: Dr M.V. Jali Title: Medical Director Seal: Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. Witness: Revana Sdevarinti 30/07/2019

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

Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

BECT048 – MR P-IV STUDY BUDGET	
Cost Description	**Amount (INR)**
Investigator, co-investigator & study team fee (INR.8,500 per Subject x 83 subjects)	7,05,500
Study coordinator fee (INR.13,500 per month x 8 months)	1,08,000
Subject travel conveyance (Rs. 500 per subject x 2 visits x 83 subjects)	83,000
Site Logistics, Setup charges (courier, Internet, AV Recording and other etc.)	50,000
Study documents archival fee (for 15 years)	50,000
Sub Total	**9,96,500**
Institutional Overheads (25% on Investigator fees)	1,76,375
Total	**11,72,875**

Total Cost (in Words): Eleven Lakhs seventy two thousand eight hundred seventy five 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. 11,72,875/- for enrolling 83 subjects, the per subject cost would be Rs. 9,500/-(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

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

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA69900906526789R
Certificate Issued Date	:	07-Aug-2019 01:41 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0864362121573410R
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	KLE UNIVERSITY JAWAHARLAL NEHRU MEDICAL COLLEGE
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

Please write or type below this line.

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

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and among

- **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre**, having a place of business at, Nehru Nagar, Belagavi-590010, Karnataka, India (the "**Institution**"), and
- **Dr. Archana Uppin**, having a place of business at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India. (the "**Investigator**"), and
- **Doclin Clinical Research** Services having a place of business at 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India. (the "**Research Company**"), and
- **IQVIA RDS (India) Private Limited, (formerly Quintiles Research (India) Private Limited)**, having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA** ").

Each a "Party" and together the "Parties".

Protocol Number:	201790
Protocol Title:	A 52-week, phase 3, multicentre, randomised, double blind, efficacy and safety study comparing GSK3196165 withplacebo andwithtofacitinib, in combination with methotrexate in participantswith moderately to severelyactiverheumatoid arthritis who have an inadequate response to methotrexate.
Protocol Date:	22 May 2019
Sponsor:	GlaxoSmithKline Research & Development Limited
Country where Site is Conducting Study	India
Investigator:	Dr. Archana Uppin "an employee of Institution"
Key Enrollment Date:	**100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)**
IRB/IEC	Name: Institutional Ethics Committee Address: JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India. Ethics Committee Chaiperson: Dr. Subarna Roy - +91 9449033133

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the GSK (defined below).

Case Report Form or CRF: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to GSK on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in 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

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or GCPs: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

GSK: means the Sponsor as identified above, GSK's Affiliates or GlaxoSmithKline group of companies, as applicable. Sponsor and GSK's Affiliates are members of the GlaxoSmithKline group of companies.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

Study Data: all records and reports, other than Medical Records, 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) required to be delivered to GSK pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

Process(ing): (in reference to Personal Data) any operation or set of operations that is performed upon Personal Data (as defined below), including without limitation collection, recording, retention, alteration, use, disclosure, access, transfer, storage or destruction.

Security Breach: the occurrence of any event that could reasonably be expected to comprise the security of Confidential Information or the security of Personal Data in accordance with Data Protection Legislation (as defined below), or the occurrence of discovering any suspected or actual

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

unauthorized disclosure, loss or theft of Confidential Information (as defined below) or Personal Data in accordance with Data Protection Legislation.

RECITALS:
WHEREAS, IQVIA is providing clinical research organisation services to GSK under a separate contract between IQVIA and GSK. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "Site") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, state and local tax and finance regulations and any laws related to protection of medical confidentiality and privacy of personal data. Site and Study Staff acknowledge that IQVIA and GSK, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by GSK and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by GSK or IQVIA, Site will submit Study Data using the electronic system provided by GSK or IQVIA or their designated representative and in accordance with GSK's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs. CRF information associated with a Subject's visit must be satisfactorily completed within seven (7) business days of the Subject's visit, after receipt of Subject's data queries, or if applicable, after receipt of the Subject's test results. Notwithstanding the foregoing, the GSK/IQVIA Study team may communicate in writing the reasonable necessity for response time to be modified (i.e. shortened) during interim analysis, urgent safety review (e.g. dose escalation timing, urgent FDA query) or study closeout periods. For dose escalation, data entry

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 queries must be answered within one (1) business day. The Institution will use reasonable efforts to meet such timing requests and

(iii) retain Medical Records and Study Data for a minimum of fifteen (15) years from the issue date of the clinical study report/summary or equivalent. GSK will inform the Investigator of the date on which the GSK-required retention period will expire. After the expiration of this period, Institution or Investigator is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention. If, at any time during the retention period, Investigator and/or Institution are unable to comply with the record retention responsibilities in this Section (e.g., Investigator retirement; Investigator is no longer employed by or associated with Institution; or, Institution site closure), Investigator or Institution shall transfer responsibility for record retention to another party at the Institution or to a third party off-site archive facility. Investigator or Institution must provide written notice to IAVIA and/or GSK prior to such transfer which specifies the name and address of the new responsible party and, if applicable, the new file location address.

(iv) take measures to prevent accidental or premature destruction or damage of these documents during the retention period. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the GSK. Upon the expiration of the retention period, Site shall comply with any applicable local, organizational, state, national and/or regulatory guidelines for records retention.

If the Investigator leaves the Institution or is otherwise unable to comply with record retention responsibilities, then responsibility for maintaining Medical Records and Study Data shall be transferred to an appropriate responsible party in accordance with applicable regulations and Investigator shall provide written notice to GSK of such transfer. Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to GSK all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and GSK for GSK's use. Site shall afford GSK and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit GSK and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and GSK, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA 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 Site's facilities, and the Site shall permit IQVIA and GSK to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

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

1.3.4. License. GSK hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness. Investigator agrees to answer queries related to CRFs submitted within seven (7) business days of the request, except for dose escalation. Investigator must respond to dose escalation queries within one (1) business day.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to GSK and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of GSK and IQVIA.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with GSK in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

GSK will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

GSK or a duly authorized agent of GSK, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by GSK and according to applicable laws and regulations, including storage in a locked, secured area at all times.

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

Upon completion or termination of the Study, the Site shall return or destroy, at GSK's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at GSK's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" GSK/IQVIA has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or IQVIA requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

1.10. Human Biological Samples

If the Study includes the collection by Site of human biological materials from Study Subjects for research use, Site will comply with all applicable laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study and with respect to any such human biological materials from the Study retained in Site's possession. Site agrees to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Study and for research use of any human biological materials, with ethics approval. Site agrees that any human biological materials collected as part of the Study that are transferred to GSK or a GSK's contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.11. Human Rights

Respectful of its employees right to freedom of association, Institution represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labour, forced labour, unsafe working conditions, discrimination of protected characteristic or cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the applicable laws on working hours and employment rights in the countries in which it operates. Institution shall be respectful of its employee's right to freedom of association' and Institution shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

2 PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs, all data required by the Protocol, including adverse events, and, if IQVIA requests, all other Confidential Information (as defined below).

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

Institution and Investigator agree that GSK may make public the amount of funding provided to Institution by IQVIA for the conduct of the Study and may identify Institution and Investigator as part of this disclosure.

3 CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of GSK and includes (i) all information disclosed by or on behalf of GSK to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of GSK, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by GSK, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;

(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by GSK, from sources other than GSK that did not have an obligation of confidentiality to GSK;

(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or

(iv) is permitted to be disclosed by written authorization from GSK.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not

(i) use Confidential Information for any purpose other than the performance of the Study or

(ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;

(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and

(iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide GSK with prompt notice so that GSK may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by GSK at any time, Site shall return to GSK, or destroy, at GSK's option, all Confidential Information other than Study Data.

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

3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4 INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or GSK shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or GSK or any of such entity's personnel in performance of the Study. GSK shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to GSK in writing, and Site, on behalf of itself and its personnel, hereby assigns to GSK all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist GSK by executing, and causing its personnel to execute, all documents reasonably necessary for GSK to secure and maintain GSK's ownership rights in Inventions.

4.4 License

GSK hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at GSK's request and expense, with GSK's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5 PUBLICATION RIGHTS

5.1 Study Transparency and Publication

Before commencement of the Study, GSK will register the Study with a public clinical trials registry. GSK will make public a summary of the Protocol and a summary of the Study results from all Study sites in one or more publicly accessible worldwide registers at any time after the commencement of the Study. GSK will also post the full Study Protocol and statistical analysis plan at the time of results summary posting. Institution and Investigator agree that GSK may make public the names of the Investigator and 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 shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit

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

any proposed publication or presentation to GSK for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, GSK shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. GSK shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable GSK to seek patent protection for Inventions. The Institution's publication will reference the GSK Publication (as defined below). Institution agrees that GSK's financial support of the Study will be disclosed in any Institution publication. Institution shall ensure that Investigator complies with the obligations identified in this Section 5.

5.2 Multi-Center Publications

GSK will seek to publish the Study results in searchable, peer reviewed scientific literature. The first publication and all subsequent publications of the Study results from all Study sites ("GSK Publication (s)") or disclosure(s) of the Study results, shall be coordinated by GSK. Once the Study is published in a scientific journal, GSK may list the Study on an external website for patient-level data sharing for further research and may also make available the full Study report on the GSK register. If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the GSK's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until GSK's Publication is published; provided, however, that if a GSK Publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data." Study Subjects' personal information, such as name or initials, shall not be publicly disclosed at any time.

Any participation of Investigator or other representatives of Institution as a named author of this GSK Publication will be determined in accordance with the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts, and Institution and Investigator acknowledge that the enrollment of Study Subjects alone is not a qualification for authorship. If the Investigator or other representative of Institution is a named author of the GSK Publication, as an author, he/she (1) will enter into a written author agreement prior to beginning work on the GSK Publication: (2) will have access to the Study data from all Study sites as necessary to fully participate in the development of the GSK Publication; and, (3) will disclose as part of the GSK Publication that GSK financially supported the Study and the GSK Publication, and will disclose any personal financial relationship with GSK. GSK will not compensate authors for authorship activities.

If considered appropriate by GSK, the Investigator or other Institution personnel involved with the Study may participate in the Publication Steering Committee ("PSC") or core writing team(s) for the Study or in public presentations of the Study results. Persons participating as a member of a PSC, in core writing team(s)' activities or in public presentation of the Study results will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

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

the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that GSK shall have the right to enforce any of the provisions of this Agreement as a third-party beneficiary.

Each Party to this Agreement acknowledges that except for the GSK, there are no third-party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

18.7 Binding Authority

IQVIA represents that GSK has granted IQVIA written authority to bind GSK to the GSK obligations expressly included in this Agreement

THIS SECTION IS INTENTIONALLY LEFT BLANK; SIGNATURE PAGE IMMEDIATELY FOLLOWS

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

ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) Private Limited:
(formerly Quintiles Research (India) Private Limited)

Name : Tanuka Ganguly

Title : Director, Site and Patient Networks

Signature: Tanuka Ganguly

Date : 26/Sep/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name : Dr. Archana Uppin

Title: Principal Investigator

Signature :

Date : 30/9/19.

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE:

By : Dr. Mallikarjun Vamadevappa Jali

Title: Medical Director and Chief Executive

Signature :

Date : 4/10/19

Doclin Clinical Research Services Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti-Kickback and Anti-Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY DOCLIN CLINICAL RESEARCH SERVICES

Name : Maruti Patil

Title (must be authorized to sign on Research Company's behalf): Managing Director

Signature: Patil

Date : 30 sep 2019

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

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	Doclin Clinical Research Services
Payee Address	Doclin Clinical Research Services, 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India.
Payee Remittance Email Address	maruti.patil171@gmail.com
Bank Name	Axis Bank
IFSC Code	UTIB0001690
Bank Account Number	919020049795418
GST Number	29AZXPP8818R1ZP
PAN Number	AZXPP8818R
Mode of Payment	Electronic Fund Transfer

The Payee's Tax Identification Number will be required before any payments can be made under this Agreement.

In case of changes in the Payee's address, Site is obliged to inform IQVIA in writing. The parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax- exempt status, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERM

IQVIA will pay the Quarterly (January, April, July, October), on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by GSK of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or GSK, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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

Major, disqualifying Protocol violations are not payable under this Agreement

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or GSK under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("**GST**") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section G of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in **Indian Rupees (INR)** and are exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

D. **SCREENING FAILURE**

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed one (1) screen failure(s) paid per three (3) subjects randomized.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

E. **DISCONTINUED OR EARLY TERMINATION**

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

F. **UNSCHEDULED VISITS**

Payment for unscheduled visits will be reimbursed in the amount up to **Eleven Thousand Six Hundred and Seventy Eight Indian Rupees** (11678 **INR** [which includes overhead]), as denoted in the Budget Table. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the unscheduled visit.

G. **INVOICES**

Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited
(formerly **Quintiles Research (India) Private Limited**)
Attn: QBAN Finance Department
Address: III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur- Marathahalli, Outer Ring Road,
Bangalore- 560103, India

Phone: +91 -080 71315909

Please note that invoices will not be processed unless they reference the GSK name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

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

- **Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of invoice and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by IQVIA and GSK, will be reimbursed upon receipt of invoice.

- **Record Storage Fee/Archiving Fee** – a record retention payment of **Ninety Thousand Indian Rupees (90,000INR)** will be paid upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain at Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

H. BUDGET TABLE

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
SC	36986.4
BL W0	25148.4
W1	17270.4
W2	22060.8
W3	5948.4
W4	19183.2
W5	5948.4
W6	5948.4
W7	5948.4
W8	19183.2
W9	5948.4
W10	5948.4
W11	5948.4
W12	31566
W13	22882.8
W14	5948.4
W15	3475.2
W16	22602
W17	3475.2
W18	5948.4
W19	3475.2
W20	6489.6
W21	3475.2
W22	5948.4
W23	3475.2
W24	28497.6
W25	3475.2
W26	5948.4
W27	3475.2
W28	6489.6
W29	3475.2
W30	5948.4
W31	3475.2
W32	6489.6
W33	3475.2
W34	5948.4
W35	3475.2
W36	22602
W37	3475.2

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

W38	3475.2
W39	3475.2
W40	6489.6
W41	3475.2
W42	3475.2
W43	3475.2
W44	6489.6
W45	3475.2
W46	3475.2
W47	3475.2
W48	13503.6
W49	3475.2
W50	3475.2
W51	9288
EoT W52	29572.8
TOTAL COST PER SUBJECT (INCLUDING OVERHEAD)	**506578.8**

OTHER VISITS	TOTAL AMOUNT (OVERHEAD INCLUDED)
Safety Follow Up Visit (SFU)	17901
Re-Screening Visit (Re-SC)	29628
Unscheduled Visit (UV)	11678

PD and Biomarkers Sub- study

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
BL W0	1032
W1	1032
W2	1032
W4	1032
W12	1032
W24	1032
Total Additional Cost Per Patient under PD and Biomarker sub study (including Overhead)	6192

I. **CONDITIONAL PROCEDURES (WITH INVOICE)**

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of an original invoice in the amount indicated in the table below (which includes overhead). Subject number and visit dates must be included on the invoice for payment to be issued.

Procedure	Total (OVERHEAD INCLUDED)
Re-consent, Informed consent performed again with the same patient	1,404
Partner pregnancy Informed consent	859
Genomics consent; DNA consent; Genetics	859
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	360
High Resolution Computed Tomography (HRCT), thorax, chest, lung for interpretation and report use R1255; (CT Scan)	31,225
Interpretation and Report; High Resolution Computed Tomography	9,163
Telephone assessment and management service provided by a qualified nonphysician health care professional to an	1,104

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

established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	1,560
Physician: Pulmonary Medicine - Per Hour	4,652
Serious adverse events (SAE)	2,828
Patient Reimbursement, Expenses, Patient Travel - Per Visit	913
Meal Reimbursement- Per Visit	795

J. **MINIMUM ENROLMENT GOAL**

Site acknowledges that Site's minimum enrollment goal is **75** subjects and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

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

ATTACHMENT B

The Site will be supplied with a Lenovo Tablet; the model number is YB1-X90L. The cost of the tablet is USD 439 (Four Hundred and Thirty Nine US dollars).

All materials and equipment provided ("Equipment") by the GSK or IQVIA/vendors contracted by the GSK shall remain the sole property of the GSK/IQVIA/vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:
a) be subject to removal at any time upon the GSK's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;

b) be used only for the purposes of the Study;

c) be used in accordance with any manuals or instructions while in possession of the Site;

d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;

e) be clearly identified as the sole property of the GSK/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and

f) upon completion or termination of the Study, IQVIA or GSK, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the GSK or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED UNLESS APPROVED BY IQVIA AND GSK

Except for GST, these amounts include all applicable taxes.

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 ◐ 2019 ◐ VP 609520

प्रधान मुद्रांक कार्यालय, मुंबई
16 AUG 2019
सक्षम अधिकारी
श्री. दि. क. गवई

PRODUCT CODE:	**SSR29263**
STUDY CODE:	**LPS14914**
STUDY NAME:	**KIDDIE**

INVESTIGATOR/INSTITUTION CONTRACT

Site Name: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgavi

Study Code / Name: LPS14914/KIDDIE **Effective date:** 16th October 2019

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

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

This Contract (hereinafter "the Contract") is made on this **7th day of November 2019,** by and among:

DOCTOR MAHANTESH V. PATIL having his address at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belguam-590010, Karnataka, India

Hereinafter the "**INVESTIGATOR**",

AND

KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESERCH CENTRE having its address Nehru Nagar, Belguam-590010, Karnataka, India represented for the purposes hereof by Dr. M. V Jali, Medical Director

Hereinafter the "**INSTITUTION**"

AND

GDD EXPERTS INDIA PRIVATE LIMITED having its address at Ground floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur – 440001, Maharashtra, India represented for the purposes hereof by Mr. Vinod Gyanchandani, Head Clinical Operations

Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a 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, CSU Cluster Head, India-South East Asia

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~~ **A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children** (hereinafter the « Study ») to evaluate Sanofi drug **Enterogermina® /Bacillus clausii /SSR29263** (hereafter the «Investigational Medicinal Product») in accordance with a protocol entitled **KIDDIE/LPS14914** 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 Pediatrics, 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, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS, the SPONSOR shall have no liability whatsoever arising out of selection and appointment of SMO and payments made to the SMO, including but not limited to any claims, demands, actions, causes of action, judgments, damages, expenses and costs, including attorney's fees, which arise out of, result from, occur during or are connected in any

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

manner with the Study or any related activities or Investigator meetings, irrespective of whether or not they are sponsored, supervised or controlled by the SPONSOR, except such liability arising directly and solely from gross negligence on the part of the SPONSOR, 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 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;

WHEREAS, the **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in 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»)/ Regulatory Authority («RA»)/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/RA/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, Nehru Nagar, Belguam-590010, Karnataka, India. (hereafter the **«Study Site»**). 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.

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.

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

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

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 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.

3.4 The INVESTIGATOR, the INSTITUTION and the SMO shall submit CRF/eCRFs to the SPONSOR. If needed, the SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a computer and/or internet connection in order to submit eCRFs for the Study. The INVESTIGATOR and any Collaborator (as such term is defined at Article 2) will be trained by the SPONSOR with respect to the use of eCRFs. Before the training process, the INVESTIGATOR, each Collaborator and the representative of the INSTITUTION/the SMO shall acknowledge statements of understanding and acceptance of their obligations regarding the eCRF process.

ARTICLE 4. TERM.

This Contract is being entered into force from **16th October 2019 ("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 13 (thirteen) 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

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

5.3 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.

5.4 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/RA/CA.

5.5 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.

5.6 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.

5.7 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.

5.8 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 **85 (Eighty Five)** Subjects, within **12 (Twelve)** 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 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.

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

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 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.

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

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 file containing the essential documents related to the Study and records generated during the Study **("Study File")** for the longest of the two following periods **(the «Retention Period»):**

- Twenty-five (25) years after the signature of the final Study report or,
- Such longer period as required by applicable regulatory requirements.

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.

If during the Retention Period, the INSTITUTION/the SMO is no longer able to retain the Study File due to exceptional circumstances (such as bankruptcy), the INSTITUTION/the SMO shall contact the SPONSOR to organize the transfer of the Study File to the SPONSOR at the SPONSOR's expense.

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 Regulatory 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.

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

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:

(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.

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

(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

(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

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

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 ("GCP") and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / the SMO/ PAYEE shall permit inspections, investigations and audits by or on behalf of the SPONSOR subject to the provisions below, and inspections by any health or regulatory authority, including, but not limited to, European Medicines Agency and U.S. Food and Drug Administration ("Regulatory Authorities"). The INVESTIGATOR and the INSTITUTION/ the SMO/PAYEE shall prepare for the abovementioned investigations, audits and inspections in cases where they are informed in advance, and shall make their best efforts to facilitate their conduct.

17.2 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.

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

17.4 As soon as the INVESTIGATOR, the INSTITUTION and/or the SMO is notified of an inspection by any Authorities which is related to the Study or may affect its conduct, they shall, to the extent permitted by applicable regulations or the relevant Regulatory Authorities (i) promptly inform the SPONSOR of the inspection (ii) prepare for such inspections in collaboration with the SPONSOR (iii) provide in advance the SPONSOR, for review and comment, with any draft of written answer to a question of an Authority, (iv) authorize the SPONSOR to participate to the aforementioned inspections, (v) provide the SPONSOR with a copy of any and all documents given to, sent or collected by the Authorities in the framework of said inspections, and (vi) provide the SPONSOR with any reports, result or analyses issued by the Regulatory Authorities in the framework of said inspections.

17.5 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, investigations or inspections.

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

17.7 The rights and obligations under this Article shall remain in effect for **25 (Twenty Five)** 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

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

provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

18.3 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 they have not accepted nor been offered any payment of money or other assets, or anything of value, for the purpose of influencing their decisions or actions to help the SPONSOR obtain or maintain business or obtain a business advantage 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").

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

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 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.

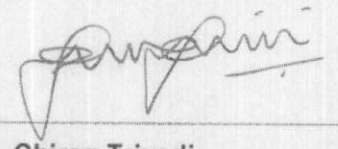
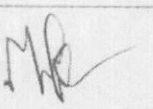
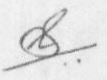
22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings 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.

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

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. Mahantesh V. Patil**
[Title]	**CSU Cluster Head, India-South East Asia**	**[Title]**	**Principal Investigator**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**S. S. Parab**	**[Name]**	Shruti H

KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE (INSTITUTION)		**GDD EXPERTS INDIA PRIVATE LIMITED (SMO)**	
[Signature]		**[Signature]**	
[Name]	**Dr. M. V Jali**	**[Name]**	**Dr. Vinod Gyanchandani**
[Title]	**Medical Director**	**[Title]**	**Head Clinical Operations**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	Revana S Devaniti	**[Name]**	Rajani Asundi

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

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 16th October 2019

1) The SPONSOR will pay **INR.1,00,000/- (Rupees One Lakh 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:

Visits	Visit no.	Per visit cost (INR) (A)	Hospitalization (5 days) (INR) (B)	Patient reimbursement (INR)	Total (INR)
V1/ Screening/ Baseline visit Day 1	V 1	19,000	1,000	1000	21,000
Day 2	V 2	13,000	1,000		14,000
Day 3	V 3	13,000	1,000		14,000
Day 4	V 4	13,000	1,000		14,000
EOT/ Day 5	V 5	15,000	1,000	1000	17,000
EOS/ Day 6	V 6	19,000	-	1000	20,000
		92,000	**5, 000**	**3,000**	**100,000**

*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 will be INR 1,000/- per visit as 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.

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

Local lab cost workings:

Parameters	Price (INR)
Hemoglobin Hematocrit Red blood cell [RBC] count Morphology [if RBC count is abnormal] White blood cell [WBC] WBC differential Neutrophils Lymphocytes Monocytes Eosinophils Basophils Platelet count Absolute neutrophil count [ANC]	1190
Blood Chemistry Sodium Potassium Chloride Bicarbonate Blood urea nitrogen (BUN) Creatinine Creatinine clearance Calcium Phosphate Total protein Albumin	950
C-reactive protein	2200

3) For screen failure, the SPONSOR will pay INR 2,000/- (Rupees Two 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 on actuals to payee, upon receipt of a valid invoice issued on letterhead of payee and receipt by Sponsor.

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

6) Monthly admin charges of INR 2,000/- (Rupees Two thousand only) per month will be paid towards stationary, internet, fax, courier and telephone charges from SIV till Study site close out visit.

7) A onetime start-up fee of INR. 75,000/- (Rupees Seventy 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.

8) Sponsor will pay INR 165 (Rupees One Hundred and Sixty Five only) per box per month after the Study Closure to PAYEE for archival and document storage for a period of 25 years from the date of site closure

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

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

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

10) 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.

11) 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 PAYEE on *Quarterly* basis upon presentation of the invoices in Indian Rupees by a bank wire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

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 Discrepancy Resolution Form/ electronic-Discrepancy Resolution Form "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
Registrar
KLE Academy of Higher Education and Research,
(Deemed to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

<SMO letterhead>

Annexure 1

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CERTIFY that GDD Experts India Private Limited is responsible for Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management of Acharya Vinoba Bhave Rural Hospital, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha- 442004, Maharashtra, India. All clinical responsibilities towards patient care has been accordingly subcontracted to GDD Experts India Private Limited who is responsible for such activities on a non-profit basis.

All Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management related money shall be credited to "GDD Experts India Private Limited" as per following details:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

ACKNOWLEDGED AND AGREED BY GDD EXPERTS:

Name: Dr. Vinod Gyanchandani

Signature: _____

Date: 19/Nov/2019

Place of Issue: Nagpur

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

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA34506370229744R
Certificate Issued Date	:	07-Nov-2019 11:54 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BELGAUM30/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKACRSFL0887327659172204R
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 जयत

Issued by
The Judicial Employees
Co-operative Credit Society Ltd.
Dist. Court Compound, 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:

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.

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

CLINICAL TRIAL AGREEMENT

Among

1. **CADILA HEALTHCARE LIMITED**, , a multinational pharmaceutical company incorporated under the laws of India, having its Registered Office at Cadila Healthcare Limited a company incorporated under laws of India, having its registered office at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India (hereinafter referred to as **"the Sponsor")**

2. **DR. MAHESHKUMAR VEERANNA KALLOLI KLE'S DR PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE** (hereinafter referred to as **"Principal Investigator"**)

3. **KLE'S DR PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE NEHRU NAGAR, BELGAVI-590010, INDIA** (hereinafter referred to as **"the Institution")**

CADILA PROJECT:

A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)

This Clinical Study Agreement ("Agreement") is executed on **01-Nov-2019** ("Effective Date") among Cadila Healthcare Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India; Dr. Maheshkumar Veeranna Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre Nehru Nagar, Belgavi-590010, India, for the study entitled A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2-Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)" (Hereinafter referred to as **'the study").**

This Agreement also covers any companion protocol(s) later developed and approved by all the Parties that are conducted concurrently with the protocol identified herein (collectively "Protocol") and that involve some or all the same subjects. The Sponsor and the Institution hereby declare that all the necessary permissions and licences required under the provisions of various acts and rules thereunder have been obtained for the performance of their respective obligations under this Agreement.

AND WHEREAS the Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study.

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:

THE PARTIES AGREE AS FOLLOWS:

NUTAN NAGRIK SAHAKARI BANK LTD. AHMEDABAD - 382210 GHODASAR BRANCH

भारत INDIA STAMP DUTY GUJARAT Rs. 00300 -1.11.2019

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

1 The Sponsor would like to test the biosimilar namely Trastuzumab Emtansine (TDM1) which will be used in patients with metastatic breast cancer aged 18 to 65 years at the time of enrollment in the study. The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) will be obtained before the start of the study.

2 The Sponsors have approached the Investigator as they desire to perform the study in regards to the said drug in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices and Local Regulations and have accordingly finalized the Clinical Trial Protocol.

3 The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled "A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients" (Project No._TDM1.17.001)". All amendments and appendices have also been read and understood. The investigator agrees to the protocol and will perform the study in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices, and applicable laws, rules and regulations.

THE PARTIES AGREE AS FOLLOWS:

4 **Investigators and Research Staff**

4.1 **Principal Investigator:** The Study will be conducted by Dr. Maheshkumar Veeranna Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre Nehru Nagar, Belgavi- 590010, India,with registration number **71566**; the Principal Investigator. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub-investigators and research staff and the Institution.

4.2 **Sub-investigators and Research Staff:** Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub-investigators or research staff.

4.3 **Obligations:** Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is responsible to the Sponsor for compliance by Investigators, with the terms of this Agreement.

4.4 **No Substitution:** The Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from the Sponsor.

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

4.5 **Delegation of Duties by Principal Investigator:** The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical trials in India.

4.6 **Compliance with Institutional Policies:** The Principal Investigator will comply with the policies and procedures of the organization/institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify the Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation

4.7 **Audit:** The Principal Investigator will make necessary arrangement for inspection of documents etc. by Sponsor's monitor, official of regulatory agency.

5 **Funding:** The conduct of the study will not impose any financial burden on the Principal Investigator or the Institution. The Sponsor declares to bear all the expenses pertaining to the conduct of the study.

5.1 **Financial Support for Clinical Trial:** The details of the financial support to investigators and the budget sheet are attached in Annexure A hereunder:

6 **Protocol:** Investigator will conduct the Study in accordance with the Protocol, Indian GCP guidelines and applicable rules and regulations in India.

6.1 **Amendments:** The Protocol may be modified only by a written Amendment, signed by both the Sponsor and the Principal Investigator.

6.2 **Emergency Amendments:** If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify the Sponsor and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by execution of a written Amendment within 30 days.

6.3 **No Additional Research:** No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

7 **Subject Enrolment:** Investigator has agreed agrees to enrol the subjects in the study as may be defined and decided by the Sponsor from time to time. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.

7.1 **Excess Enrolment:** If Investigator enrols the maximum number of qualified subjects, the Sponsor may or may not invite Investigator to enroll additional subjects. However, the Principal Investigator shall not enroll more than maximum number without prior approval by the Sponsor.

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

7.2 **Failure to Enroll:** If Investigator fails to enroll subjects at a rate adequate to meet the enrollment requirement, the SPONSOR shall be free to terminate the Study early (see Section 23, Termination).

8 **Study Conduct:** Investigator will conduct Study in accordance with the Protocol, the Sponsor's written instructions, Indian Good Clinical Practices (Indian GCP) guidelines and all applicable governmental laws, rules, and regulations.

8.1 No Charge for Investigational Drug or Reimbursed Services: Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Section 13, Investigational Drug) or for any services reimbursed by the Sponsor under this Agreement.

9 **Independent Ethics Committee/Institutional Review Board:** Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a 'IRB') that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

10 **Study Disapproval:** If, through no fault of Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 23.1.a, Disapproval by IRB, below.

11 **Data Protection:** Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Cadila Healthcare Limited group of companies, to representatives and contractors working on behalf of the Sponsor group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause 11. The Principal Investigator shall be responsible for obtaining Sponsor's permission before publication or conference presentation of any Sponsors' data.

12 **Informed Consent and Authorization to Use and Disclose Health Information**

12.1 **Informed Consent:** Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow the Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 16).

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

13. **Adverse Events:** Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone, e-mail or facsimile. The Investigator shall, so far as is lawful, have full responsibility for the reporting of all serious and unexpected adverse events and/ or deaths to local regulatory authorities as per prevailing regulations. The Sponsor has and will maintain during the Study, an insurance policy adequate to cover adverse events or injury to Study Subject(s) as a direct result of participation in the Study. . **Investigational Drug: The** Sponsor will provide Investigator with sufficient quantities of the investigational drug(s) needed to conduct the Study.

13.1 **Custody and Dispensing:** The Principal Investigator will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except sub-investigators or research staff. The Principal Investigator shall maintain the records of inventory of the Investigational drug.

13.2 **Use:** Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

13.3 **Ownership of Investigational drug:** Investigational drug remains the property of the Sponsor except for, and limited to, the use specified in the Protocol, the Sponsor grants Investigator no express or implied intellectual property rights in Investigational drug or in any methods of making or using the Sponsor's DRUG.

14. **Confidential Information:** During the course of the Study, Investigator may receive or generate information that is confidential to the Sponsor. Any information marked by the sponsor as confidential and provided to the investigator 1 year before the execution of this agreement will also be treated as confidential information.

14.1 **Definition:** Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
d. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
e. Any other information related to the Study, the Sponsor's DRUG, or The Sponsor technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2 **Exclusions:** Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,
b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,
c. is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or

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. Is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 **Obligations of Confidentiality:** Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.
b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 **Disclosure Required by Law:** If disclosure of Confidential Information to any party other than the IRB relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. Notifies the Sponsor in writing in 15 working days advance of the disclosure so as to allow the Sponsor to take legal action to protect its Confidential Information,
b. Discloses only that Confidential Information required to comply with the legal requirement, and
c. Continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Individually Identifiable Health Information**: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.

14.6 **Survival of Obligations:** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the study and marketing of the drug.

14.7 **Return of Confidential Information:** If requested by the Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Study Data, Biological Samples and Study Records:

15.1 **Study Data:** During the course of the Study, Investigator will collect and submit certain data to the Sponsor or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to the Sponsor or its agent within the reasonable time period.

a. **Ownership of Study Data:** Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), the Sponsor is the exclusive owner of all Study Data.

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

b. **Non-exclusive License:** The Sponsor grants Investigator no right to use study data for any purpose including internal research and/or education purpose.

c. **Data Management and statistical Analysis:** The Sponsor or its representative shall carry out the data management and statistical analysis. The Sponsor may consult and / or provide the Principal Investigator for interpretation during report writing.

d. THE SPONSOR is the exclusive owner of study data.

15.2 **Biological Samples:** If so specified in the Protocol, Investigator may collect and provide to the Sponsor or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. **Use:** Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. **Analysis samples:** The Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.

c. **Ownership:** The Sponsor is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

15.3 **Study Records:** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. **Retention:** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 5 years after termination of the Study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor before destroying any Study Records after the required retention period. Investigator further agrees to permit the Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. Monitoring, Inspections and Audits

16.1 **Monitoring:** The Sponsor shall be entitled at its absolute discretion (and in such form as the Sponsor sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit the Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by the Sponsor will relieve the Investigator of any of its obligations hereunder.

16.2 **Inspections and Audits:** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. The Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

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

a. **Notification:** Investigator will notify the Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.
b. **Cooperation:** Investigator will cooperate with regulatory agency or the Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.
c. **Resolution of Discrepancies:** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.
d. **Inspection Findings and Responses:** Investigator will promptly forward to the Sponsor copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide. The Sponsor with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.
e. **Data Clarification Form:** The Sponsor may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the Principal Investigator or his nominee shall clarify within 7 working days.
f. **Study Conduct Evaluations:** The Sponsor or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor will use these evaluations solely for internal purposes.

17. Inventions:

17.1 **Notification:** If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the SPONSOR

17.2 **Assignment:** Investigator will assign all interest in any such Invention to the Sponsor, free of any obligation or consideration beyond that provided for in this Agreement.

17.3 **Assistance:** Investigator will provide reasonable assistance to the SPONSOR in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

18. Publications:

18.1 **Prepublication Review:** The Sponsor has no objection to publication by Investigator of any information collected or generated by Investigator, whether or not the results are favourable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Investigator will provide the Sponsor, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.
a. **Submission to the Sponsor:** Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation, etc.) to the Sponsor at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.
b. **Redaction of Confidential Information:** Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

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

19. **Debarment and Exclusion:** The Principal Investigator and Investigator each certify that it/s/he / she is not debarred and that it/s/he/she is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify the SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. **Use of Name:** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify the Principal Investigator and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. **Assignment and Delegation**

21.1 The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If the Sponsor authorizes delegation or subcontracting, Institution remains responsible to the Sponsor for the performance of all delegated duties.

21.2 The Sponsor may not assign its rights or delegate its duties under this Agreement without written permission from the Principal Investigator. Any attempt to so assign or delegate is invalid. However, the SPONSOR may freely subcontract Study-related duties to an external provider upon advance notice to the Principal Investigator, and also may freely assign its rights or delegate its duties to any of the Sponsor affiliate. If the SPONSOR delegates or subcontracts any duties, the Sponsor remains responsible to the Principal Investigator for the performance of those duties.\

21.3 **Affiliates:** As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the Sponsor

21.4 **Successors and Assigns:** This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. **Conflict with Attachments:** If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. **Indemnity:** Each Party upon receipt of prompt notice and opportunity to defend, shall indemnify and hold the other party harmless, and hereby forever releases and discharges the other Party from and against claims, demands, liabilities, damages and expenses including attorney fees arising out of the negligence of the indemnifying Party in connection with the work performed under this Agreement, provided, however, each party shall not be obligated to indemnify, defend or hold harmless the indemnified party to the extent the claim is caused by gross negligence or willful misconduct of that party.

24. **Term and Termination:**

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

24.1 **Termination** Conditions: This Agreement terminates upon the earlier of any of, the following events:

a. **Disapproval by IRB:** If, through no fault of Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.

b. **Study Completion:** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by the Sponsor of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.

c. **Termination Upon Notice:** The SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d. **Immediate Termination by the Sponsor:** The Sponsor further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the Sponsor 's opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.

e. **Termination Upon Notice by Investigator:** The Principal Investigator may terminate the study, if the Sponsor does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to the SPONSOR fifteen days prior to termination and the Sponsor shall have fifteen days to cure its default.\

f. **Immediate Termination by Investigator:** Investigator reserves the right to terminate the Study immediately upon notification to the SPONSOR if requested to do so by the responsible IRB or if such termination is required to protect the health of Study subjects.

24.2 **Payment upon Termination:** If the Study is terminated early in accordance with Section 23.1 Termination Conditions, above, the Sponsor will provide a termination payment equal to the amount owed for work already performed, less' payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 23.1.a, Disapproval by IRB, above), the Sponsor will reimburse Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by the Sponsor

24.3 **Return of Materials:** Unless the Sponsor instructs otherwise in writing, Investigator will promptly return all materials supplied by the Sponsor for Study conduct, including unused Investigational Drug, unused Case Report Forms, other study related material and any the Sponsor - supplied Equipment.

24.3.1 **Electronics Items**: On completion of the clinical study, the Investigator will return all the electronic items & their accessories in the working condition (if any) as provided by the Sponsor during the study.

24.4 **Treatment Code (Blinded Studies Only):** Upon request, the Sponsor will provide Investigator with a treatment assignment list that identifies, by subject number, the treatment that each Study subject received. Unless otherwise specified in the Protocol, the Sponsor will provide such treatment assignment information only after the Study is completed {or has been terminated and all data submitted) at all participating sites.

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

24.5 **Survival of Obligations:** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, and Debarment and Exclusion survive termination of this Agreement as does any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

25. **Modification:** Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

26. **Entire Agreement:** This Agreement and any Exhibits and Attachments and the Indemnity at Exhibit represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

27. This agreement shall be interpreted and enforced under the laws of India and the Courts of Ahmedabad shall have exclusive jurisdiction to resolve any dispute under this Agreement.

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

Executed by the parties:

SPONSOR:

(Mr. Mukund Thakkar)	**(Dr. Sanjay Maroo)**
SVP-Legal	**GM, Clinical R&D**

PRINCIPAL INVESTIGATOR: Dr. MaheshKumar Veeranna Kalloli

Sign: _____

INSTITUTION: KLE'S Dr. Prabhakar Kore Hospital and MRC
Dr Mallikarjun Vamadevappa Jali
Designation: Medical Director and Chief Executive

Sign: _____

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

Sign: _____

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

Annexure A:

Budget Sheet and other expenses:

Investigational drug		Trastuzumab emtansine		Clinical trial phase		III
Investigators & Center		Dr. Mahesh Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre				
Protocol title/number(s)		A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256;Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine(Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients: TDM1.17.001				
Budget:		Rate per patients	No. of patients	No. of visit	Total cost	Maximum payable amount
Investigators' Professional Fees:						
	Screening	13000	1	1	13000	103000
	Enrollment visit without PK	10000	1	1	10000	
	Follow up visits (cycle 2-8 and End of study visit)	10000	1	8	80000	
Patients reimbursement:						
	Screening	1000	1	1	1000	10000
	Enrollment visit	1000	1	1	1000	
	Follow up visits (cycle 2-5 and End of study visit)	1000	1	8	8000	
Study co-ordinator:						
	Screening	4000	1	1	4000	26500
	Enrollment visit without PK	2500	1	1	2500	
	Follow up visits (cycle 2-5 and End of study visit)	2500	1	8	20000	
Phlebotomist:						
	Screening	500	1	1	500	5000
	Enrollment visit without PK	500	1	1	500	
	Follow up visits (cycle 2-5 and End of study visit)	500	1	8	4000	
Radio Diagnostic Tests						
	Screening (contrast CT_Chest, abdomen with pelvis)	14000	1	1	14000	47000
	*Enrolled (CT scan-Contrast-Chest and Abdomen with Pelvis)	14000	1	2	28000	
	Bone scan	5000	1	1	5000	

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

	Special Clinical Examination (2D ECHO)					
	Screening	2000	1	1	2000	2000
	Special Clinical Examination (Chest X-Ray)					
	Screening	450	1	1	450	450
	Special Clinical Examination (ECG)					
	Screening	300	1	1	300	2700
	***Enrolled**	300	1	8	2400	
	Hospitalization charges:					
	Enrolled	3500	1	8	28000	28000
	Administration costs:					
	Phone/fax calls					2000
	Couriers/Xerox					
	Drug Storage					
	Institutional Overhead (25%)- only PI and CRC					32375
	Total				**226650**	**259025**
Note	(1) Maximum amount paid per completed patient without PK will Rs.				**259025**	
	(2) First installment is for ethics committee fees(As per actual).					
	(3) Reimbursement of all expenses against monthly invoices with supporting vouchers (if required).					
	(4) Final payments made will be only on the basis of subjects completed in the trial. Cost of screen failures is adjusted in the payments for the enrolled subjects as per the above projections.					
	(5) Payments will not be done for wrongly enrolled subjects.					
	(6) Of the total eligible payment,70% will be paid while the study is on-going at regular intervals, 20% will be paid after completion of data management and remaining 10 % on signing of the clinical study report.					
	(7) Upto 10% of the drop-outs in the study will be reimbursed as per the actual expenses. Drop-out above 10 % will not be reimbursed.					
	(8) Tax deduction at source (TDS)/GST as per the applicable regulations. GST as per applicable rules.					
	(9) Archival charges of INR 42,000 will be paid extra to archive study documents for 15 years.					
	(10) No monthly payments will be processed if no patients are enrolled within two months from date of study was conducted at site					
	(11) Local pathology/pharmacy/any other investigations charges as per actuals.					
	(13) Payee details: Payee name: MG CLINICAL RESEARCH Payee address: sector no 12, Plot no 17, M M Nagar, Jain bhasti, Karnataka-590018, Belgaum Bank name: HDFC BANK Bank account name: MG CLINICAL RESEARCH Bank account number: 50200044101301 IFSC code: HDFC0000253					

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

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

NUTAN NAGRIK SAHKARI BANK LTD. AHMEDABAD
GUJ/SOS/AUTH/AV/2/2005 INDIA
Rs. 0000300 -1.11.2019
00000 SPECIAL ADHESIV
363080 GUJRAT

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"	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.

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 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.

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

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.

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

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

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

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.

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

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."

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 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 : KLE's Prabhakar Kore Hospital & MRC

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

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	9000	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[1] - 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

Dr. Maheshkumar Kalloli, 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

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.)

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

- 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.

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

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

(I) **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

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

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".

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

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.

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

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

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) 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.

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

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.

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

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**

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

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

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

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.

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

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA41796185066833R
Certificate Issued Date	:	01-Jul-2015 05:28 PM
Account Reference	:	NONACC (FI)/ kaksfc08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08103668694584498R
Purchased by	:	IQVIA RDS INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PVT LTD
Second Party	:	KLES DR PRABHAKAR KORE HOSPITAL AND M R C
Stamp Duty Paid By	:	IQVIA RDS INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARHALLI SOUHARDA CREDIT COOPERATIVE LTD. 3395/2015-16

Please write or type below this line

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.

GOVERNMENT OF KARNATAKA GOVERNMENT OF KARNATAKA GOVERNMENT OF KARNATAKA GOVERNMENT OF KARNATAKA GOVERNMENT OF KARNATAKA GOVERNMENT OF KARNATAKA

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Institution**"), and
- **Dr. Rohan Bhise**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Investigator**"), and
- **GDD Experts India Private Limited**, having a place of business at Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India (the "**Research Company**")
- **IQVIA RDS (India) Private Limited,** (formerly **Quintiles Research (India) Private Limited**), having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA**").

Each a "**Party**" and together the "**Parties**".

Protocol Number:	SAMSON-II
Protocol Title:	A Randomized, Double-blind, Parallel Group, Equivalence, Multicenter Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer. **EudraCT no.:** 2017-005175-78
Protocol Date:	Version 1.0 – 22 April 2019
Sponsor:	Prestige BioPharma Pte Ltd
Country where Site is Conducting Study	India
Investigator:	Dr. Rohan Bhise
Key Enrollment Date:	**100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)**
IRB/IEC	Name: Institutional Ethics Committee, KLE University Address: KLE University, JMNC Campus, Nehru Nagar, Belagavi - 590010, Karnataka, India. Chairperson Name: Dr. Subarna Roy Chairperson contact number: +91 9449033133

The following additional definitions shall apply to this Agreement:

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

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or **CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or **GCPs**: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, 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) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

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

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's

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

expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA 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 Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures

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

to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.
Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment C hereto. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA or Sponsor with respect to such facility improvements.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment 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-590 010,Karnataka

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or IQVIA requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

3. CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;

(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;

(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or

(iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not:

(i) use Confidential Information for any purpose other than the performance of the Study or

(ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;

(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and

(iii) use reasonable measures to protect Confidential Information from disclosure.

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

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

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

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data."

5.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("**Unpublished Data**") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public

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

clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data and may be used by IQVIA, Sponsor, and their affliates in compliance with applicable law, including as set forth below and for the length of time reasonably necessary for the purpose below.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to financial dislocures or other potential conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials and/or statistical analysis;
(ii) verification by governmental or regulatory agencies, the Sponsor, IQVIA, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;
(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials or other business and;
(vi) anti-corruption compliance.

Investigator's personal data may be transferred to countries outside of Investigator's country, which may not provide for the same level of protection as is applicable in Investigator's country. In such event, IQVIA or Sponsor, as applicable, will make sure that appropriate safeguards are secured in advance of any transfer in accordance with IQVIA's or Sponsor's, as applicable, legal obligations to ensure the protection of Investigator's personal data according to the data protection laws and regulations applicable in Investigator's country.

Names of members of Study Staff may be processed in IQVIA's study contacts database for study-related purposes only.

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions.

6.3 Data Controller

The Sponsor shall be the data controller for such personal data except that, if IQVIA deals with any personal data under this Agreement in the manner of a data controller, IQVIA shall be the data controller of such personal data to the extent of such dealings.

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

IQVIA may process "**personal data**", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "**Data Protection Legislation**"), of the Investigator and Study Staff for study-related purposes and all such processing will be carried out in accordance with the Data Protection Legislation.

6.4 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7. STUDY SUBJECT INJURY

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:
(a) failure by Institution, Investigator or Research Company or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
(b) negligence or willful misconduct by Institution, Investigator or Research Company or any of their respective personnel, or
(c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any

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

regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.
Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners,

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

directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.
In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution and Research Company and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or Research Company or their staff.

t is hereby agreed and acknowledged by the Parties and Sponsor that IQVIA has no relationship whatsoever with the Research Company and that the Research Company is acting as an independent contractor of the Institution.

15. TERM & TERMINATION

15.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

15.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable

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

control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered:

(a) in person;
(b) by certified mail, postage prepaid, return receipt requested;
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report; or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Prestige BioPharma Pte Ltd 2 Science Park Drive, Ascent Tower B, #04-13/14, Singapore 118222 Phone : +65-6924 6535 Fax : +65-6924 2053
To IQVIA	**IQVIA RDS (India) Private Limited** III Floor, Etamin Block,Prestige Technology Park, Sarjapur - Marathahalli Outer Ring RoadBangalore – 560103, Karnataka, India Tel: +91 8071317778 and IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution	Name: Dr. M. V. Jali Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: 0831-2473777
To Investigator	Name: Dr. Rohan Bhise

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

	Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: +91 8312470400
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India Tel: +91 9923000560

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS

18.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

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.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

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

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

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

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED
(formerly **Quintiles Research (India) Private Limited**):

By: Tanuka Ganguly

Title: Director, Site & Patient Networks

Signature: Tanuka Ganguly

Date: 26/July/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Rohan Bhise

Title: Principal Investigator

Signature: Rohan

Date: 29 - July 2019

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: Dr. M. V. Jali

Title : Medical Director

Signature:

Date: 14 Aug 2019

Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti Kickback and Anti Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD :

By: Dr. Vinod Gyanchandani

Title : Head-Clinical Operations

Signature:

Date: 22/Aug/2019

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

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	GDD EXPERTS INDIA PVT. LTD.
Payee Address	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Payee Phone and E-Mail address	Phone Number: +91 9923000560 Email ID: vgyanchandani@gddexperts.com
Bank Name	Axis Bank Ltd
Bank Account Number	910020034162231
IFSC code	UTIB0000048
GST Registration Number	27AADCG0363Q1ZA
Permanent Account Number (PAN) of Payee	AADCG0363Q
PAYMENT METHOD	Electronic Fund Transfer

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing. The Parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT TERM

IQVIA will pay the Payee **quarterly**, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Site shall be responsible 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 that relate to the Investigator, the Institution and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("**GST**") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

C. **PAYMENT DISPUTE**
Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. **MINIMUM ENROLMENT GOAL**
Site acknowledges that Site's minimum enrollment goal is 3 (three) subjects and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

E. **DISCONTINUED OR EARLY TERMINATION**
Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

F. **SCREENING FAILURE**

Reimbursement for all screen failures will be made at the amount indicated on the screening visit of the attached Budget.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

G. **UNSCHEDULED VISITS**
Payment for unscheduled visits will be reimbursed in the amount of is **Twelve Thousand Seven Hundred Fifty Nine Indian Rupees (INR 12,759)**. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the unscheduled visit.

H. **INVOICES**

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

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited
(formerly **Quintiles Research (India) Private Limited**)
Attn: Finance PSC – Accounts Payable (Investigator Payments)
Address: III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India
Phone: +91 8071317779

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number, Investigator name, Site number and Payee GST registration number. Upon receipt and verification of the invoices, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- **CONDITIONAL PROCEDURES:**

Payment for conditional procedures performed out of a visit, may be reimbursed including overhead upon receipt of original invoice. Invoice must reference date when the procedure was performed, list of procedures, and subject numbers.

Conditional Procedure	Amount/Currency
Re-consent, Informed consent performed again with the same patient	INR 1,400
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**HD204/EU-Avastin**); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**Carboplatin/Paclitaxel**); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (**Carboplatin/Paclitaxel**); each additional hour	INR 2,000
Pharmacy, Complex (**Carboplatin/Paclitaxel**) - Per Preparation; dispense drug	INR 1,693
Immunogenicity sampling - ADA/NADA - central lab	INR 350
Lab handling and/or shipping to central lab	INR 300
Haematology: Haemoglobin, white blood cell (WBC), Platelets and absolute Neutrophil count	INR 800
Blood chemistry panel: alanine aminotransferase (ALT/SGPT), Alkaline Phosphatase, total Bilirubin, Serum or Plasma creatinine, sodium, Potassium, Total calcium, BUN or Urea, Albumin	INR 1,800
Blood chemistry panel: Magnesium (Mg)	INR 600
Coagulation panel: International Normalized Ratio (INR)	INR 1,000
Coagulation panel: Thromboplastin time, partial (PTT) (aPTT);	INR 900
Urinalysis	INR 500
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	INR 900

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

Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative	INR 1,800
12 lead ECG: Includes tracing, interpretation and report	INR 1,390
Meal (Patient) - Per Meal	INR 609
Meal (Caregiver) - Per Meal	INR 609
Patient Reimbursement, Expenses, Patient Travel - Per Visit	INR 1,179
Caregiver Reimbursement, Expenses, Caregiver Travel - Per Visit	INR 1,179
Patient Reimbursement, Stipend - Per Visit	INR 2,180
Caregiver Reimbursement, Stipend - Per Visit	INR 2,180
Daily Facility Charge - Per Day, for Study Infusion Visits only	INR 2,294
Tumor Assessment (RECIST 1.1)	INR 2,106
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 20,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material; can be used for peripheral artery tomography	INR 17,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	INR 4,800
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 40,636
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 6,723
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 14,456
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 4,094
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 13,475
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 3,631
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 11,667
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 3,286

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

Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); with contrast material	INR 33,826
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); with contrast material	INR 4,191
Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); without contrast material	INR 30,610
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); without contrast material	INR 4,247
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 16,300
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14,000
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14000
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 56790
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 7578
Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 42368
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 6597
Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 51367
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 6650
Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 38147
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 5797
Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 41730

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

Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 5343
Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 46768
Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 6205
Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 53115
Interpretation and Report; Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 8023
Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 49712
Interpretation and Report; Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 8931
Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 16,800
Interpretation and Report; Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 3,400
Radiologic examination, chest; single view	INR 1000
Interpretation and Report: Radiologic examination, chest; single view	INR 490
Serious adverse events (SAE)	INR 2800

EC/IRB/IEC FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of appropriate documentation.

Start-up Fee

A one-time, non-refundable payment will be paid in the amount of Eighty Thousand Indian Rupees (INR 80,000) to cover Study start-up activities upon completion and receipt by IQVIA of all original contractual and regulatory documentation and receipt of an original invoice.

Archiving Fee

A one-time record storage payment will be paid in the amount of Fifty Thousand Indian Rupees (INR 50,000) upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site 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

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts exclude all applicable taxes.

All payments for this Study in accordance with the attached budget will be paid by IQVIA by wire transfer.

BUDGET TABLE

Visits	Amount/Currency
Screening Visit	Rs 40,104
Cycle 1	Rs 37,296
Cycle 2	Rs 38,002
Cycle 3	Rs 34,143
Cycle 4	Rs 38,359
Cycle 5	Rs 24,128
Cycle 6	Rs 27,987
Cycle 7	Rs 24,128
Cycle 8	Rs 24,128
Cycle 9	Rs 24,128
Cycle 10	Rs 26,623
Cycle 11	Rs 24,128
Cycle 12	Rs 24,128
Cycle 13	Rs 24,128
Cycle 14	Rs 26,623
Cycle 15	Rs 24,128
Cycle 16	Rs 24,128
Cycle 17	Rs 24,128
EoT	Rs 31,423
Total amount per subject	Rs 541,840
Safety Follow-Up Visit (not included in Total)	Rs 4,550
Dosing after 12 months (not included in Total)	Rs 23,426

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

ATTACHMENT B
APPROVAL LETTER

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

ATTACHMENT C
EQUIPMENT (*optional*)

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 ◐ 2019 ◐ VW 951258

जिल्हा कोषागार कार्यालय ठाणे

जिल्हा कोषागार कार्यालय, ठाणे
- 1 JAN 2020
पुढांक प्रमुख लिपीक / लिपीक

CLINICAL TRIAL AGREEMENT

This clinical study agreement ("**Agreement**") is executed as of this the **30th day of December 2019**
("**Effective Date**") by and between:

Mediclin Clinical Research a firm, a Contract Research Organization, having its office at **Fourth Floor, Ambika Industries, Penkar Pada, Opposite Thakur Mall, Mira Road (E), Thane- 401 104, India** through its authorized signatory which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the **"CRO"**).

AND

Doclin Clinical Research Services located at **445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka -590008, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the **"SMO"**)

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

जोडपत्र १

मुद्रांक विक्री नोंदवही अनुक्रमांक .... दिनांक .... 3 JAN 2020

दस्ताचा प्रकार ....

दस्त नोंदणी करणार आहेत का ? :- होय/नाही ....

मिळकतीचे थोडक्यात वर्णन .... MEDICLIN.CLINICAL.RESEARCH

मुद्रांक विकत घेणाऱ्याचे नांव व पत्ता .... 4th floor, Ambika Industries....

Penkar Pada Road,

दुसऱ्या पक्षकाराचे नांव व पत्ता .... Western Express Highway,

हस्ते असल्यास त्यांचे नांव/पत्ता .... Mira Road (East), Thane - 401 107

हस्ते सही ...... D.B.Patil ....

परवानाधारक मुद्रांक विक्रेत्याची सही [illegible]

मुद्रांक विक्रीचे पत्ता - [illegible]

परवाना क्रमांक [illegible]

- 3 JAN 2020

मुद्रांक खरेदी केल्यापासून [illegible]

479861

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. P.B. Kore Hospital & Research Center located at **Neharu Nagar Belgaum-590010, Karnataka, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**").

AND

Dr. Smitha K. S. affiliated to the institution, (hereinafter referred to as the "**Investigator**")
(Each a "Party" and collectively, the "Parties")

WHEREAS:

A. The Institution is a health care organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;

B. Investigator is interested to conduct clinical trial in the Institution under his / her guidance and supervision.

C. CRO is a clinical services offering firm. CRO will perform on behalf of **Ajanta Pharma Ltd.** (sponsor)

D. CRO desires Institution and Investigator to conduct a study entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."**

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

1. SCOPE

1.1 The Study is of mutual interest and benefit to CRO and Institution and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.

1.2 The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."**

2. CONDUCT AND PERIOD OF THE STUDY

2.1 The Investigator and the Institution shall conduct the study in accordance with the Protocol. The CRO, Investigator and Institution shall perform it in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945: Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

2.2 The Study will be initiated in the institute only after EC associated with the institute approves the study.

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

MediClin Clinical Research MUMBAI

2.3 The Institution agrees that the CRO or its designee as clinical monitor may conduct routine monitoring visit at mutually convenient times and upon reasonable advance notice to the Institution. The clinical monitor will have direct access to all records and documents pertaining to the Study to ensure that it is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement.

2.4 The Study does not involve any Biological Samples to be tested as part of it.

2.5 The Clinical Trial will be effective on the 30th day of December 2019 and continue until the study is completed at Investigational Sites. The parties agree that no patient enrolment will occur until there is IRB/IEC approval of the Protocol by all the involving investigational site.

3. OBLIGATIONS, REPRESENTATIONS & WARRANTIES OF THE PARTIES

3.1 The Institution shall ensure proper conduct of Study.

3.2 The Investigators appointed by the Institution shall be responsible for obtaining signed informed consent form from each Subject prior to the Subject's participation in the Study from the designee.

3.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a study subject to participate or to continue to participate in this Study.

3.4 The investigator shall take reasonable efforts to recruit the agreed number of Subjects on a timely basis and the Parties shall take reasonable efforts to conduct the Study in accordance with the agreed time period.

3.5 The Institution and Investigator shall not permit the use of the material (instruments provided to capture voice) for any purpose (whether directly or indirectly) other than the conduct of the Study.

3.6 To the extent permitted by law, the Institution shall immediately inform CRO of:

3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or

3.6.2 Any queries by State or Central Information Commission under Right to Information Act (amended up to date) in connection with the Study and forward promptly to the CRO copies of any correspondence from any such authority.

3.7 The Institution and the Investigator shall keep complete and accurate records of the conduct of the Study and of all data in accordance with generally accepted industry standards and practices and applicable Law. The Institution will retain the documents in a safe and secure lock-and-key facility until the study ends. After the study is over, Institution will hand-over those to the CRO.

4. FINANCIAL ARRANGEMENTS

4.1 Cost and payment terms are set forth in **Appendix-B** attached to this Agreement and incorporated by reference.

4.2 The Mediclin Clinical Research shall reimburse the Investigational Site for all direct and indirect costs incurred in connection with the Clinical Trial up to **INR.19,125/ Subject** ("Cost"). The Mediclin Clinical Research shall pay EC fees as per actual cost which is in the amount of **INR. 88500/-** and which is payable upon signing of this agreement. Mediclin Clinical Research will pay the EC fees directly to the site Ethics Committee.

4.3 The parties agree that the Cost is based upon the reasonable costs for similar studies at like institutions and Investigational Sites have not been induced to participate in

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

Mediclin Clinical Research MUMBAI

this Clinical Trial based on inducements from Mediclin Clinical Research. The parties estimate that the Cost is sufficient to support the Clinical Trial, but if certain patient care costs are expected to be covered by insurance or another third party payers and such patient care costs are denied, Sponsor on behalf of Mediclin Clinical Research agrees to reimburse the Investigator for the patient care costs not covered by insurance or third party payer which are necessary to conduct the Clinical Trial.

4.4 The Mediclin Clinical Research will not be liable for any payment in excess of the Cost except upon Investigator's written agreement.

4.5 Mediclin Clinical Research in turn will make the payment in accordance with the Payment Schedule to the Investigator as attached in **Appendix-B** incorporated herein.

4.6 Mediclin Clinical Research will pay amount to investigator by Cheque/ NEFT/ RTGS, as per terms and conditions applied.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective date and will continue for a period of 5 years from the Effective Date or upon completion of the Study, whichever is earlier. 'Effective Date' means the date when this Agreement becomes effective which shall be the date of last signature hereto by the Parties.

5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by CRO to the Institution or any other person under this agreement.

5.3 CRO may terminate this Agreement upon thirty (30) days prior written notice to the Institution or such shorter notice period as required by a Regulatory Authority, for any reason whatsoever.

5.4 Without limiting the generality of the foregoing, CRO may terminate this Agreement:

- 5.4.1 if the Institution is not performing the Study as required in the protocol;
- 5.4.2 in case of failure of the Institution to provide access to CRO representatives /Clinical monitor /Auditors all original medical records necessary to verify entries on study case report forms;
- 5.4.3 in case of an unauthorized replacement of Investigator;
- 5.4.4 if CRO determines that business or scientific considerations require termination of this Agreement (either full or in part);
- 5.4.5 if any malpractices adopted either by the Investigator or Institution or both.

5.5 Within Thirty days after the termination of this Agreement, the Investigator shall deliver to CRO completed CRF pages.

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the CRO and its respective directors, officers, employees and agents (the "Indemnities") and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a

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

Mediclin Clinical Research MUMBAI

third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or wilful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;

6.1.2 Arising out of errors or omissions by Institution;

6.1.3 Arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of CRO concerning the Clinical Study; or

6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.

6.2 To the maximum extent permitted by applicable laws, CRO agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting out of (i) the breach of any of CRO representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the device used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.3 Each Party shall use reasonable efforts to inform the other Party promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Party reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 6. The Parties further agree that they have a right to retain their own counsel to conduct a full defence of any such claim or proceeding.

6.4 The Institution and CRO shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.

6.5 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party (ies). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), informed consent form, subject cards, 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 CRO or CRO's Affiliates that are: (1) provided to the Institution in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

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

MediClin Clinical Research MUMBAI

7.1 Confidential Information and all tangible expressions, in any media, of CRO are the sole property of CRO. Each party shall endeavour to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution agrees to treat CRO's Confidential Information as it would be its own proprietary and confidential information. Institution will only accept information from CRO which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Institution will make sure that it and Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose CRO's Confidential Information to any third party. Institution agrees not to disclose CRO's Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. The parties understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. INTELLECTUAL PROPERTY RIGHTS

8.1 All Intellectual Property Rights owned by or licensed to CRO prior to and after the date of this Agreement are and shall remain the exclusive property of CRO.

8.2 All Intellectual Property Rights owned by or licensed to the Institution prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical study, are and shall remain the exclusive property of the Institution.

8.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Studies, the Investigational drugs, mobile application or the Protocols (the "Clinical Trial Intellectual Property") shall be the exclusive property of CRO/Sponsor and for this purpose, the Institution hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to CRO (or its nominate designee), all their rights and title in and to the Study tool throughout the world on perpetual basis. The Institution shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at CRO's expense, do all such other acts as CRO may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in CRO or its nominate designee.

8.4 The Institution shall promptly disclose to CRO any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

9. MISCELLANEOUS

9.1 All notices required to be given by one Party to the other shall be deemed to have

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

MediClin Clinical Research MUMBAI

been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.

9.2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

9.3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

9.4 The Institution will be responsible for payment to its employee study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the Investigators, study team members or employees or agents may be entitled to receive for performing services. Institution will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions, benefits, dues etc. that may be payable to its employees and/or agents.

9.5 This Agreement constitutes the entire Agreement between the Parties and supersedes all prior oral and written understandings between the Parties on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties.

9.6 The Parties hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.

9.7 Institution will not assign this Agreement without the prior written consent of CRO. CRO may assign any or all of its rights and obligations under this Agreement at any time, provided that CRO ensures the assignee is bound by the terms hereof.

9.8 Institution shall not subcontract the whole or any part of the performance of the clinical Studies without the prior written consent of CRO. This Agreement ensures to the benefit of and binds the Parties and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.

9.9 This Agreement and the obligations of the Parties shall be governed by and construed in accordance with the laws of India. The Parties agree to submit to the exclusive jurisdiction of courts at Pune in connection with this Agreement.

9.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

MediClin Clinical Research MUMBAI

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

9.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

10. INTERPRETATION

10.1 Unless the context requires otherwise:

10.1.1 References to this Agreement are to this Agreement as it is from time to time amended;

10.1.2 Headings are for convenience only and shall not affect interpretation;

10.1.3 References to the singular include the plural and vice versa, and references to one gender include all genders;

10.1.4 Any phrase introduced by the expressions "including", "include" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

10.1.5 Reference to any law: shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

10.1.6 References to "writing" or "written" include any modes of reproducing words in a legible and non-transitory form but do not include writing on the screen of a visual display unit or other similar device;

10.1.7 References to a numbered clause are references to the clause of or to this Agreement so numbered.

10.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favouring or disfavouring any party by virtue of the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

BY CRO **Name:** Dr. Ravindra Mote **Designation:** Director **Signature with Stamp:** **Date:** 30 DEC 2019
BY SMO **Name:** Mr. Maruti Patil **Designation:** Managing Director **Signature with Stamp:** **Date:** 21 JAN 2020

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

MediClin Clinical Research MUMBAI

BY INVESTIGATOR **Name:** Dr. Smitha K. S. **Designation:** Principal Investigator **Signature with Stamp:** **Date:** 21 JAN 2020
BY INSTITUTION **Name of Hospital:** KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India **Name:** M.V. Jali **Designation:** MD and CEO **Signature with Stamp:** **Date:** 05 Feb 2020

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

MediClin Clinical Research MUMBAI

APPENDIX- A

Study Name	A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.
Protocol ID	APL/CT/18/03
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India
Name of Investigator	Dr. Smitha K. S.

Instruction for Payment Payee Details	
Payee Name	Doclin Clinical Research Services
PAN No	AZXPP8818R
GST No	29AZXPP8818R1ZP
Bank Account Number	919020049795418
Bank Name	Axis Bank
Bank Swift Code / IFSC Code	CHASUS33/UTIB0001690
Bank Branch Address	Nehru Nagar, Ratna Plaza, Cts. No. 10593 A& B, Kolhapur Circle, Belgaum 590010

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

MediClin Clinical Research MUMBAI

APPENDIX-B

Given below is the suggested financial break-up of total trial grant allocated to each center. You are requested to go through the same & revert as soon as possible regarding approval of this budget, following which the final financial agreement will be sent for your signature.

Payment Head	Amount (INR)
Total amount	INR. 19125/Subject.

Protocol ID: APL/CT/18/03		
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010. Karnataka, India	
Investigator Name	Dr. Smitha K. S.	
Target of enrolment of subject		25
Note: This is a competitive recruitment trial having 210 subjects.		
Visit Description (Per Patient/ Visit)		
Visit Details	**Day wise Visit**	**Cost (INR)**
Screening (V1)	Day -3	2,000/-
Baseline/ Randomization (V2)	Day 0	1,500/-
Visit 3 (V3)	Day 14 ± 2 days	2,000/-
Visit 4 (V4)	Day 28 ± 2 days	1,500/-
Visit 5 (V5)	Day 56 ± 2 days	2,000/-
Visit 6 (V6)	Day 84 ± 2 days	2,000/-
Screening to End of Treatment Total		**11000/-**
Laboratory Investigations and ECG (at Visit-1 and Visit-6) Inclusive of all		3,500/-
IOH @ 25%		3,625/-
Subject travel reimbursement		1000/-
Grand Total		**19125/-**
Note: 1. Maximum cost per subject should not be more than INR.19125/-.		

EC fees as per actual.
After monitoring visit, Monitor will assure the subject data as per regulatory requirements and will release the payments within 15 working days.

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

MediClin Clinical Research MUMBAI

600

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. Jyothi Hattitholi, Consultant Chest Physician* **("Principal Investigator")** at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010 Karnatka 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 the COPD; and is associated with the Institution in her capacity as *Consultant Chest*

WHEREAS, the INSTITUTION is a Private Multispecialty Hospital

WHEREAS, the SMO is engaged in management of the trial at the Institute ad assisting the Principal Investigator; and;

WHEREAS, SPONSOR is engaged in the research and development of human pharmaceutical products;

WHEREAS,SPONSOR is the Sponsor of the clinical study CLR 18 09 Titled **Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative 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 Chronic Obstructive Pulmonary Disease 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 CLR_18_09, titled a "Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative 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").

For Thane Bharat Sahakari Bank Ltd.
Branch Thane
Authorised Signatory

Thane Bharat Sahakari Bank Ltd.
Main Branch, Naupada, Thane.
D-5/STP(V)/C.R. 1055/1/04/1905-07/04

भारत 69126 INDIA
Special Adhesive
FEB 03 2020 15:30
135209
Rs. 0000600/- PB5151
STAMP DUTY
महाराष्ट्र MAHARASHTRA

ATTESTED

SIRO CLINPHARM PVT. LTD. THANE 400 604

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

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 will be followed. Any party who becomes aware of the need for a 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 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 and SMO**

2.1. 2.1 The Principal Investigator and SMO 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 and SMO will also be responsible for the direction of the Clinical Study in accordance with any applicable Institution policies. The Principal Investigator and SMO shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator, SMO or the INSTITUTION 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) working days of the Effective Date of this Agreement. In the absence of any such intimation by the Principal Investigator, SMO or the INSTITUTION, the terms of the Protocol and this Agreement shall prevail The Principal Investigator and SMO 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 about June 2020,and that the Clinical Study will be completed on or about December 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 Dec 2020, the Principal Investigator and / or SMO 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 enrollment of a maximum of **07**subjects (provided there may be an increase in enrollment upon SIRO request) meeting all Protocol eligibility requirements ("Subjects"). SIRO shall not be obligated to pay any sums for tests performed on subjects who do

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

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 (parent and/or legal guardian of the infant) 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 International Councilon Harmonisation ("ICH") 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 ICH-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 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. Representations And Warranties

5.1. **No Inconsistent Obligations or Constraints**. Institution and Principal Investigator each represents and warrants that it is qualified and permitted to enter into this Agreement and that the terms of this Agreement are not inconsistent with its other contractual arrangements. Institution and Principal Investigator each warrants that it is not constrained by any existing agreement in performing its obligations under this Agreement.

5.2. **Legal and Binding Agreement.** Institution and Principal Investigator each represents and warrants that this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms.

5.3. **No Impairment; No Conflict.** During the term of this Agreement, Institution and Principal Investigator each warrants that it shall not enter into any agreement to provide services which would in any way (a) materially impair his, her or its ability to complete participation in the Study or (b) constitute a conflict of interest with Sponsor's development of Study Product.

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

5.4. **No Pending Litigation; No Action by FDA.** Institution and Principal Investigator each represents and warrants that (a) it is not currently involved in any litigation, and is unaware of any pending litigation proceedings, relating to Institution's and/or Principal Investigator's role in the conduct of a clinical trial for any third party; and (b) it has not received any warnings from the FDA or other Regulatory Authority relating to services it has provided to third parties during the conduct of a clinical trial.

6. Insurance Coverage

6.1. 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 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.

6.2. INSTITUTION, SMO 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.

7. Ethics Committee Approval

7.1. The Study will only be started, when full written approval of/ favorable opinion on the Protocol has been obtained from the concerned local or regional Ethics Committees (EC) / 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.

8. Study Management

8.1. Case Report Form Handling. The Principal Investigator and/ or SMO shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

8.1.1. 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.

8.1.2. 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.

8.1.3. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator and/ or SMO shall

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

ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to SIRO/SPONSOR.

8.1.4 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.

8.1.5 If CRFs are not complete the Principal Investigator and/ or SMO shall be obliged to complete them on request of SIRO/SPONSOR.

8.2. Source Data. The Principal Investigator and/ or SMO 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. x rays, ECG tracings).
- 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.

8.3. **Investigator Study File and Archiving.** The INVESTIGATOR and/ or SMO shall prepare and maintain complete and accurate study documentation in compliance with ICH-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:

- 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.
- Patient insurance certificate.
- CRFs (investigator's copy).
- Data correction forms (copies).
- 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.

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

- 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.

8.4. **Documentation and Material (Supplies).** All supplies provided to the Principal Investigator and/ or SMO 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 the identification and quantity of each unit of study medication, the method of destruction, and the person in charge must be documented.

8.5. **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:

- 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.

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

Study protocol, patient information leaflet/consent forms, CRF and trial report as well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at SIRO.

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 a contract organization selected by SPONSOR.

For monitoring visits and in case of audits and inspections by authorities the Principal Investigator and/ or SMO 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.

8.6. **Confidentiality of Patient Records.** The INSTITUTION, SMO and the Principal Investigator 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 and SMO 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 and SMO 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.

8.7. Principal Investigator and SMO agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose SIRO and Sponsor Confidential Information to any third party. Institution and Principal Investigator agrees not to disclose SIRO and Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Principal Investigator shall safeguard SIRO and Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to EC is "Confidential and Privileged"

8.8. The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations under this Section shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

9. **Budget**

SIRO CLINPHARM PVT. LTD. THANE 400 604

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

Cost and payment terms with all the Payee details(along with the GSTIN of all the Parties) 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 payments payable by SIRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. GST will be paid, if applicable, on generation of valid invoice showing the amount of GST to be charged before any payment is made under this Agreement.

All invoices should have GSTIN (Goods and Service Tax Identification Number) along with HSN code for services as mandated by GST provisions. This is mandatory to ensure compliance with GST.

In case the site defaults in making timely GST payments then SIRO shall retain 18% of each payment of the contract price payable to the Institution for a period of 45 days from the release of payment. However, such retention shall not be applicable in case the Institution discharges the applicable GST and files the GST Returns in relation to such payments, and the same is being reflected in SIRO's Returns.

In case of any non-compliance of any provisions under the GST Legislations by Institution, such Institution alone shall be liable to compensate SIRO for any losses arising to SIRO due to such non-compliances as well as shall also be liable to pay interest and/or penalty imposed by the Statutory Authorities and/or other legal fee or expenses incurred by the SIRO in this regard.

10. Data and Information

10.1. **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 SMO 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 by SIRO or SPONSOR ("Information"). The obligation of non-disclosure shall not apply to the following:

10.1.1. Information at or after such time that it is or becomes publicly available through no fault of the Principal Investigator; and/ or SMO;

10.1.2. Information that is already independently known to the Principal Investigator and/ or SMO as evidenced by their prior written records;

10.1.3. Information at or after such time that it is disclosed to the Principal Investigator and/ or SMO on a non-confidential basis by a third party with the legal right to do so;

10.1.4. Information developed by the Principal Investigator and/ or SMO without the use of SIRO's or SPONSOR's Information as evidenced by their written records; or

10.1.5. Information required to be disclosed by law.

10.2. **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

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

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.

10.3. **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 and SMO 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.

10.4. **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 and SMO 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, SMO 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.

10.5. **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.

11. Drug Safety

11.1. 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.

11.2. 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 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.

11.3. The Principal Investigator must immediately report all serious adverse events (as defined in protocol)(within 24 hrs 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 following addressee given below. The SAE Report form will be used for documentation and reporting.

SIRO CLINPHARM P... THANE 400 6...

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

Licensing authority: All SAE forms are to be e-mailed or faxed at Email ID: dci@nb.nic.in and Fax no :011-23236973

Sponsor: All Initial and follow up SAE reports are to be sent on the following email ID: CT.SAE@sunpharma.com and Mahesh.kumbhar@sunpharma.com and clinical.safety@sparcmail.com /of the Sponsor

Ethics Committee: All Initial and follow up SAE reports are to be sent viae- mail – kleclinicalresearch@gmail.com

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.

- **Licensing authority:** For all SAEs as hard copy via courier at DCGI address

The Drugs Controller General (India)
CDSCO Extn Office , *3rd Floor, CGHS Dispensary Sector-3* *Sadiq Nagar, New-Delhi-110049* *Fax: 011-23236973*

- Chairman of Ethics Committee: For all SAEs as hard copy via courier at
  Dr Subarna Roy- Chairman
  Institutional Ethics Committee, KAHER
  JNMC Campus Nehrunagar Belagavi-590010 Karnataka India
  Email: kleclinicalresearch@gmail.com
- Head of the Institution: For all SAEs as hard copy via courier
  Dr. M.V.Jali – MD & CEO
  KLES Dr Prabhakar Kore Hospital & Medical Research Centre
  Nehrunagar Belagavi-590010 Karnataka India
  medicaldirector@klehospital.org

11.4. 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 SIRO shall be informed by telephone and followed immediately by fax but not later than within 24 hours of occurrence of SAE.

11.5. SIRO undertakes to notify the Principal Investigator of all Suspected Unexpected Serious Adverse Reactions (SUSARs), which occur during the course of the Study in any other location and Periodic SAE listings, which are reported by SPONSOR to health authorities, at an interval of every 3 months. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, SUSARs, Periodic SAE listings and of 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.

11.6. SIRO will be responsible to notify on time the health authorities in 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

12. **Study Drug and Study Materials**

12.1. **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.

12.2. **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.

13. **Publications**

13.1. The Principal Investigator 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.

13.2. Any publication or disclosure by the Principal Investigator, SMO and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

14. **Use of Name and Advertising**

14.1. **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.

14.2. **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

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

advertisement to SIRO / SPONSOR for prior approval. In addition, Principal Investigator will obtain Institutional Review 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).

14.3. Any use of name and advertising or disclosure by the Principal Investigator and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

15. Intellectual Property Rights

15.1. All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor.

15.2. All Intellectual Property Rights owned by or licensed to the Institution or the Principal Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Principal Investigator, as applicable.

15.3. All Intellectual Property Rights owned by or licensed to SIRO prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of SIRO, as applicable.

15.4. All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial, the Investigational drug or the Protocol (the "Clinical Trial Intellectual Property") shall be the exclusive property of Sponsor and for this purpose, the Institution and the Principal Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis. The Institution and the Principal Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

15.5. The Institution, SMO and the Principal Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

16. Compliance with Law; Financial

16.1. The Principal Investigator and the INSTITUTION shall perform the Clinical Study in compliance with generally accepted standards of Good Clinical Practice as defined in U.S. Code of Federal Regulations, 21 C.F.R., the Protocol, instructions provided by SIRO and all applicable

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

local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the International Conference on Harmonization ("ICH") Tripartite Guideline for Good Clinical Practice ("GCP"), the Indian Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Rules, 1945 and any Rules and amendments thereunder, the CDSCO-GCP,. The Principal Investigator shall provide SIRO with sufficient accurate financial information to allow SIRO to submit complete and accurate certification or disclosure statements as required under U.S. Code of Federal Regulations, 21 C.F.R. 54.The Principal Investigator shall also promptly update this information if any relevant changes occur during the course of the Clinical Study and for one year following the completion of the Clinical Study. 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 and by agencies such as the FDA.

17. Debarment

17.1. The Principal Investigator certifies that neither the Principal Investigator nor any person employed by the Principal Investigator or any 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.

18. Indemnification

18.1. To the maximum extent permitted by applicable laws, SPONSOR warrants that they shall defend, indemnify and hold harmless SIRO, PRINCIPAL INVESTIGATOR, INSTITUTION, SMO 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 use of the Clinical Study Drug during the course of the Clinical Study in accordance with the Study Protocol.

18.2. The indemnity granted in this Article 18.1 shall not apply in the event when such liability, damage, loss, or expense was caused by the failure of an Indemnitee to:

18.2.1. adhere materially to the terms of the Protocol;

18.2.2. comply with government regulations or requirements; or

18.2.3. conduct the Clinical Trial in accordance with generally accepted medical standards including avoidance of negligence and willful misconduct; or

18.2.4. carryout its obligation without any error or omission.

18.2.5. the reason of loss/ damage is not directly and solely attributable to the SPONSOR.

18.3. SIRO warrants that it shall indemnify, defend and hold harmless SPONSOR, INSTITUTION, SMO and Principal Investigator, including their agents and employees (the "Indemnitees of SIRO") from

SIRO CLINPHAR THA 400

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

any and all liabilities, claims, actions or suits for personal injury or death directly arising out of (i) 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; (ii) breach of confidentiality; (iii) non-compliance with the applicable laws; (iv) .

18.4. The indemnity granted in Article 18 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.

18.5. Each party warrants that it shall provide a 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.

18.6. The Principal Investigator/ INSTITUTION/ SMO shall promptly notify SIRO and SPONSOR of any claim for which indemnity may be sought. The Principal Investigator /SMO/ INSTITUTION 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.

18.7. 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.

18.8. The 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.

18.9. The 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 INSTITUTION in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

ii. Principal Investigator's and/or INSTITUTION's violation of any and all applicable Central, State or Local laws rules and regulations of 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

iii. Principal Investigator's and/or INSTITUTION's breach or default in performance of its obligations in connection with a Study;

iv. Principal Investigator's and/or INSTITUTION'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 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 Principal Investigator and INSITUTION above includes reference to its agents and employees.

19. **Independent Contractor**

19.1. The parties to this Agreement hereby agree that the Principal Investigator and Institution are independent contractors hereunder and are not employees or agents of the SPONSOR or SIRO. The Principal Investigator 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.

20. **Termination**

20.1. This Agreement may be terminated:

20.1.1. by the Principal Investigator upon thirty (30) days' prior written notice;

20.1.2. by SIRO on behalf of SPONSOR immediately upon thirty (30) days written notice;

20.1.3. by SIRO immediately if the Principal Investigator is unable to continue to serve and a successor acceptable to SIRO is not available; or

20.1.4. upon the occurrence of an event qualifying as a termination event as described in the Protocol

20.2. 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:

20.2.1. all services properly rendered and monies properly expended by the Principal Investigator and/ or SMO prior to the date of termination and not yet paid for; and

20.2.2. reasonable non-cancelable obligations properly incurred for the Clinical Study by the Principal Investigator prior to the effective date of termination.

SIRO CLINPHARM PVT. LTD. THANE 400 604

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

20.3. The Principal Investigator and/ or SMO 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.

20.4. 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.

20.5. 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 4.2,8.2,9, 10, 12.2 and 18 survive the termination or expiration of this Agreement.

21. Miscellaneous

21.1. **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.

21.2. 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.

21.3. Subject to 21.2 above the courts of Mumbai will have exclusive jurisdiction to try and entertain any dispute arising out of this Agreement.

21.4. The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.

21.5. **Amendments.** This Agreement may only be amended by the mutual written consent of the parties hereto.

21.6. **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.

21.7. **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.

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

21.8. **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.

21.9. **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.

21.10. **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. Jyothi Hattitholi
Consultant Chest Physician
KLES Dr Prabhakar Kore Hospital & MRC
Nehrunagar Belagavi-590010 Karnataka India

If to INSTITUTION:

Dr. M.V. Jali
Medical Director & CEO
KLES Dr Prabhakar Kore Hospital & MRCNehrunagar Belagavi-590010 Karnataka India

If to SIRO:

Dr Ganesh Divekar
Head, Clinical Research & Medical Services
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

With a Copy to:

Maruti Patil
Managing Director
Doclin Clinical Research Services
445, Maruti Galli, Main Road, Hangarge, Mandoli,Belagavi –Karnataka India 590008

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in Quadripartite by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

Signature: 04 Feb 2020

Name:Dr Ganesh Divekar

Designation: Head Clinical Research & Medical Services

INSTITUTION

Signature:

Name: Dr M V. Jali

Designation: MD & CEO

SIRO CLINPHARM PVT. LTD. THANE 400 604

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

Date: 04 Feb 2020

Date: 25 Feb 2020

PRINCIPAL INVESTIGATOR

Signature:

Name: Dr Jyothi Hattiholi

Designation: Principal Investigator

Date: 12 Feb 2020

SMO(Doclin Clinical Research Services)

Signature:

Name: Maruti Patil

Designation: Managing Director

Date: 12 feb 2020

EXHIBIT A: PROTOCOL

As annexure 1

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

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : *Dr. Jyothi Hattitholi*

Site Address :KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi- 590010 Karnatka India

PAYMENT SCHEDULE

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

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
INR 62,220 per patient.	Includes the following • PI and site team payment including Co- Investigator (s), Site coordinator(s) • Local lab cost, Study related tests • **Hospitalization cost (on basis of actual number of days of hospitalization per subject)** • Institutional overhead 25% • Patient travel reimbursement as approved by the EC.

Budget Bifurcation

Visits	PI & CRC fees per Visit (INR)	IOH 25% (INR)	Lab + test charges (INR)	Hospitalization (per actual No of days)	Patient travel reimbursement (INR)	Total Paymen Per Complete Patient (INR)
Screening / Placebo Run-in	6000	1500	5310	NA	NA	12,810
Period 1	6000	1500	NA	7000	500	15,000
Period 2	6000	1500	NA	7000	500	15,000
Period 3	6000	1500	4410	7000	500	19,410
Total	24,000	6,000	9,720	21,000	1500	62,220

SIRO CLINPHARM PVT. LTD. THANE 400 604

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

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 advance payment is as follows:

1] Study Study start up cost (**Advance**/ pre payment) INR. 50,000/-
The advance payment (pre payment) provided to the PI **will be adjusted against first two invoices** raised by PI as per the PI grant.

The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.

2] CRO will pay only INR5000/- for 1 screen fail subject per site. 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).

3] Archival fees: CRO shall pay INR 90,000 per year towards archival of study documents for 15 years from time of site close out.

4] IP Management fees of 30,000 per year

Payee Details

Payee Name (or institution)	Doclin Clinical Research Services
Payee Address	445,Maruti Galli, Main Road, Hangarge. Mandoli, Belagavi Karnataka,590008
Bank Name and Address	Axis Bank -Nehru Nagar, Ratna Plaza, Cts. No. 10593 A& B, Kolhapur Circle, Belgaum 590010
Cheque/Draft (in favor of)	Doclin Clinical Research Services
Account Number	919020049795418
PAN Card Number	AZXPP8818R

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

GST Number	29AZXPP8818R1ZP
IFSC Code	UTIB0001690
Contact person for payments	Mr Maruti Patil

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator / SMO 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 fourty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:

Send invoices to: Siro Clinpharm Pvt Ltd Contact Person: Study PM

Address : Siro Clinpharm Pvt Ltd
Kalpataru prime,
1st floor, Units 3 and 4, Plot D3, Road 16
Wagle industrial estate, Thane west 400604

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

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 manager, and all data queries for Institution have been resolved satisfactorily.

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

1. All amounts above are in Indian Rupee (INR).
2. Lab Investigations: The study requires lab examination at specific visits. The local lab investigation charges if any will be reimbursed on actual, as per invoices.
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 total amount for one randomized patient only i.e. INR. 12424/- 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. A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the site in the budget.
7. A GST (as applicable) will be considered on total grant subject to availability of GST registration number with service provider. GST will be paid and applicable to service provider, provided the GST registration number is reflected 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.

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