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

MEMORANDUM OF UNDERSTANDING

DATED THIS ____ DAY OF ____, 2017

BETWEEN

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI

AND

ROTARY CLUB OF BELGAUM, BELAGAVI (ROTARY DISTRICT 3170)

AND

NATIONAL BURNS CENTRE (NBC) & ROTARY CLUB OF BOMBAY NORTH (RCBN)

THIS MEMORANDUM OF UNDERSTANDING is made and confirmed into at Belagavi on this _____day of_____ 2017.

BETWEEN

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavihaving their office Nehru Nagar, Belagavi, represented by their duly authorised representative, Medical Director & Chief Executive, (hereinafter referred to as "KLESH");

AND

Rotary Club of Belgaum, Belagavi, (Rotary District 3170) an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCB")

AND

(i) **National Burns Centre** a public charitable society registered under the Bombay Trusts Act, and having their office at National Burns Centre, Sector 13, Plot No.1, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai- 400708 represented by their duly authorised representative, Dr. Sunil Keswani, (hereinafter referred to as "NBC"); and (ii) **Rotary Club of Bombay North,** an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCBN") which together operate the RCBN Skin Bank as an unregistered association (hereinafter referred to as "RN") (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include the members of the Governing Council / Board of RN, their successors or successor the survivors or survivor of them and the heirs, executors and administrators of the last surviving member and his / her / assigns) of the First Part;

NATIONAL BURNS CENTRE

Medical Director & Chief Executive
KLE
Me Hospital
AGA

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

KLESH, RCB and RN are hereinafter collectively called the 'Parties",

AND WHEREAS KLESH has a 11 Bedded Burns Care facility serving over 100 Burns victims annually and has the necessary infrastructure and expertise in treating victims of Burns.

AND WHEREAS the RCB is a charitable organization bringing together business and professional leaders to provide philanthropic and humanitarian service, encourage high ethical standards in all vocations and help build goodwill and peace and is a part of the Rotary International.

WHEREAS RCBN has set up a skin bank known as RCBN Skin Bank at NBC situated at Plot No 1, Sector 13, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai 400 708 in collaboration and with the guidance of Euro Skin Bank for promoting and spreading awareness of skin donation and is in the process of setting up skin banks in various places in India.

AND WHEREAS the RCB desires to set the Skin Bank/Skin Collection Centre through KLESH as part of its Community Service Project (CSP) and desires to participate in the Project.

AND WHEREAS KLES Hospital with the objective to reduce the intensity of suffering and the number of deaths due to burns, intends to participate in setting up of a skin bank within the city of Belagavi with the assistance from RCBN and NBC, in the space provided by KLESH within the KLES Dr. Prabhakar Kore Hospital premises. The purpose of such a skin bank/ skin collection centre as a part of "the Project" shall be harvesting of cadaver skin on call, processing, preservation of the skin and dispensing the skin to the burn victims being treated within, nearby Hospitals and elsewhere at a reasonable cost without any discrimination to any group, caste, colour, creed or place and to make available this service to the public at large as a HUMANITARIAN SERVICE.

AND WHEREAS the Parties have willingly agreed to participate in the collective Project and provide all resources and assistance to establish a skin bank to make it a success.

NOW THIS MEMORANDUM OF UNDERSTANDING WITNESSETH AND IT IS HEREBY AGREED AND UNDERSTOOD BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

1. The Project shall be implemented in accordance with the technical guidance from NBC/RCBN Skin Bank and the funds of $ 31500 for the implementation of the Project will be provided by RCB &through The Rotary Foundation. The project will be implemented as Global grant project no. 1746862 registered with Rotary Foundation and after the necessary sanction and disbursal of funds from the Rotary Foundation.
2. The Skin Bank/ Skin Collection Centre shall have the plaque in the following format

KLE ROTARY SKIN BANK/ SKIN COLLECTION CENTRE
in technical collaboration with RCBN Skin Bank and NBC
financed by Rotary Club of Belgaum under the Global Grants of the Rotary Foundation

3. The Parties have agreed to cooperate with each other in collectively executing the Project and to achieve the objectives of the Project and for this purpose the Parties shall constitute a joint committee comprising of three nominees of KLESH, one nominee of NBC and three nominees of RCB (hereinafter called the "**Supervising Committee**"). The Supervising Committee shall be responsible for taking all decisions relating to the Project. The Supervising Committee meetings should be conducted as and when required, but at least once every month to review the progress of the Project and to take necessary steps for the smooth establishment and functioning of a Skin Bank and reports of all aspects of its activities shall be recorded in the minutes of such meetings and provided to the Parties.

NATIONAL BURNS CENTRE

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Research Centre BELAGAVI

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4. The Supervising Committee will supervise the setting up of the Skin Bank /Skin Collection Centre and monitor the functioning of Skin bank/Skin Collection Centre thereafter, in consultation with and under the supervision and guidance of RN.

5. The roles and responsibilities of the parties to this MOU are defined as follows:

5.1. KLESH: HOST

5.1.1. KLESHshall be responsible to maintain and operate a state of the art Skin Bank /Skin Collection Centre as per international guidelines with guidance from NBC/RCBN Skin Bank and maintain adequate records and report statistics of Beneficiaries periodically to RCB and RCBN.

5.1.2. KLESH shall provide and maintain a dedicated air-conditioned clean room space of about 1000 square feet with adequate lighting, furniture and partitions within KLES Hospital Premises.

5.1.3. KLESH shall procure all necessary clearances, approvals and/or permissions from the local, municipal, civil, government departments such as Tissue Bank License for the purpose of legitimate execution and functioning of Skin Bank/Skin Collection Centre.

5.1.4. KLESH shall maintain the dedicated skin harvest vehicle provided by RCB and will ensure that it shall be available 24 hours a day and for 365 days and provide alternative vehicle in case of its break down.

5.1.5. KLESH shall be responsible for recruitment, training and monitoring of dedicated human resources required for harvesting, processing, preservation, dispensing the cadaver skin and also the remuneration payable to the human resources including their salaries, fees, ESI, Provident Fund Contribution, Gratuity and all other statutory dues. The staff appointed shall be of KLESH only and they shall not have any relation or privity of contract with RCB/RCBN/NB.

5.1.6. KLESH shall ensure uninterrupted supply of all essential consumables, electricity, water, gas, telephone and anything else that may be required for the smooth functioning of Skin Bank.

5.1.7. KLESH will provide all their expertise and assistance to RCB in procuring all the necessary equipment as well as consumables.

5.1.8. KLESH shall maintain and keep all equipment provided by RCB for the Project in good working condition and shall enter into AMC contracts by paying charges for the maintenance of the equipment at the Skin Bank.

5.1.9. KLESH surplus to be reinvested for maintenance shall reinstate any equipment owned and provided by RCB for the Skin Bank after the expiry of its useful life or break down after its warranty period.

5.1.10. KLESH shall maintain a daily log record book and registries wherein, it shall record the calls for donation, requests, registered volunteers, details of skin donations, size of skin harvested, size of skin in store, details of beneficiaries in such format and periodically as may be mutually agreed amongst the Parties. Upon request, one copy of this shall be sent to RCB and the Donor every month for their records.

NATIONAL BURNS CENTRE

Medical Director & Chief Executive
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Belagavi-590 010,Karnataka

5.1.11. KLESH shall dispense skin from its Skin Collection Center at a very nominal fee on Non-Profit basis to make it affordable to all segments of public. KLES Rotary Skin Bank shall set up a separate Bank Account to secure the funds raised from dispensing of skin and donations received towards the Project. Such funds shall be exclusively used towards up keeping, expansion and promoting the benefits of the Skin Bank.

5.1.12. KLESH shall designate a Faculty member of Department of Plastic Surgery, as an In-Charge of the Skin Bank to ensure the smooth functioning of Skin Bankat any given point in time.

5.1.13. KLESHshall manage day to day activities of the centre.

5.1.14. KLESH along with RCB shall be responsible for creating awareness and creating publicity for the Skin Bank and the importance of skin donation in consultation with RCBN Skin Bank.

5.1.15. All the responsibilities of KLES Rotary Skin Bank under this MOU shall be at the expense of KLES Rotary Skin Bank Account.

5.2. RCB : ROTARY COMMUNITY SERVICE

5.2.1. RCB shall procure and deliver the Capital equipment and instruments as required for a full-fledged Skin Bank (hereinafter referred to as the "said equipment" and more particularly listed in Schedule 1 hereto). RCB shall take into account the recommendations made by KLES & NBC RN in respect of the equipment to be procured.

5.2.2. RCB shall be responsible for the Installation of the said equipment as prescribed by NBC and RCBN Skin bank from time to time.

5.2.3. RCB shall provide a dedicated skin harvest vehicle spacious enough to harvest skin from cadaver on board and shall ensure that at all times the Skin Harvest Vehicle has the necessary capital instrumentation.

5.2.4. RCB shall be entitled to monitor the functioning of the Skin Bank and check the records, reports, impact on beneficiaries as well as the maintenance of the said equipment.

5.2.5. RCB shall support KLESH in creating public awareness about skin donation and promoting the usage of cadaver skin in burn care in the region using its Rotary Network.

5.3. RCBN & NBC: GUIDE

5.3.1. RN shall provide all the necessary guidance required during the establishment of the Skin Bank.

5.3.2. RCBN Skin Bank shall provide Standard Operating Procedures (SOPs) and Protocols to be adhered to by the Skin Bank as per International Guidelines.

5.3.3. RN shall train the human resources recruited and designated by KLESH to operate the Skin Bank.

NATIONAL BURNS CENTRE

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI

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

(5)

5.3.4. RN shall conduct periodic audits of the Skin Bank twice a year for the first two years and carry out an annual audit thereafter every year. The result of the audits shall be conveyed in a timely manner to the other parties. The expenses on local hospitality for the auditing will be provided by the skin bank. Travelling expenses will be borne by the auditing organization RN.

5.3.5. RN shall conduct yearly meetings with the entire Skin Harvesting Team and the Supervising Committee of the Skin Bank and give necessary technical assistance and guidance and share the experiences and research in skin harvesting, processing and storage with them. In the first year RN shall conduct meetings twice a year to Iron out teething problems.

5.3.6. RN shall be entitled to provide all the details in respect of the Skin Bank including contact details of members of KLESH and RCB involved with the Project on its website along with direct links to the websites of the Skin Bank, RCB and RCBN.

5.3.7. The Skin Bank/ Skin Collection Centre shall provide periodic reports every 3 months to RN in agreed formats.

6. KLESH shall be solely responsible for obtaining all statutory permissions and consents as may be required for harvesting of cadaver skin and neither NBC nor RCBN shall be held responsible for any non-compliance by KLESH in respect of obtaining permission and consent.

7. KLESH & RCB shall have the right to nominate the person who will inaugurate the Skin Bank on the inauguration date.

8. KLESHshall have the right but not an obligation to monitor and supervise the operations of the Skin Bank and also collect data and reports of the patients and other hospitals who receive support from the Skin Bank every quarter.

9. KLESH, RCB and RN shall organize a press meet to promote the importance of skin donation and creating a Skin Bank. All Parties will make all efforts to promote the message of skin donation. KLESH &RCB will have a complete right to carry out their PR activity before, during and after the inauguration of the Skin Bank. Any public announcement with regard to the Project, contents or subject matter of this MOU shall be made only with the mutual agreement of the Parties as to content and timing of such announcement.

10. KLESH shall permit visitors introduced by RCB and/or RN to showcase the Skin Bank as well as to inspect its functioning with prior appointment and without disturbing the operations of the Skin Bank.

11. All intellectual property rights belonging to each of the Parties as well as RCBN Skin Bank shall belong to each of them respectively and none of the Parties hereto shall utilize or misuse any such intellectual property of the others of them or claim any rights in respect thereof. It is agreed that wherever any names, trademarks or other intellectual property of the Parties hereto or RCBN Skin Bank is to be used by any one or more of the parties hereto for the Project, they will seek written permission of the party owning such name, trademark or other intellectual property before any such use.

NATIONAL BURNS CENTRE

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

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

12. This MOU has been entered into with good faith by the Parties for providing service to burns victims with the intention to save more lives. NBC will make all efforts to provide good technical training to the KLESH technicians and help set up the Skin Bank using their expertise and RCB together with RN will use their respective organizations for facilitating the development of the Skin Bank and KLESH will use the Skin Bank to provide better treatment and outcomes to burns patients.

13. The Parties undertake not to operate the facility as a commercial enterprise and agree to provide the Skin Bank services on HUMANITARIAN CONSIDERATIONS only.

14. The tenure of this MOU shall be for a period of five years. Subsequently, upon evaluation, if the RN and KLESH& RCB are satisfied with functioning of the Skin Bank, this MOU will be renewed on such terms as may be mutually agreed upon at that time. Notwithstanding what is stated in this MOU if in the opinion of RN the Skin Bank is not running as per the standards suggested or laid down by RN then RN may at its discretion and without being subject to any liability terminate this MOU forthwith.

15. KLESHhereby indemnifies, and agrees to defend and hold harmless NBC, RCBN& RCB and their nominees from any and all actions, losses, claims, demands actions, causes of action, suits, costs, damages, expenses, compensation, penalties, liabilities and obligations of any kind (hereinafter collectively referred to as 'Loses') resulting from acts, misconduct or omissions of KLES Rotary Skin Bank or the **Supervising Committee**its agents or employees including but not limited to obtaining all statutory permissions and consents for harvesting, processing and storing of cadaver skin.

16. All disputes, differences and/ or claims arising out of this MOU or the construction, meaning or effect thereof or the rights, obligations and liabilities of the parties hereto or otherwise relating to the Skin Bank shall be referred to arbitration to be-conducted in accordance with the Arbitration and Conciliation Act, 1996 or any statutory amendments or re-enactment thereof by appointing a Sole Arbitrator as mutually agreed upon between the parties and such Arbitration shall be held in Belagavi The Award of the Sole Arbitrator shall be final and binding.

17. This MOU shall be executed in three counterparts, each of which shall be deemed to be an original and each party to this MOU shall retain a counterpart. All three counterparts shall constitute one and the same MOU.

18. This MOU may be reviewed and renewed by mutual agreement of the parties to this MOU.

IN WITNESS WHEREOF the Parties hereto have set and subscribed their respective hands the names to this writing on the day and the year first hereinabove written.

Medical Director & Chief Executive
KLES Dr Prabhakar Kore Hospital &
Medical Research Centre BELAGAVI.

NATIONAL BURNS CENTRE

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)

Signed and delivered by the
Within named **KLES Dr. P K Hospital & MRC, Belagavi**
Represented by :
1. Dr. M. V. Jali,
Medical Director& Chief Executive
KLES Dr. P K Hospital & MRC, Belagavi

3/3/2017
Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

Witnesses:

1. Dr. Rajesh Powar
   Chief Consultant
   Department of Plastic Surgery
   KLES Dr. P K Hospital & MRC, Belagavi
2. Mr. Vinay Bedre
   Administrator- Finance & Accounts
   KLES Dr. P K Hospital & MRC, Belagavi

Signatures:

Dr. Rajesh S. Powar
Senior Consultant & Head
Dept. of Plastic & Reconstructive Surgery
KLES Dr. Prabhakar Kore Hospital &
MRC- Belgaum.

Administrator - Finance & Accounts
KLES Dr. Prabhakar Kore Hospital &
MRC - BELGAUM.

Signed and delivered by the
Within named **Rotary Club of Belgaum**
Represented by its Trustee President
Dr. Satish Dhamankar
Rotary Club of Belgaum

Dhamankar

Witnesses:

1. Dr. Mukund Udachankar
   Vice President
   Rotary Club of Belgaum
2. Mr. Sachin Bichu
   President Elect
   Rotary Club of Belgaum

Signatures:

Bichu

Signed and delivered by the
Within named **National Burns Centre& Rotary Club of Bombay North**
Represented by :
Dr. Sunil Keswani

NATIONAL BURNS CENTRE

INDIAN BURNS RESEARCH SOCIETY

Witnesses:

1. Sangita Panda.
   Res. officer.
2. Reshmi Varghese
   Research Associate

Signatures:

Spanda

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

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Purchased by	:	DR BHAGYASHRI PATIL
Description of Document	:	Article 12 Bond
Description	:	UNDERTAKING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DR BHAGYASHRI PATIL
Second Party	:	MD AND CEO KLES DR PRABHAKAR KORE HOSPITAL AND MRC
Stamp Duty Paid By	:	DR BHAGYASHRI PATIL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
For Awami Urban Co-op. Credit Society Ltd., Belagavi

.....Please write or type below this line.....

TO.

THE M D & 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. BHAGYASHRI PATIL.

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

Sir.

I DR. BHAGYASHRI PATIL the undersign is Principal investigator for the clinical trial and the Phase 3 Study for Prospective, Multi-Centric, Double Blind, Parallel Group, Active Controlled Randomized Study to Evaluate the Efficacy and Safety of Bilastine in Adult and Adolescent Patients with Seasonal Allergic Rhinitis. I have Co-Investigator is Dr. Shama Bellad Research Coordinator is Miss Snehal Wandre.

I hereby give an undertaking that I will conduct the investigations/clinical trials as per the agreed terms and deposit 20% of the total funds (as and when received from time to time) to the second party (Medical Director & CE KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi) to the institution as mentioned in the Judicial agreement made. The payment from sponsors

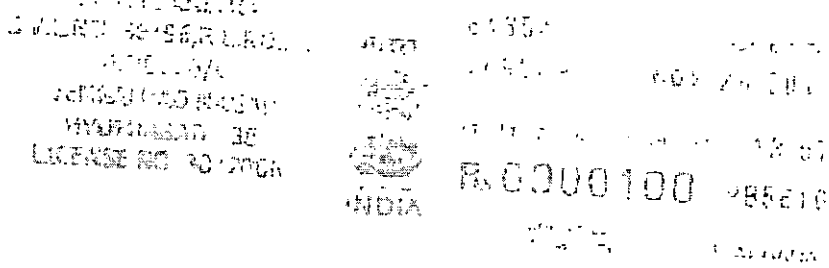
I will maintain records of all the receipts from the third party as well as payments to second party throughout the trial period and submit a final report about the finances including institutional charges, when I conclude the trial. The payments if any, to the associated staff will also be clearly brought out in the periodical reports.

Date: 2 Jan 2015

Signature of PI

Place: Belagavi

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



CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("The Agreement") is made and executed on 28th November 2017 by and between

HETERO LABS LIMITED (hereinafter referred to as "SPONSOR"), with its CIN # *U24110TG1989PLC009723* 7-2-A2, Hetero Corporate, Industrial Estates, Sanathnagar, Hyderabad – 500 018. Telangana State, India, a company registered under the companies Act 1956, represented by its Director and hereinafter called "Sponsor" (which expression unless repugnant to the subject or context therein shall mean and include its assignees, affiliates, employees, subsidiaries, nominees, agents and successors-in-interest) of the one part;

And

CLINSE LABS PRIVATE LIMITED a Company incorporated under the Companies Act, 1956 with its CIN # *U24239AP2005PTC047265* and having its Registered at 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad – 500018 (hereinafter referred to as "CRO", which expression shall unless repugnant to the context or meaning thereof shall mean and include its successors and permitted assigns) of the Second Part

And

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. Patil Bhagyashri Bhimgonda, KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India Hereinafter referred to as the "Principal Investigator" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the Third part,

And

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

And

KV Clinical Research Services, MIG II/253 Sector -1,Pt.Deendayal Upadhyay Nagar, Raipur-492001, Chhattisgarh hereinafter referred to as the "Site Management Organization" Hereinafter referred to as the "SMO" (which expression unless repugnant to the subject or context therein shall mean and include his heirs, executors and successors-in-interest) of the Fifth part

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

WHEREAS

The Sponsor has appointed CRO for conducting a clinical trial entitled, Study title: -

" A Prospective, Multi-Centric, Double Blind, Parallel Group, Active Controlled Randomized Study to Evaluate the Efficacy and Safety of Bilastine in Adult and Adolescent Patients with Seasonal Allergic Rhinitis (Exhibit A)

A. A. Vide letter dated 23rd Aug 2017, the Principal Investigator agreed to conduct the aforesaid Clinical Trial at **KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India.** Adult and Adolescent Patients with Seasonal Allergic Rhinitis to confirm the efficacy and tolerability and Safety of the aforesaid drug.

Dr. V.A.Kothiwale
Registrar
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B. SPONSOR is the owner of Protocol and is desirous and willing to conduct this Clinical Trial through the CRO herein by engaging the PRINCIPAL INVESTIGATOR.

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

D. CRO has confirmed its ability to perform the Services designated by Sponsor in accordance with terms and conditions of the Clinical Service Agreement and the applicable provisions of law, guidelines, the standards and practices that are generally accepted in the industry in performing similar services including but not limited to the terms and conditions of this Agreement.

E. CRO further agreed to act professionally and responsibly as the necessary interface between the Principal Investigator, Institution, Site and SPONSOR:

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

1.0 The Clinical Trial Period shall be approximately 06 months from the date of this agreement, which may be extended by mutual consent in writing.

2.0 The Principal Investigator will conduct the Clinical Trial strictly as per Protocol ID No. HCR/III/BISAR/03/2017 (Annexure I) ("Clinical Trial Protocol") as approved by the Institutional Ethics Committee in accordance with applicable regulatory requirements.

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

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

2.3 The Principal Investigator further represent, warrant and covenant that the Principal Investigator is and at all times, during the term of this Agreement, shall be: (a) in good

Dr. V.A.Kothiwale
Registrar
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professional standing, (b) in possession of all requisite professional licenses, (c) fully qualified to conduct the Study and to act as the Principal Investigator under the Agreement, (d) fully experienced and knowledgeable with respect to all matters pertaining to the study and (e) responsible for the supervision of all persons who may assist the Principal Investigator or otherwise be engaged in the study. The Principal Investigator shall be responsible for the performance of the study as per the highest standards of medical and clinical research practices. Prior to commencing the Study, Principal investigator shall require and each Collaborator engaged in the Study to complete and return to SPONSOR the Disclosure of Financial Interests and Arrangements, if any, in the study.

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

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

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

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

The Sponsor appoints Dr. Neetu Naidu Rayala Clinical Development & Medical Affairs as Monitor for the Clinical Trial and reserves its right to nominate any other person as Monitor.

The Sponsor will supply the aforesaid Drug to the Principal Investigator free of cost, case record forms, consent forms, patient information sheets and other stationery as may be required. The Sponsor will bear the Consultation Charges, Research Assistant Fee, Laboratory Investigation charges, other miscellaneous and sundry expenses as detailed in Annexure III. All amounts will be paid by means of crossed cheque with available payee details.

The Sponsor has to provide appropriate Instruments/Equipments to conduct the study at site. In case of injury or death during a clinical trial, patient shall be given free medical management as long as required by the sponsor.

In case the injury occurring to the clinical trial subject is related to the clinical trial, the subject or the subject's nominee(s) shall also be entitled for financial compensation as

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per order of Licensing Authority defined under clause (b) of rule 21 and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

The expenses on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

The Sponsor undertakes to indemnify and hold harmless Principal Investigator and other employees of, KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India who are directly involved in the Clinical Trial under their supervision, from any claims, demands, costs or judgments arising out of adverse reactions to the patients on Clinical Trial involving the Clinical trial Drug provided, however, the Sponsor shall not be responsible for any liability, loss or damages resulting from a failure by Principal Investigator and/or the employees and/or the agents KLES Dr Prabhakar Kore Hospital and Medical Research Centre Nehrunagar, Belgavi-590010, Karnataka, India to comply with the terms of this agreement or any/all applicable laws, regulations, guidelines and/or acts of malice, negligence, or fraud.

3.0 Dispute Resolution:

This Agreement shall be governed by and shall be construed in accordance with Indian Laws. The Parties agree that they shall in good faith work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be referred to Arbitration in terms of Arbitration & Conciliation Act, 1996. All disputes, controversies or claims arising out of or relating to this Agreement including interpretation thereof, or breach, termination or invalidity thereof shall be referred to arbitration to a sole arbitrator to be appointed mutually by the Sponsor and the Institution. The Venue of Arbitration at Hyderabad and the Arbitration proceedings shall be conducted in English language. The decision of such arbitrator shall be final, binding and conclusive on the Parties.

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- Term. The validity of the agreement is for a period of four years from the date of the agreement or the completion of the Clinical Trial, whichever is earlier.

5.0 Termination: This agreement may be terminated-

5.1 By either party if the other party commits breach and fails to remedy such breach within 30 days from the date of receipt of written notice detailing the same. The other party on receipt of the notice shall immediately take all steps to cease conduct of the trial as soon as possible to protect the welfare of subjects participating in the trial. Further, either party may terminate this Agreement with immediate effect by written notice to the respective party if the Investigator is no longer available and Institution and the Sponsor fail to appoint an Investigator mutually.

5.2 By Sponsor with 30 days prior written notice:
Sponsor, in its sole discretion, shall have the right to terminate agreement and stop the conduct of the trial at any time by giving notice to the principal investigator accordingly

5.3 Termination by the Institution / Investigator:
Institution / Investigator shall have the right to terminate the conduct of the trial if necessary to protect the welfare of the subjects by giving notice to sponsor.

Respective obligation in the event of early termination: If the trial is terminated prior to its completion, the Sponsor shall pay to the remuneration detailed in the Agreement by the milestones that have been duly achieved to the date of termination. In the case of early termination of the trial for any reason, the Institution / Principal Investigator shall provide all such assistance as Sponsor shall reasonably require to ensure an efficient handover of conduct of trial to a third party and with due regard for the welfare of the subjects.

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

Return of Material: Principal Investigator shall return to SPONSOR any unused Study Drug and all SPONSOR Confidential Information, as defined in the Confidentiality Section of this Agreement, on the conclusion of the Study or termination of this Agreement as the case may be.

6.0 Ownership of Data, Confidentiality and Publication:

6.1 Ownership. All case report forms and other data (including without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Principal Investigator in the course of conducting the Study (the "Data") shall be property of SPONSOR, which may utilize the Data in any way it deems appropriate, subject to and in accordance with all applicable (a) Indian laws and regulations and (b) privacy and security laws of India and other countries. Any copyright work created in connection with performance of Study and contained in the Data (except any publication by the Principal Investigator as provided for hereinafter) shall be property of SPONSOR as the author and the owner of copyright in such work

6.2 All information, including, but not limited to, the Study Drug or SPONSOR operations, such as SPONSOR's patent applications, formulas, manufacturing processes, basic scientific data, prior clinical data and formulation information supplied by SPONSOR to and/or Principal Investigator and not previously published (the "SPONSOR Confidential Information") are considered confidential and shall remain the sole property of SPONSOR. Both during and after the term of this Agreement, and Principal Investigator will use diligent efforts to maintain in confidence and use only for the purposes contemplated in this Agreement (i) the information which is identified in the preceding sentence as confidential or which a reasonable person would conclude as confidential and proprietary property of SPONSOR and which is disclose by or on behalf of Principal Investigator and (ii) Data which is generated as a result of this Study. The preceding obligations shall not apply to data or information (i) which has been published through no fault of Investigator, or (ii) which SPONSOR agree, in writing, may be used or disclosed, or (iii) which is published in accordance with paragraph C of this Section (iv). The provisions in this paragraph shall survive the termination or expiration of this Agreement for a period of ten years.

Dr. V.A.Kothiwale
Registrar

6.3 Publication: The Principal Investigator acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor which is disclosed to the Principal Investigator is and shall always remain the sole and exclusive property of Sponsor. The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the Principal Investigator may publish data generated at their (own) site, only after getting written approval from Sponsor and only after the first publication of such data by the Sponsor or as mutually agreed by the Parties.

6.4 Patents: All rights to any discovery or invention conceived and reduced to practice as a result of the work conducted under this Agreement shall belong to SPONSOR. The Principal Investigator agree to assign to SPONSOR, the sole and exclusive ownership thereto, upon the payment of costs by SPONSOR, if any, incurred by principal investigator in assisting SPONSOR in their filling, prosecution, or maintenance of any patent application or patent issued thereon. Such patent applications, if any, shall be filed and prosecuted by SPONSOR. Principal Investigator shall promptly disclose to SPONSOR any invention or discovery arising under this Agreement. Principal Investigator shall execute and shall have its employees execute all documents necessary to transfer all rights, titles and interests in and to any such invention or discovery to SPONSOR.

7.0 Data Use Agreement:

7.1 Encoding study data: Principal Investigator shall ensure that the patient identifiable information that is disclosed during the study and provided to the SPONSOR under this study fulfilled all privacy obligations under applicable legislations and regulations.

7.2 SPONSOR use of data set: SPONSOR shall not use or disclose information that would violate the requirements of any privacy legislation. SPONSOR will limit access to the data to personnel responsible for research and development function within their respective organization or within affiliated companies of SPONSOR. SPONSOR may also provide access to contract research organizations and other consultants or agents working with the research and development functions of these entities on the research activities detailed above. SPONSOR will ensure that all such

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parties assume the data protection responsibilities of SPONSOR as set forth in paragraph (c) of this section.

7.3 Protection of the data. SPONSOR shall, with respect to the information continued in the data (i) not use or further disclose the information other than as permitted or required by this agreement or as otherwise required by law; (ii) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) report to Principal Investigator any use or disclosure of information not provided for by this agreement of which it becomes aware; (iv) ensure that any agent or assignee, including a subcontractor, to whom it provides the information agrees to the same restrictions and conditions that apply to SPONSOR with respect to the data and (v) not identify the information or contracts of the individuals to whom it pertains.

8.0 Insurance

8.1 SPONSOR shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study) Insurance coverage for general liability in amounts appropriate to the conduct of business activities and the services contemplated by the study.

8.2 Principal investigator shall secure and maintain in full force and effect, through the performance of the study (and following termination of the study to cover any claims arising from the study) Insurance coverage for medical, professional and medical malpractice liability, in amounts appropriate to the conduct of business activities and the services contemplated by the study.

8.3 Upon request, each party shall provide to the other party a copy of the insurance certificate setting forth the foregoing coverage.

Dr. V.A. Kothiwale
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9. Debarment / Financial Disclosure: Principal investigator shall not employ, contract with or retain any person directly or indirectly to perform service under this Agreement if such a person incurs any disqualification of any nature under any statute in force either in India. Upon written request from SPONSOR, principal investigator shall, within ten days, provide written confirmation that it has complied with the foregoing obligation. Principal investigator shall also provide to SPONSOR all information necessary to comply with any disclosure requirements mandated Drugs & Cosmetics Act 1940, including any information required to be disclosed in connection with any financial relationship between SPONSOR and Principal Investigator. This disclosure requirement shall require disclosure of information involving immediate family members of those involved in the study.

10. Independent Contractor: Principal Investigator act in the capacity of independent contractor hereunder and not as agents or employees of SPONSOR. The Principal Investigator will make no claim against SPONSOR for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers compensation, disability or unemployment benefits or employee benefits of any kind, including right/status as an employee of SPONSOR.

11. Publicity: None of the parties shall use the name of any other party for promotional purposes without the prior written consent of the party whose name is proposed to be used nor shall either party disclose the existence or substance of this Agreement except as required by law.

12. Agreement Modifications: This Agreement or any of its Exhibits shall not be altered, amended or modified except by written document signed by all parties Hereto.

13. Assignment: SPONSOR shall have the right to assign this Agreement to an affiliate of SPONSOR upon prior written notice to Principal investigator. In all other instances, neither party shall assign its rights or duties under this Agreement to another without prior written consent of the other party. Subject to the foregoing, this Agreement shall bind and inure to the respective parties and their successors and assigns.

11

Dr. V.A.Kothiwale
Registrar

14 Conflict with protocol: If any of the provisions of this Agreement conflict with any provision of the protocol, this Agreement shall take precedence.

In witness whereof, the parties have caused this agreement to be executed by their authorized representative on the date, month and year first above mentioned

Hetero Labs Limited

Dr. Shubhadeep Sinha
Authorized Signatory

HETERO LABS LIMITED * HYDERABAD *

Hetero Labs Limited

M. Jayapal Reddy
DGM-Legal

Clinse Labs Private Limited

B. Mohan Reddy
Senior Manager – Clinical Research

KLES Dr Prabhakar Kore Hospital&
Medical Research Centre

2/1/2018

Authorized Signatory

Principal Investigator

2 Jan 2018

Dr. Patil Bhagyashri Bhimgonda

KV Clinical Research Services

Dr. Vikas R Chandrakar
Managing Director

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Annexure I

DCGI NOC

(Attached Separately)

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Annexure II

CLINICAL TRIAL PROTOCOL

(Attached Separately)

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Annexure- III

PAYMENT TERMS AND SCHEDULE

Estimated cost per one completed patient:

S.No	Details	Per Visit	Visit	No. of Visits	Total
1	Investigator Consultation Charges	2000	1	4	8000
2	12 Lead ECG	500	1	4	2000
3	Patient Conveyance	500	1	4	2000
4	Institutional charges [20% of items 1]				1600
	CRC Fee	V1(800),V2(700),V3(700),V4(800)			
	Total Cost of the project for 1 completed patient				13600

1. Payment terms:

a. Payments will be made every month as per the invoice received against e-CRF Completion and all queries should be resolved for completed visits.

b. Payment of Rs. 50,000/- will be paid as an advance after signing the agreement before or after the site Initiation visit. This amount will be adjusted in the subsequent invoices received.

c. The final payment to the site will be paid based on the number of patients enrolled, completed, Withdrawn/dropout and screen failures before the site closure visit.

d. If the site is terminated or doesn't progress in terms of recruitment for at least 3 months after Initiation / paying the advance, then the amount paid should be returned by the PI/Institution to the Sponsor after making necessary deductions and adjustments

e. The archival of study documents after site closeout and the complete responsibility hold with the Sponsor/CRO for 15 years.

f. GST as per applicable government rules

g. TDS will be deducted at final payment (after deduction of GST) as per income tax applicable rules

h. Screen failure cost as per completed screening visit

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Registrar

2. Payee Details :

The CRO will make the payment after tax deduction at source. The account payee crossed cheques will be issued in

Payee Name	KV Clinical Research Services
Payee Address	KV Clinical Research Services, MIG II/253 Sector -1,Pt.Deendayal Upadhyay Nagar,Raipur-492001, Chhattisgarh
Tax ID Number (PAN Number)	AAPFK7058P
GSTIN	22AAPFK7058P1ZM

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CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr.Niranjana Mahantshetti, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20140444 entitled "A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Denosumab in Pediatric Subjects With Glucocorticoid-induced Osteoporosis", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay

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Belagavi-590 010,Karnataka

94

Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: Prolia® ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will reimburse the Site for the cost of the Required Material(s) as detailed in a proper invoice. Such purchase or reimbursement costs shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company under this Order. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

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Belagavi-590 010,Karnataka

95

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study (**"Required Equipment"**): Laptop . Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop .

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop .

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Dr. Niranjana S Mahantashetti **"Payee"**
TAX ID	ABCPN5383J

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

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

97

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 23rd Jan '18

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: DR M.V. Kuli

(print or type name)

Title: MD & CE

Date: 16 Feb 2018

DR.NIRANJANA MAHANTSHETTI

(signature)

By: DR NIRANJANA MAHANTSHETTI

(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 29 JAN 2018

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

98

Protocol Number	20140444
Site Number	30005
Investigator	Dr. Niranjana Mahantshetty
Contract Number	
Number of Subjects	4
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 1,92,282	4	Subject(s)	INR 7,69,128
SUBJECT RADIOLOGY FEES				INR 29,200
SCREEN FAILURES	INR 21,831	3	per Site	INR 65,493
ADDITIONAL SUBJECT FEES				INR 1,29,000
ADMINISTRATIVE FEES				INR 41,400
CONTRACT TOTAL				INR 10,34,221

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs and laboratory costs*

SUBJECT FEES (20% Hospital overhead)

VISIT TABLE: STUDY	Schedule A
Screening Day -35 to -1	INR 21,831
Day 1 Visit	INR 18,368
Day 10 Visit	INR 9,030
Day 30 Visit	INR 9,030
Month 3 Visit	INR 11,830
Month 6 Visit	INR 19,905
Month 12 Visit	INR 23,168
Month 18 Visit	INR 19,905
Month 24 Visit	INR 21,605
Month 30 Visit	INR 14,705
Month 36/ET Visit	INR 22,905
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A
Per Subject Fee - Treatment	INR 1,54,672
Per Subject Fee- LTFU	INR 37,610
MAXIMUM PER SUBJECT FEE	INR 1,92,282

Screening costs are inclusive of costs associated with potential re-screens
The Maximum Per Subject Fee includes Subject travel (1,000.00 INR) and meal (400.00 INR) reimbursement for each protocol required in-clinic visits

RADIOLOGY FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
X-Ray Knee	INR 500	7	per Subject	INR 14,000
X-Ray Dental Single view	INR 800	2	per Subject	INR 6,400
DXA Hip (Sreening or Day 1)	INR 1,700	1	per Subject	INR 6,800
X-Ray Spine (Screening or Day 1)	INR 500	1	per Subject	INR 2,000
SUBTOTAL, RADIOLOGY FEES				INR 29,200

** X Ray Knee to be performed only in children with open growth plates who do not have bilateral hardware*
**DXA hip could be performed at Screening or Day 1*
**X Ray Spine could be performed at Screening or Day 1*
**X Ray Dental Single View to be performed based on visual inspection*

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 21,831
MAXIMUM SCREEN FAIL	INR 21,831

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ADDITIONAL SUBJECT FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
Infrastructure Fee	INR 75,000	1	per Site	INR 75,000
ISD Line Rental	INR 1,500	36	per Site	INR 54,000
SUBTOTAL, ADDITIONAL SUBJECT FEES				INR 1,29,000

Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be optained by site from study team before placing order for the infrastucture.
ISD line charge will be provided on monthly basis after site initiation untill final monitoring visit.

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
Document Storage, Archiving Total Cost	INR 41,400	1	per Site	INR 41,400
SUBTOTAL, ADMINISTRATIVE FEES				INR 41,400

Archival fee will be paid at the time of site close-out

PAYMENT DISTRIBUTION

Initial Payment	50,000.00 *Amgen will pay Institution this initial payment upon execution of the Agreement. In orc to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Dr. Niranjana S Mahantashetti' (Tax Id ABCPN5383J)
The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made in the favor of 'Registrar, KLE University, Belagavi'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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This Clinical Trial agreement made between:

Dr. Richard Saldanha, Chief Cardiothoracic Surgeon, KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

(PI/Investigator),

And

KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

And

Phoenix Cardiac Devices Pvt. Ltd, having a place of business at # 1-7-23/26, JSN Colony, Street No: 8, Habsiguda, Hyderabad - 500 007 T.S., India (the Sponsor).

PROTOCOL NUMBER:	**BACE – CT003**
PROTOCOL TITLE:	**Evaluation of safety and efficacy of the BACE™ [Basal Annuloplasty of the Cardia Externally] device in the treatment of Functional Mitral Valve Regurgitation (FMR)**
PROTOCOL DATE:	**BACE CT003; Version No. 1.2, dated: Nov 18, 2017**
SPONSOR:	**Phoenix Cardiac Devices Pvt. Ltd**
PRINCIPAL INVESTIGATOR:	Dr. Richard saldanha

WHEREAS, the Investigator and Institution, if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (Study), in accordance with the above-referenced protocol and any subsequent amendments thereto (Protocol) and Phoenix Cardiac Devices Pvt Ltd requests the Site to undertake such Study;

NOW THEREFORE, the following is agreed:

1 Sponsor hereby appoints the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol, the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other the attachments hereto, which all are incorporated by reference herein (Agreement), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has adequate time and resources to perform the Study according to the quality standards required.

2 Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made upon successful completion of the Study and submission of all Case Report Forms Modules in-house and submission of final Study report in terms of the Protocol and, if sponsor requests, all other Confidential Information as defined in Attachment A, Article 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder. The parties agree that the payee (Payee)designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following Payee:

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Belagavi-590 010,Karnataka

101

PAYEE NAME:	**CMS Clinical research Pvt. Ltd.**
PAYEE ADDRESS:	**Inox Tower-B, Plot No. 17, Sector 16A, Film City, Noida, India 201301**
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	**AAFCC8457M**

It should be noted that 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 and Sponsor will deduct the tax at the time of making payments if required by the tax laws.

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

The parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement. **Investigator acknowledges that if Investigator is not the Payee, Sponsor will not pay Investigator even if the Payee fails to reimburse Investigator.**

3. This Agreement will become effective on the date on which it is last signed by the parties In the event of a conflict between the Protocol and this Agreement; the terms of the Agreement will govern.

ACKNOWLEDGED AND AGREED BY

For and on Behalf of Phoenix Cardiac Devices Pvt. Ltd

Authorised Signatory: Gopal Muppirala, CEO

Jan 30th, 2018
Date

ACKNOWLEDGED AND AGREED BY

Name of ~~the Principal Investigator~~: Dr. Richard saldanha

Dr. Richard Saldanha
MS.,MCh.,DNB.
Chief Cardio Thoracic Surgeon
KLES Dr. Prabhakar Kore Hospital &
Medical Research Center,
Nehru Nagar, BELAGAVI - 10.
Reg. No. KMC 19161

31/1/2018
Date

ACKNOWLEDGED AND AGREED BY

For and on Behalf of KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010 Karnataka, India

Authorised Signatory:
Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

05/02/18
Date

Dr. V.A.Kothiwale
Registrar
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Belagavi-590 010, Karnataka

102

ATTACHMENT A TERMS AND CONDITIONS

1) **Conduct of the Study.** The parties to the attached agreement (the "Agreement") agree that the clinical trial described therein (Study) will be performed in strict accordance with the applicable protocol, and any subsequent amendments thereto applicable federal, state, and local laws, regulations and guidelines, and good clinical practices (GCPs).

The Principal Investigator (PI/Investigator) will provide copies of the CIP and all pertinent information to the study personnel, will discuss this material with them, and will ensure they are fully informed regarding the device and the conduct of the study.

The Investigator shall review all case report forms (CRFs) to ensure their accuracy and completeness, shall review and understand the information in the investigator's brochure or device labeling instructions, as applicable, shall ensure that all informed consent requirements are met, and shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs) are obtained.

The Investigator and the institution(s), conducting the trial (jointly, Site) agree to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Sponsor or their designee (CRO to be named) and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources.

The Site agrees to cooperate with the representatives of Sponsor who visit the Site, 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 use the device being tested (the Investigational Product), provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Investigational Products in a locked, secured area at all times. Upon completion or termination of the Study, the Site shall return all unused Investigational Products, equipment, and materials and all Confidential Information (as defined below).

2) **Disclosure of Protected Health Information [Patient Privacy]:**

During the course of this study, the research team [e.g., Investigators, study Coordinators, Medical Monitors, data analysts] will be collecting protected health information. The research team will take appropriate steps to keep protected health information private when possible, and it will be protected according to state and federal Law. This patient information will only be shared with the parties named below, per the requirements of health Canada. These may include federal agencies, the Sponsor, or the IRB; these entities might view or receive this information to collect data or to meet legal, ethical, research, and safety-related obligations. The authorization for Informed Consent and will expire at the end of the study.

3) **Confidential and Proprietary Information.**

All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product), provided to the Site by Sponsor, or their designees, (whether verbal, written or electronic), and all

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data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor.

The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. These confidentiality obligations shall continue until fifteen (15) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form; e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law.

4) **Intellectual Property.**

The existing inventions and technologies of Sponsor, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising as a result of the Study. The Site will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or discoveries.

The Site shall have exclusive ownership of any inventions or discoveries conceived by the Site during the time that the Study is taking place that do not arise in whole or in part from the Study or any Confidential Information, but the Site shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions or discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

In the event of a dispute, inventorship of any inventions, developments, or discoveries, whether patentable or not (Collectively referred to as "Intellectual Property"), resulting from the performance of the study, shall be allocated according to U.S. Patent Law (Title 35 U.S. Code) in effect at the time the intellectual property was created.

5) **Publication.**

Sponsor has no objection to publication by institute of the results of the study based on information collected or generated by institution, whether or not the results are favorable to sponsor. However, to ensure against inadvertent disclosure of confidential information or unprotected inventions, at least thirty (30) days before submitting or presenting a manuscript or other materials relating to the study to a publisher, reviewer, or other outside persons, the site shall provide to sponsor a copy of all such manuscripts and materials, and allow sponsor thirty (30) days to review and comment on them.

If any patent action is required to protect inventions, institution agrees to delay the disclosure for a period not to exceed ninety (90) days from the date institution initially submitted the proposed publication, or other type of disclosure, to sponsor for review.

The Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials, if Sponsor requests. No party hereto shall use any other party's name, or Sponsor's name, in connection with any advertising, publication or promotion without sponsor's prior written permission.

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If Study is part of a multi-centre study, Institution agrees that the first publication is to be a joint publication covering all centres. However, if a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of study at all participating sites, institution is free to publish its results separately.

6) **Inspection and Debarment.**

When given reasonable notice, the Site agrees to allow Sponsor, or their designee, or regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. The Site shall immediately notify the Sponsor of this, and provide the Sponsor 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 the Sponsor or their designee to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections.

The Investigator and the Institution, if any, shall be jointly responsible for maintaining essential Study documents for the time and in the manner specified by current good clinical practice (GCP) guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. If an investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify the Sponsor or their designee of his or her new address.

The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify the Sponsor or their designee immediately if any such investigation, disqualification, debarment, or ban occurs.

7) **Termination.**

The Sponsor may terminate this Agreement by giving prior written notice of fifteen (15) days in the event the Sponsor does not wish to continue the Study for any reason whatsoever or without assigning any reason. Notwithstanding any termination of this Agreement, Site will be entitled to payments due and payable till the date of termination. Upon termination, the Investigator will submit an up to date report on the Study conducted and return all confidential information of the Sponsor 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 the Sponsor shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the payment schedule.

Neither the Sponsor nor their designee shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to patient safety, the Sponsor may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

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Belagavi-590 010,Karnataka

8) **Claims and Disclaimers.**

The Site shall promptly notify the Sponsor or their designee in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Investigational Product and allow Sponsor to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor in its handling of the claim.

9) **Indemnification and Insurance.**

Sponsor shall indemnify, defend, and hold harmless institution from any damages and liability that arise out of the proper administration of the study device, study-required procedures, sponsor's use of the results, or sponsor's negligence or breach of the agreement.

The Sponsor expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product.

Neither the Sponsor nor their designee will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any loss, claim, or demand arising from any injuries or damages resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain the informed consent, unauthorized warranties, breach of this Agreement or willful misconduct The Site shall maintain a commercially reasonable level of insurance, and, upon request, shall provide a certificate of insurance alternatively, if applicable insurance is provided by a governmental agency, the Site shall satisfy all requirements necessary to remain eligible for such governmental insurance during the Study.

10) **Subject Injury.**

The sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a study subject that is directly related to the administration of the investigational device or the proper performance of any other procedure, each in accordance with the protocol and the sponsor's written instructions to the institution (or to the extent that the sponsor's written instructions conflict with the protocol, the sponsor's written instructions to the institution only). The sponsor is not required under this section to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the institution nor the study subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the protocol or other misconduct or negligence, in each case by any agent or employee of the institution (including the study staff), (d) due to the natural progression of the investigational device and unrelated to the proper performance of any other procedure required by the protocol or sponsor's written instructions to the institution.

11) **Additional Contractual Provisions.**

The Site shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of the Sponsor or their designee. This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. This Agreement shall be effective upon the date it is signed by all the parties and shall continue until completed or terminated.

No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the parties and their successors and assigns. The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of the Sponsor. The Sponsor may assign this Agreement to

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Belagavi-590 010,Karnataka

106

themselves or to a third party, and thereafter the Sponsor shall not have any obligations or liabilities under this Agreement, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee. 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. This Agreement shall be interpreted under the laws of the state or province and country in which such Site conducts the Study.

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ATTACHMENT B

BUDGET AND PAYMENT SCHEDULE

Consideration

In consideration of Site conducting the Study and complying with all other terms of this Agreement, the Sponsor or their designee shall pay to the Site all inclusive sum of **Rs. 1,60,000 (Rs. One lakh sixty thousand)** per patient recruited for the Study. Payments made by the Sponsor or their designee will be subject to tax deduction at source unless an exemption certificate issued by an appropriate authority is provided to the Sponsor or their designee.

IRB/EC and additional Infrastructure/Equipment Payment:

IRB/EC and additional Infrastructure/Equipment costs will be reimbursed on a pass-through basis (upon receipt of a valid invoice) and are not included in the attached Budget. Any subsequent IRB/EC re-submissions or renewals, upon approval by the Sponsor, will be reimbursed upon receipt of appropriate documentation.

Payment Break-Up for Per Patient Grant (Rs. One lakh and sixty thousand) for the study and it will be remitted at the following instalments

Milestone	**Amount (INR)**
Implant (week 0)	1,00,000/
Follow up visit (1, 3, 6, 12, 18 & 24 months)	60,000/- (10,000 each visit)
Total per completed patient	**160,000/-**

"In addition to the payment of Rs. 160,000/-, Phoenix Cardiac will be providing the BACE device free of cost to the patient as well as all study related tests (ECG, ECHO, stress EKG, lab test etc.) and reasonable patient travel cost (excluding air travel) to site will be reimbursed within one month of submitting invoice, based on actual cost incurred. In addition, any cost requirement in regard to any device related SAE event will be directly borne by the Sponsor"

Site will also be provided additional funding for BACE implant related expenses such as surgery cost, hospitalization cost, etc, if required for the study.

Site has to provide supportive bills for the reimbursement.

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 ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr. Veerappa Kothiwale, KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru nagar, Belgaum-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20170199 entitled "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay

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Belagavi-590 010,Karnataka

109

Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 145 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

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110

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study (**"Required Equipment"**): Laptop .

5.2 Company-Provided Required Equipment. The parties agree that for this Order, Company will supply the following Required Equipment, which equipment is specified in Schedule A: Laptop (**"Company-Provided Required Equipment"**).

The supply of the Company-Provided Required Equipment shall be part of the compensation for services rendered by Site under this Agreement. The current value of Company-Provided Required Equipment is identified in the Schedule A. At the expiration or earlier termination of the Agreement, Site will pay or Company will deduct from the final payment the then current value (as amortized) of such Company-Provided Required Equipment and ownership and title to such Company-Provided Required Equipment will transfer to Site. Company-Provided Required Equipment shall be transferred "as is".

5.3 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.4 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop .

5.5 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop .

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Dr. Veerappa A. Kothiwale **"Payee"**
TAX ID:	AEBPK3989H

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator

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111

is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized

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112

representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

(signature)

By: Mansi Malkan

Title: Senior Country Manager

Date: 14th Feb 2018

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: DR M.V. Jali
(print or type name)

Title: MD AND CE

Date: 21 Feb 2018

DR. VEERAPPA KOTHIWALE

(signature)

By: DR V.A. KOTHIWALE
(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 19 Feb 2018

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

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113

Protocol Number	20170199
Site Number	30006
Investigator	Dr. Veerappa Kothiwale
Contract Number	
Number of Subjects	5
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 73,655	5	Subject(s)	INR 3,68,275
SCREEN FAILURES	INR 25,800	2	per Site	INR 51,600
ADDITIONAL SUBJECT FEES				INR 1,51,950
ADMINISTRATIVE FEES				INR 41,000
MAXIMUM CONTRACT TOTAL				**INR 6,12,825**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs and laboratory costs.*

SUBJECT FEES (20% overheads)

VISIT TABLE: STUDY	Institution
Screening	INR 25,800
Day 1	INR 14,970
Week 4	INR 4,045
Week 8	INR 12,170
Week 12 (EOS)	INR 16,670
SUBJECT VISIT TABLE SUBTOTAL(S)	Institution
Maximum Per Subject Fee	INR 73,655
MAXIMUM PER SUBJECT FEE	**INR 73,655**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel (800.00 INR) and meal (500.00 INR) reimbursement for each protocol required in-clinic visits

VISIT TABLE: SCREEN FAILURE	Institution
Screen Failure	INR 25,800
MAXIMUM SCREEN FAIL	**INR 25,800**

ADDITIONAL SUBJECT FEES (Institution)	UNIT COST	UNIT(S)	TYPE	TOTAL
Optional Visit (Week 2/ 6) - apheresis subjects only	INR 4,045	2	per Subject	INR 40,450
Chart review/ database search (per Hour- Study Coordinator)	INR 1,500	5	per Site	INR 7,500
Infrastructure Fee	INR 50,000	1	per Site	INR 50,000
ISD Line Rental (per month)	INR 1,500	36	per Site	INR 54,000
SUBTOTAL, ADDITIONAL SUBJECT FEES				**INR 1,51,950**

Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastucture.
Broadband ISD line charge will be provided on monthly basis after site initiation untill final monitoring visit.

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Institution)	UNIT COST	UNIT(S)	TYPE	TOTAL
Document Storage, Archving Total Cost for duration of site obligations	INR 41,000	1	per Site	INR 41,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 41,000**

Archival fee will be paid at the time of site close-out

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114

PAYMENT TERMS

Initial Payment	50,000.00 *Amgen will pay Institution this initial payment upon execution of the Agreement. In o to receive further funds towards Subject related costs, the amount earned must exceed this initi payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of '_____' (Tax id _____)
The EC for this study will be '_____' and the payment of the EC fees will be made in the favor of '_____'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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DEPT. OF STAMP & REGISTRATION INDIA Rs.0000100 PB6948

STAMP DUTY KARNATAKA

Jayanagar, Bangalore

INVESTIGATOR CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this 23rd day of February 2018 by and between

Biocad India Pvt. Ltd. Registered office address: #163/C, 3rd Cross, 3rd Phase, JP Nagar, Bangalore-560078, Karnataka, India., duly represented by Mr. Krishnamurthy Rao, Managing Director (**herein after referred to as "Biocad")**

AND

Dr. Shivakumar Patil (hereinafter referred to as the "**Principal Investigator**" or "**PI**")

AND

KLES DR Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi, Karnataka - 590010, India (hereinafter referred to as the "**Institution.**")

And

Genesis Research Kolhapur (hereinafter referred to as the "SMO.")

in connection with conduct of clinical trial - "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis" bearing the protocol/study ID: **BCD-057-2.**

PI, Institution and Biocad hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company responsible for execution of a clinical trial in India.

2. Biocad India is the Indian subsidiary of CJSC "BIOCAD" (Sponsor) which is a Russian biotechnology company, established in 2001. CJSC Biocad has both research and development and full cycle manufacturing facilities. Biocad India desires to engage the services of the PI to conduct/assist in this clinical trial ;

3. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

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116

1. **Provision of Services**

1.1 The services to be provided by the PI to Biocad are described in detail in the statement attached hereto and incorporated herein by references as **Exhibit A** (hereinafter referred to as "**the Proposal**").

1.2 The Study will be conducted at the Institution under the supervision and direction of the Investigator, wherein Investigator shall control any individual performing any portion of the Study at the Institution. Site will carry out Study-related laboratory services and investigations as may be required for the Study.

1.3 The PI will conduct various activities with respect to the Clinical Trial (hereinafter referred to as "**activities**") in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B**)
- All applicable International Conference on Harmonisation (ICH) Good Clinical Practice (hereinafter referred to as "**GCP**") guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.

1.4 Biocad will provide the PI with all the information, documents, and materials which, in Biocad's reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.5 Biocad transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.6 Biocad will appoint a representative (hereinafter referred to as the "**Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)**") to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Biocad and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Biocad may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

1.7 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Biocad.

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117

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

3. Termination and Consequences of Termination

Termination:

3.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

3.2 Either Party may terminate this Agreement by written notice of **forty five (45) days** to the other Party without assigning any reason thereof and **with no penalty on either side.**

3.3 Either Party may terminate this Agreement by written notice of **thirty (30) days** in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

3.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 3.3 above.

3.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

3.6 Upon expiry or termination of this Agreement, Biocad shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Biocad to the PI under this Agreement exceed the project costs as set forth in the study Budget.

3.7 Upon expiry or termination of this Agreement, the PI shall, at Biocad' option, either immediately transfer to Biocad or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

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118

4. **Intellectual Property Ownership;**

4.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor (Biocad) which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor (Biocad).

4.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the PI may publish data generated at their (own) site:

- only upon getting written approval from Sponsor and
- only after the first publication of such data by the Sponsor.

5. **Representations; Indemnification**

5.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

5.2 The PI will be covered by a professional indemnity of sufficient value as decided by Biocad, which shall be in force through out the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

6. **Conflict of Interests**

Site warrants that neither Institution nor Investigator has any conflict of interest that would affect the conduct of the Study. PI shall notify Biocad promptly and within twenty four (24) hours, if a conflict of interest arises during the term of this Agreement

7. **Payment**

7.1 The total fees and expenses payable by Biocad to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B.**

7.2 This study is non-negotiable and includes all costs associated with the conduct of the study, including pharmacy fees, laboratory fees, dry ice, procedure cost, study coordinator/investigator fees, patient payments, all overhead charges and administrative fees.

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Belagavi-590 010 Karnataka

Unless and otherwise agreed in writing, Biocad India shall make no payment for patients whom the investigator entered into the study in violation of protocol (i.e, the patient is not a qualified participant)

7.4 Biocad shall pay the **SMO** (Genesis Research) for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

7.5 Payment shall be made by account payee Cheque / DD only.

8. Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9. Arbitration

9.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

10. Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

11. Record Keeping

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

12. Review of Work, Audit

12.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Biocad.

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120

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

14. **Notices & Service of documents**

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Biocad shall be addressed to:

Biocad India Pvt. Ltd.
#163/C, 3rd Cross,
3rd Phase, JP Nagar,
Bangalore-560078
Phone No. 080-41699773
Fax No. 080-41699773

All the correspondence/ notices to be sent by Biocad to PI shall be addressed to:

Dr. Shivakumar Patil
SMO, Second Floor , Sharavati ward
KLEs Dr Prabhakar Kore Hospital and MRC
Nehru Nagar, belagavi – 590010
Karnataka, India.

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FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao Managing Director Biocad India Private Limited	Genesis Research Mr. Satyjit Patil	Principal Investigator Dr. Shivakaumar Patil	Institute Head DR. M. V Jali
Seal:	Seal GENESIS RESEARCH 4122 Near Apoorva Hospital Jadhavwadi KOLHAPUR-416005	Seal Dr. Shivkumar Patil Consultant Dermatology KMC Reg No. 72067	Seal: Medical Director & Chief Exe KLES Dr. Prabhakar Kore Ho Medical Research Centre, BE
Witness	Witness	Witness	Witness

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Exhibit B: Proposal (Budget)

Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Biocad India Pvt. Ltd. offers to pay the PI **Rs. 2,16,250*** which will be paid per subject as per Annexure I who completes full study (complete all study visits and procedures as required by the protocol)
   This payment is inclusive of all patient related cost as well as non patient related cost such as all Overhead expenses, completion of case report forms, audits, administrative costs (e.g. Internet, telephone, Fax, Xerox, prints etc.), Hospitalization and infusion charges, pharmacy fees and lab costs for testing {for example CBC, Biochemistry, ECG, ECHO, as per protocol requirement}, patient travel costs, including unscheduled visits as per protocol, study/site staff fees. (Subject to deductions as per point No.4 below):

   *The payment will be made as per the visits completed by the patient

3. For Screening Failure, Rs. 5000 will be paid to PI which includes institutional overhead charges.

   Reimbursement will be not be made for any additional testing, treatment or procedures not required by the protocol, unless such additional testing, treatment or procedures are pre-approved by the sponsor.

   Below laboratory tests should be performed at the institution/local laboratory.
   ECG, CBC, ESR & Biochemistry

   The costs for these are included in the budget. All other protocol specified laboratory examinations will be performed at sponsor identified central lab.

Terms of Payment:

- Payment will be made after verifying completed case report forms and completion of Resolution of Data Clarification Form/ Data queries raised by Data Management for that respective visit.
- In case the patient does not complete the milestone visits then the payment would be made as per the earliest milestone visit.
- Payment to the PI on the above milestones will be made on monthly basis only by a crossed A/C Payee Cheque in favour of Genesis Research. No payment shall be made in cash.
- The final payment will be subject to a final reconciliation, meaning after (i) all subjects have completed the study, and the database has locked, (ii) all study specific queries and issues (including data queries) has been satisfactorily

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4. The following deductions will be made, if applicable:
   - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
   - Any capital expenses for the site incurred by Biocad on behalf of PI will be deducted from the fee payable to PI.

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao Managing Director Biocad India Private Limited	Genesis Research Mr. Satyjit Patil	Principal Investigator Dr. Shivakaumar Patil	Institute Head DR M. V Jali
Seal: BIOCAD INDIA PVT. LTD. # 183/C, 3rd Cross, 3rd Phase, J.P. Nagar BANGALORE	Seal GENESIS RESEARCH 4/22 (Near Apoorva Hospital Jadhavwadi) KOLHAPUR-416005	Seal Dr. Shivkumar Patil Consultant Dermatology KMC Reg No. 72067	Seal: Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital Medical Research Centre, BELAGAVI
Witness	Witness	Witness	Witness

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BUDGET SHEET

Treatment

er of visit	Screening	1	1-1	1-2	1-3	1-4	1-5	1-6	2	3	4	5	6	7	8	9	9-1	9-2	9-3	9-4	9-5	9-6	10	10-1	10-2	10-3	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	Final Visit 29
py week		0							1	3	5	7	9	11	13	15	15	15	15	15	15	15	16	16	16	16	17	19	21	23	25	27	29	31	33	35	37	39	41	41	45	47	49	51	55
	-4-0	1	2	3	4	5	6	7	1	1	1	1	1	1	1	1	2	3	4	5	6	7	1	2	3	4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Grant	4000	3500	1000	2000	2000	2000	2000	2000	2000	3000	2500	2000	2500	2000	1000	2000	2000	2000	1000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	1500	2000	1500	1500	1500	2000	1500	1500	1500	2000
20%	800	500	400	400	400	400	400	400	400	400	500	400	500	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	300	400	300	300	300	400	300	300	300	400
Fees	1750	1000	750	750	750	750	750	750	750	750	1000	750	1000	750	1000	750	750	750	750	750	750	750	1000	750	750	750	750	750	1000	750	500	500	1000	500	500	500	500	500	500	500	500	500	500	500	500
s the extent and severity of psoriasis with PASI	X	X									X		X		X								X						X				X		X		X				X				X
s psoriasis severity with PGA	X	X									X		X		X								X						X				X		X		X				X				X
date the body surface area affected by psoriasis (BSA)	X	X									X		X		X								X						X				X		X		X				X				X
s psoriasis involvement of nails with NAPSI	X																						X												X										X
s itch with visual analog scale (0-100 mm)	X																						X												X										X
s DLQI questionnaire		X																					X												X										X
s SF-36 questionnaire		X																					X												X										X
mple (phlebotomist)		500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500															
ing Charge	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	
	300																														300														300
X-ray	500																														500														500
NTIFERON-TB Gold test	3500								I																						3500														3500
plete blood count (Hemoglobin, Hematocrit, RBC, Leukocytes, lets, Neutrophils, Lymphocytes Eosinophils, ESR)	500										500		500		500								500						500		500						500						500		500
d biochemistry (Glucose, ALT, AST, GGT, AP, Total Bilirubin, inine)	1800										1800		1800		1800								1800						1800		1800						1800						1800		1800
e Analysis	250																														250														250
nancy test (Determination of hCG in urine)	400								I																																				
s for HIV, HCV, HBV, syphilis	2000																																												
nd Total	213250																																												

referral to be done at third party site.
FNAL as per actual
RI-MRI as per actual, any
icated above Rs. 500, prior
oval from Dr. of India must be obtained.
ONSULT: As per actual, any
icated above Rs. 500, prior
roval from Dr. of India must be obtained.
ent of travel reimbursement: Rs. 500 Visit
AE payment as per actual basis
hospitalization: Rs 1500 per day. Hospitalization is not required, reimbursement stay for out station patients on case to case basis

Medical ... Executive
KLE ... Hospital &
Med ... BELAGAVI

Dr. ...
Consultant Dermatology

Clinical Trial Agreement-BCD-057-2

GENESIS RESEARCH
4/22 Near Apoorva Hospital Jadhavwadi

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Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the 'Agreement) is entered on the _ day of _ 2018 between 1) **Dr. Sameer Haveri ("Investigator"), Consultant Orthopedics at KLE's Dr. Prabhakar Kore Hospital** and **2) KLE's Dr. Prabhakar Kore Hospital** ("**Institution**") both having its address at **KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India 3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

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

PROTOCOL NUMBER:	RLS/OST/2016/05
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
STUDY PRODUCT:	R-TPR-045 / Prolia®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Sameer Haveri**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OST/2016/05** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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126

WHEREAS the Institution has engaged **Genesis Research** a Site Management Organization of **KLE's Dr. Prabhakar Kore Hospital & M.R.C.**, authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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127

E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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128

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 **Site Visits.** The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 **Study Product.**

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

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129

c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

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130

including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights -** All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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Belagavi-590 010,Karnataka

131

time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

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Belagavi-590 010,Karnataka

133

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii)any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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Belagavi-590 010,Karnataka

134

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee.

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Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts:** During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name:** Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically

136

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

authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

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Belagavi-590 010,Karnataka

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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Belagavi-590 010,Karnataka

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 19 March 18

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Sameer Haveri

Title: Consultant Orthopedics

Date: _____

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. M. V. Jali.

Title: KLE's Dr. Prabhakar Kore Hospital & M.R.C.

Date: _____

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 26 Mar 2018

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137

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	Genesis Research
PAYEE ADDRESS:	4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India
TAX ID NUMBER (PAN Number)	CQJPP0528D
GSTIN	27CQJPP0528D1ZX

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research** in Indian Rupees.

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

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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Belagavi-590 010,Karnataka

140

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

7) Start-up fee of Rs. 60000/- will be released by Reliance at the time of site initiation before screening first patient in the study.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

141

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Belagavi-590 010,Karnataka

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: RLS/OST/2016/05

Investigational Product: R-TPR-045

Clinical Trial Budget		
	Project Name:	Denosumab
	Project Code	K069
	Name of PI	Dr. Sameer Haveri
		Unit Cost/Visit
Investigator fees		5,750
1	Principal Investigator	4,000
2	Clinical Research Coordinator	1,500
4	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,000
1	Travel reimbursement	500
2	Hospitalization charges	2,500
Administrative overhead-20% of Investigator Fee		800
Laboratory Testing Charges		
	Name	Cost
	Investigation	
1	Dexa Scan (BMD)	3,000
2	Spinal X-ray	500
3	12 lead ECG	300
4	Chest X Ray	500
5	X-ray (Maxillofacial region-Jaw)	500
	Study Start-up fee	60,000

- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study
- Hospitalization charges mentioned are for 24 hrs. Patient participating in PK will be hospitalized for 2 days.

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Belagavi-590 010,Karnataka

142

A.2 Per Visit Payment schedule:

Total study Budget/patient						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		5500	4800	500	800	11600
Day 1	0 hrs	5750	300	3000	800	9850
Day 3	48 hrs	250	0	3000	0	3250
Day 5		250	0	500	0	750
Day 7		250	0	500	0	750
Day 9		250	0	500	0	750
Day 11		250	0	500	0	750
Day 13		250	0	500	0	750
Day 15		250	0	500	0	750
Day 22		250	0	500	0	750
Day 29 (1M)		5750	0	500	800	7050
Day 43		250	0	500	0	750
Day 57		250	0	500	0	750
Day 85 (3M)		5750	0	500	800	7050
Day 113		250	0	500	0	750
Day 141		250	0	500	0	750
Day 183 (6M)		5750	4300	500	800	11350
9 Month		5750	0	500	800	7050
12 Month		5750	4300	0	800	10850
TOTAL		43000	13700	14000	5600	76300
					Total budget per subject excluding GST	76300
					cGST(9%) sGST(9%) iGST(18%)	90034

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Belagavi-590 010,Karnataka

143

Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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

144

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 04 Day of Apr 2018 by and between.

Veeda Clinical Research Pvt. Ltd, an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Mahesh Kalloli ("Principal Investigator"), having its place of work at KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

And

KLES Dr.Prabhakar Kore Hospital and MRC ("Institution") having its principal place of business at Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

(Hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 (herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 17-VIN-0855 entitled " A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition."; and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

Dr. V.A.Kothiwale
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1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement, excluding subject medical records. Data shall be the sole and exclusive property of Sponsor and may be freely utilized by Sponsor and their representatives. Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.
- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Council for Harmonization, Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
- "IEC" means the Independent Ethics Committee/Institutional Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Capecitabine tablets, 500 mg of Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

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146

2.2 Conduct of Study Principal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be 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 Veeda on a regular basis;

c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;

d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Veeda'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;

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147

g) Maintenance of drug accountability records, study documents including study drug acknowledgment receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol; and

i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

j) The Principal Investigator is responsible for training and supervision of sub-Investigators and other site study team member 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 Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle 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. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGI), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

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148

In case of SAE other than death the investigator will send the detailed report within 14 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 14 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal 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 deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda 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, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorized facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Investigational Medicinal Product i.e. both unused and retention samples will be retained at the site after completion of the study for a desired period, as per USFDA/sponsor requirement and also as per the written instruction given by Veeda/Sponsor at free of cost. The samples will be retained for a period of at-least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at-least 5 years following the date of completion of bioavailability study in which the sample from which the reserve sample was obtained was used. Investigational Medicinal Product i.e. both unused and retention samples will continue to remain at the site unless further information is received from Veeda/Sponsor.

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149

2.3.11 Principal Investigator/ Institute will intimate to CRO and Sponsor about any inspection/s from any regulatory authorities for the study , within 48 business hours of their notification.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of 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.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written notice. Principal Investigator shall submit written reports, as directed *by* Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information

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150

provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigator and Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five

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151

(45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".

The "Per Subject Fee" 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 Source & CRF completion
- time and effort of Principle Investigator and other site staff
- study coordinator salary
- all diagnostic tests and other investigations (ECG,Echo, X-ray Chest etc)
- housing or hospital stay for patients including meals
- Patient conveyance/compensation
- miscellaneous (telephone, fax, courier, etc)
- all overhead costs

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 accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.

- Name of Ethics Committee: **Institutional Ethics Committee, KLE University**
- Relationship between the site/institution and Ethics committee: **Institutional Ethics Committee**

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- Ethics committee payee name: **Registrar KLE University.**
- Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **NA**
- PAN no. of the payee: **AABTK0881E**
- Ethics Committee Fees: **Rs. 88500/- (Excluding TDS)**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG,ECHO, X-ray Chest, and SAE or in case patient withdraw consent.

h) 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.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will manage SAE reimbursement for medical management expenses towards AE/SAE directly to the patient or LAR and SAE compensation payment directly to the patient / LAR with prior written approval from the sponsor and will get for reimbursement for those expenses.

k) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enroll any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.

Details of Payee are:

Name of Payee: Genesis Research

PAN No. : CQJPP0528D

GSTIN No. : 27CQJPP0528D1ZX

Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

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153

3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts. The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. 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 however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 7 days from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 20 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: KLES Dr. Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator / Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal

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154

Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an

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155

individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded as per local regulatory requirement.

This is in case requirement of Audio visual recording. During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorized on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial. Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created here under for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information

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Belagavi-590 010,Karnataka

156

are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments

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

157

thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Notwithstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program.

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Belagavi-590 010,Karnataka

158

Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:

Veeda Clinical Research Pvt. Ltd.

Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.

Attention: Dr. E. Venu Madhav

Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:

Name: Dr. Mahesh Kalloli

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone : +918312470400
Fax: +918312493099

If to Institution:

Name: Dr M.V. Jali

Dr. V.A.Kothiwale
Registrar
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Designation: MD and CE

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone: +918312470400
Fax: +918312493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services here under, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be

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Belagavi-590 010,Karnataka

160

Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

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Belagavi-590 010,Karnataka

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 05 Apr 2018

Veeda Clinical Research Ahmedabad

For, Principal Investigator

Name: Dr. Mahesh Kalloli
Title: Principle Investigator

Date: 14 Apr 2018

For, Institute

Name : Dr. M. V. Jali
Title: MD and CE

Date: 28 APR 2018

Witness:

Name: Snehal Wandre

Contact Details: 9657279369

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Belagavi-590 010,Karnataka

162

SCHEDULE "A"

PROTOCOL

TITLE:

"A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition."

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Belagavi-590 010,Karnataka

163

SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

Screen failure will be paid an amount of 5,000 INR respectively.

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Belagavi-590 010,Karnataka

a) Trial Budget

Visit	Screening	Day 0	Day 1	Day 2	Day 3	EOS	Sub-total
Study Team Grant							
Principal Investigator Grant	4000	4000	6000	6000	6000	4000	30000
Study coordinator grant	2000	1500	1500	1500	1500	2000	10000
Phlebotomy Charges for Central lab sample collection	200					200	400
Phlebotomy Charges for PK sample*			1500	1500	1500		4500
Study Assessment Grant							
Local lab ANC and Platelet Count		200**					200
Heamoglobin in local lab			100	100	100		300
International Normalized Ratio	700					700	1400
Urine Pregnancy Test		150					150
Urine Drug screen test & Alcohol Breath Analyzer	150	150					300
ECG	500					500	1000
2D Echo	1500					1500	3000
X-Ray Chest	500						500
Stationary, Phone, Courier and Fax charge	200	100	200	200	200	200	1100
Hospitalization & Meal Charges		2500	2500	2500	2500		10000
Institutional Overhead (20%)	**1200**	**1100**	**1500**	**1500**	**1500**	**1200**	**8000**
Total	**10950**	**9700**	**13300**	**13300**	**13300**	**10300**	**70850**
IGST (18%)	**1971**	**1746**	**2394**	**2394**	**2394**	**1854**	**12753**
Total							**83603**
Visit	**Screening**	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**EOS**	**Sub-total**

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Belagavi-590 010,Karnataka

165

Patient Compensation	1000	1000	1000	1000	1000	1000	6000
* Phlebotomy charges for PK sampling will be paid only if site phlebotomist is used. ** Prior to dosing on day 0 (can be done after last dose in period I & at local laboratory).							
Note: Per Patient budget inclusive of all applicable taxes. Archival fee is 20,000/- Rs. for 5 years.							

Taxes:

- All payments shall be made to the Principle Investigator / Institution / any other payee party as defined in the agreement, after deducting of withholding tax (TDS) as applicable from time to time as per the Income tax act. The TDS certificates for the withholding tax will be provided at the end of the financial year.

- Patient compensation will be treated as a reimbursement and TDS will be not deducted from the patient compensation subject to production of original bills and supporting documents (signed by patient) without any mark up by the Principle Investigator and Institution.

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Belagavi-590 010,Karnataka

166

CORPUSCLES

AlfaCorpusclesPvt.Ltd

Office . 25/36, First Floor,
East Patel Nagar,
New Delhi -110008, India.
T . +91 11 43572941

Factory . L-149, Sector-1,
Bawana Industrial Estate,
New Delhi -110039, India.
T . +91 9811105289

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (CTA) is made in Delhi between Alfa Corpuscles Pvt Ltd, (also called the Company) 25/36, First Floor, East Patel Nagar, New Delhi 110008, India, represented by Dr. Atul Sardana, Head of Research and Product Development (also called as the Principal Investigator)

AND

Dr. Dnyanesh Morkar - (M.B.B.S, M. D, D.N.B.), (also called as Site Investigator) at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

AND

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India (also called as Site).

AND

GDD Experts (India) Pvt. Ltd., (also called as SMO) Ground Floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India

Whereas Alfa Corpuscles wishes to conduct the following Indian Council of Medical Research (ICMR) (also called as the Sponsor) Funded Study with Dr. Dnyanesh Morkar as the Site Investigator at the above mentioned site:

1. Title: A Multicenter, open label, prospective study to evaluate safety and effectiveness of the safety syringe developed by Alfa Corpuscles Pvt. Ltd. India in patients who require dose administration by parenteral route using the syringe or phlebotomy procedure as a part of their treatment/ diagnosis

Protocol No.: 14-VIN-527

The objectives of the trial are to assess the effectiveness of safety syringe by evaluating usage, acceptance, perception of safety & other determining factors on which consumers base their decision for routine usage and to monitor the safety of the patients

It is hereby agreed by and between Alfa Corpuscles Pvt. Ltd. And the Site Investigator here to as follows:

1. The site of the trial would be KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India.
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Site investigator will be paid a sum of INR 750 / Syringe Use
4. A total of 333 subjects will be enrolled in the study for the Safety Syringe Arm and a total of 333 subjects will be enrolled in the study for the Comparator Syringe Arm
5. The payments will be done to the designated Payee on a Monthly basis to the following account details

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

167

- Payee Name / Name of the account holder: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK LTD
- Account Number: 910020034162231
- Bank Address: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road. Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- IFSC Code: UTIB0000048
- PAN Card Number: AADCG0363Q
- GST Number: 27AADCG0363Q1ZA

Role and responsibilities of Dr. Dnyanesh Morkar (Site Investigator)

1) To conduct the above referenced Study as the Site Investigator.
2) The Site investigator has to complete 133 intramuscular administrations, 133 intravenous administrations, 17 subcutaneous administrations and 50 phlebotomy procedures using the safety syringe. The number of patients can be increased by Alfa Corpuscles Pvt Ltd.
3) The recruitment period for the study is three months. The Company expects a total of 333 syringes data from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Site investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The Site Investigator should be available and permit monitoring and auditing by the representative of the Company/ Principal Investigator, and inspection by the appropriate authority
6) The Site Investigator should ensure that all persons assisting with the study are adequately informed about the protocol; the investigational product(s), and their trial-related duties and functions.
7) The Site Investigator should conduct the trial in compliance with the protocol agreed to by the Sponsor and Principal Investigator and, which was given approval/favourable opinion by the IEC.
8) The Site Investigator should not implement any deviation from, or changes of the protocol without agreement by the Principal Investigator and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects,
9) The Site Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

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Belagavi-590 010,Karnataka

10) All serious adverse events (SAEs) should be reported immediately to the Principal Investigator/ Company except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) The Principal Investigator would like to have intermittent report every as and when required during the course of the study.
12) The Principal Investigator would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator.
13) Contents of the report during the clinical trial should be kept confidential and not be revealed to any other company in India or outside India without written permission from the Principal Investigator.
14) The data obtained during the trial will not be published by the Site Investigator. The Company and the Principal Investigator will have the right to use this for publication of a research paper.
15) In case the Site Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Site Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Alfa Corpuscles Pvt Ltd.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of GDD Experts:

GDD Experts will be assisting PI in Trial Management, Project Management and Quality Management.

Role and responsibilities of Alfa Corpuscles Pvt Ltd (Company) and Principal Investigator

1) The Company and Principal Investigator is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The Company and Principal Investigator is responsible for securing agreement from all involved parties including Site Investigator and Site etc.
3) The Company and Principal Investigator is responsible to provide appropriately qualified individuals to, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The Company and Principal Investigator will be responsible for providing insurance to the study subjects and Indemnification to the entire site if required.

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5) The Company and Principal Investigator will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

6) The Company and Principal Investigator will be responsible for monitoring and auditing of the study.

It is hereby agreed by and between Alfa Corpuscles Pvt. Ltd.(Company) and Dr. Honey Susan Raju (Site Investigator) to all the terms and conditions as mentioned in this agreement

Acknowledged and agreed on behalf of Alfa Corpuscles Pvt. Ltd, 25/36, First Floor, East Patel Nagar, New Delhi 110008, India

By:

Name: Dr. Atul Sardana
Title: Head of Research & Product Development
Date: ~~21/09/2017~~ 23/04/2018

Acknowledged and agreed on behalf of KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

By:

Name: Dr. M. V. Jali
Title: Medical Director
Date: 23/6/18

Acknowledged and agreed by Site Investigator at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India

By:

Name: Dr. Dnyanesh Morkar
Title: Site Investigator
Date: 20 Jun 2018

Acknowledged and agreed on behalf of GDD Experts India Pvt. Ltd., Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India

By:

Name: Dr. Vinod Gyanchandani
Title: Head- Clinical Operations
Date: 07/May/2018

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

170

Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 29 day of May 2018 between **1) Dr. Rekha Mudhol ("Investigator"), Consultant Ophthalmologist,** at KLES Dr.Prabhakar Kore hospital and Medical research Centre **2) KLES Dr.Prabhakar Kore hospital and Medical research Centre ("Institution")** having its office at Neharu Nagar, Belagavi-590010, Karnataka, India, **3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business ("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

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

PROTOCOL NUMBER:	RLS/OPT/2016/06
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration.
STUDY PRODUCT:	R-TPR-024 / Lucentis®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Rekha Mudhol**
INSTITUTION/SITE:	**KLES Dr.Prabhakar Kore hospital and Medical research Centre, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OPT/2016/06** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

Dr. V.A.Kothiwale 171
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010.Karnataka

WHEREAS the Institution has engaged **Genesis Research ("SMO")** a Site Management Organization of **KLES Dr.Prabhakar Kore hospital and Medical research Centre** authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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

E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 **Site Visits.** The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 **Study Product.**

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

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Belagavi-590 010,Karnataka

175

including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

176

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

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177

7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. **Subject Injury Reimbursement**

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. **Inspection and Debarment.**

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from

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Belagavi-590 010,Karnataka

178

time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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

179

iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or

(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or

(iii)any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,

(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or

(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;

b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.

c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and

d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and

e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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Belagavi-590 010,Karnataka

181

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators; (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

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Belagavi-590 010,Karnataka

182

13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts**: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name**: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

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

183

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment.. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and

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184

Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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185

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 09 May 2018

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Rekha Mudhol

Title: Consultant Ophthalmology

Date: 11 May 2018

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: DR M.V. Jali

Title: MD & CE

Date: 29 May 2018

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 10 may 2018

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186

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research ("SMO")**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research, kolhapur**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research ("SMO")** in Indian Rupees.

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

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory

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187

documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: RLS/OPT/2016/06
Investigational Product: R-TPR-024

A.2 Per Visit Payment schedule:

Clinical Trial Budget		
	Project Name:	Ranibizumab
	Project Code	K071
	Name of PI	Dr. Rekha Mudhol
		Unit Cost/Visit
Investigator fees		6,250
1	Principal Investigator	4,000
2	Clinical Research Coordinator	2,000
3	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,100
1	Travel reimbursement	500
2	Hospitalization charges	2,500
3	Consumables	100
Administrative overhead-25%		1,000
Laboratory Testing Charges		3,500
	Name	Cost
	Investigation	
1	Ocular Examination Including visual acuity Test	500
2	Slit Lamp Examination	500
3	Tonometry	500
4	Optical coherence tomography	2,000

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189

Total Budget						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		6250	3500	500	1000	11250
Day 0	0 hrs	6250	1500	3000	1000	11750
	6hrs	250	0	0	0	250
	12hrs	250	0	0	0	250
	24 hrs	250	0	0	0	250
Day 2	48 hrs	250	0	600	0	850
Day 7		6750	1500	500	1000	9750
Day 30 (W4)	(predose third dosing)	6000	3500	500	1000	11000
Week 8		6000	3500	500	1000	11000
Week 12		6000	3500	500	1000	11000
Week 16		6250	3500	500	1000	11250
Week 20		6000	3500	500	1000	11000
Week 24		6250	3500	500	1000	11250
TOTAL		56750	27500	7600	9000	100850
					Total budget per subject excluding GST	100850
					IGST(18%)	18153
					Grand Total Per Subject	119003

Note:-

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- * In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll minimum 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).
- Advance payment of Rs. 50000/- will be paid after site initiation visit for this study at this center.

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190

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

191

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ADDENDUM TO CLINICAL TRIAL SITE AGREEMENT FOR 0804-16 STUDY ("Addendum")

1 PREAMBLE AND INTENTION

The Parties are,

1.1 **Lambda Therapeutic Research Ltd.**, a company incorporated in accordance with the laws of India with its registered office at Lambda house, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India (herein referred to as "Lambda") (which expression shall unless repugnant to the context or meaning thereof be deemed to include its affiliates, employees, subsidiaries, nominees, successors - in - interest and assigns)

AND:

Principal Investigator, **Dr. Shiva Kumar Patil**, KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND:

KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 590010, Karnataka, India
(Hereinafter referred to as the "Institute")

AND:

Site Management Organization, KV Clinical Research Services Office no. 615, 6th Floor Golden Trade Centre New Rajendra Nagar, Raipur – 492001, Chhattisgarh
(Hereinafter referred to as the "SMO")

CRO, Site, SMO and Principal Investigator are hereinafter individually referred to as a "Party" and collectively as the "Parties".

WHEREAS:

1.2 Parties have entered into a Clinical Trial Site Agreement dated April 05, 2018 (herein referred to as "Agreement"), pursuant to which CRO, acting as an independent contractor on behalf of SPONSOR desires to coordinate a clinical research study, Site and Principal Investigator agreed to facilitate and carry out the Study as detailed in Agreement.

1.3 The Parties wish to amend and supplement certain of the terms of the Agreement as recorded herein ("Addendum").

LAMBDA Research Accelerated

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192

1.4 This Addendum forms part of and is to be read with the Agreement as from **June 21, 2018** ("Effective Date").

2 AMENDMENTS

As requested by Investigator to increase the "Investigator Grant" amount of **INR 49,920** (per patient) as per **attachment – A (Revised Budget);**

In addition to this LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the SMO, Institution & PI. Details of Payee are:

Payee Details:

Payee Name	:	"KV Clinical Research Services Payable" at Raipur
Payee Address	:	AAPFK7058P
PAN / TAN Number	:	MIG II /253 Sector -1, Pt. Deendayal Upadhyay Nagar, Raipur – 492001, Chhattisgarh
GST Number	:	22 AAPFK7058P1ZM

LAMBDA
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193

A. Revised Budget:

FINANCE SUMMARY BOX	
Invoice Currency	**INR**
Study Base	**Visit-based**
Effective Date	**The revised budget will be applicable from 21 June 2018**

Sr. No.	Payment Head	Screening/Visit 01	Visit 02	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9/ EoT + EoS	Total
		Up to 14 days prior to dosing	Day 0	Day 7	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84 + 7 days	
1	Investigator Grant	3200	2250	2250	2250	2250	2250	2250	2250	3000	21950
2	Study Coordinator Grant	1500	1200	1200	1200	1200	1200	1200	1200	1500	11400
3	ECG (12 Lead)	500	[redacted]							500	1000
4	X-Ray	500									500
5	Institutional Overhead (20%)	1140	690	690	690	690	690	690	690	1000	6970
6	Target Lesion Photograph Print	[redacted]	450	450	450	450	450	450	450	450	3600
	Total										
7	Patient Compensation (actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grand/patient										**49920**
8	**Local Laboratory Investigation**										
8a	Haematology	420	[redacted]							420	840
8b	Blood/Serum Biochemistry	1430								1430	2860
8c	Immunology	1200								1200	2400
8d	Urinalysis	150								150	300
8e	Pregnancy Tests	150	**UPT kit will be provided by Lambda**							150	300
	TOTAL OF SECTION 8										**6700**
	***Local lab Investigations: Haematology, Biochemistry, Immunology, Serum pregnancy test and Urine analysis investigations will be done as per protocol requirement on Visit 1 and Visit 9 only.**										
	Note:										

1. The above referenced per patient grant will remain same throughout the study. Additionally investigator/site will get a bonus amount of INR 20,000 after enrollment of every 10th patient in the study.

2. Phlebotomist activities will be completed by site team only. No additional cost will be paid for the same.

3. Patient compensation will be provided based on actual bills only (provided is upper limit)

3 **GENERAL**

3.1 As of the Effective Date, this Addendum 1 shall be read together with and shall be deemed to be incorporated in the Agreement and shall be governed by the terms, conditions and definitions set forth in the Agreement, as if such terms were fully set forth herein.

3.2 Except as expressly amended hereby, the terms and conditions of the Agreement shall continue in full force and effect and are hereby confirmed and ratified.

SIGNATORIES

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

Lambda Therapeutic Research Ltd.

By: Ravesh
Printed Name: Dr. Ravesh Patel
Title: AVP - CTM
Date: 23 Jun 2018

PRINCIPAL INVESTIGATOR

By: _____
Printed Name: Dr. Shivakumar Patil
Title: Consultant Dermatologist
Date: 29 Jun 2018

SMO

By: _____
Printed Name: Kirti Kumar patel
Title: Founder & COO
Date: 21/ July /18

INSTITUTION

By: _____
Printed Name: Dr. M. V. Jali
Title: MD & CE, KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010.
Date: 16 Jul 2018

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA99742282543376P
Certificate Issued Date	:	07-Sep-2017 12:29 PM
Account Reference	:	NONACC (FI)/ kacrsfi08/ JAYANAGAR4/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL0848737927088555P
Purchased by	:	QUINTILES RESEARCH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	QUINTILES RESEARCH INDIA PVT LTD
Second Party	:	KLES
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

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196

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. Kothiwale Veerappa Annasaheb** , 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 Pvt. Ltd.**' having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur-440001, Maharashtra, India (the "**Research Company**")and

- **Quintiles Research (India) Private Limited**, having a place of business at B-101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road, Ahmedabad - 380 051, Gujarat, India ("**Quintiles**"),

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

Protocol Number:	1002-043
Protocol Title:	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFECTS OF BEMPEDOIC ACID (ETC-1002) ON THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCULAR DISEASE WHO ARE STATIN INTOLERANT
Protocol Date:	24 June 2016
Sponsor:	Esperion Therapeutics, Inc.
Country where Site is Conducting Study	India
Investigator:	Dr. Kothiwale Veerappa Annasaheb
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	Ethics Committee of KLE University JNMC Campus, Nehru Nagar, Belgaum - 590010, Karnataka , India EC chairperson/chairman name : Dr. Subarna Roy Contact No. of the EC chairperson/chairman: +91 9449033133

The following additional definitions shall apply to this Agreement:

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197

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

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198

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).

Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

RECITALS:

WHEREAS, Quintiles is providing clinical research organisation services to Sponsor under a separate contract between Quintiles and Sponsor. Quintiles' 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 Quintiles 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 and MCI Regulations and state and local tax and finance regulations. Site and Study Staff acknowledge that Quintiles 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 Quintiles, Site will submit Study Data using the electronic system provided by Sponsor or Quintiles 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

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199

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 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 Quintiles and Sponsor for Sponsor's use. Site shall afford Sponsor and Quintiles and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and Quintiles 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 Quintiles 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 Quintiles of, and provide Quintiles 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 Quintiles 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 solely (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

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Belagavi-590 010,Karnataka

200

information in the Investigator's Brochure, 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 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 Quintiles 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 Quintiles.

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 Quintiles, 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 Quintiles 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 Quintiles or Sponsor in relation to the Study, then Site

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Belagavi-590 010,Karnataka

201

shall enter a separate written agreement with Quintiles or Sponsor with respect to such facility improvements.

1.7. Enrollment of Patients

The Effective Date of this Agreement is as listed in Section 15. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any payment until the validity 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 Quintiles may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/Quintiles has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or Quintiles 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 Quintiles has received all properly completed CRFs and, if Quintiles requests, all other Confidential Information (as defined below). Institution and Investigator acknowledge and confirm that if Investigator is a named payee hereunder, such payment arrangement is in accordance with the modalities laid down by the Institution for receipt of funding for the Study and is not in violation of the MCI Regulations.

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;

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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka
202

(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, provided that such persons are subject to a written agreement or otherwise bound by a duty of confidentiality, respecting the Confidential Information in the manner set forth in this Agreement;
(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 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

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Belagavi-590 010,Karnataka

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", solely for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

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 5. 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

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Belagavi-590 010,Karnataka

204

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 Quintiles 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 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 Study Team Member 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.

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

205

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

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, Quintiles, 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; and
(vi) anti-corruption compliance.

Names of members of Study Staff may be processed in Quintiles' 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 Quintiles deals with any personal data under this Agreement in the manner of a data controller, Quintiles shall be the data controller of such personal data to the extent of such dealings.

Quintiles 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 Quintiles 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

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

206

(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. QUINTILES DISCLAIMER

Quintiles 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 Quintiles.

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

9. CONSEQUENTIAL DAMAGES

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

Notwithstanding anything contained herein the Institution shall be liable:

(a) for any act or omission of the Investigator with respect to the payment received by the Investigator in the capacity of the Payee; and
(b) any consequential damages including but not limited to loss of profits and opportunities arising out of the act or omission of the Investigator as set out above.

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 regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify Quintiles 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 Quintiles' 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 Quintiles a financial and conflict of interest disclosure form that has been

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

207

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.

Quintiles 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, Quintiles, 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 Quintiles 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 Quintiles 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, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or Quintiles 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 Quintiles 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

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Belagavi-590 010,Karnataka

208

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, Quintiles may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if Quintiles 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 Quintiles and Sponsor and shall not be considered the employees or agents of Quintiles or Sponsor.

Neither Quintiles 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.

It is hereby agreed and acknowledged by the Parties and Sponsor that Quintiles 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". Quintiles 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, Quintiles shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, Quintiles 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, Quintiles 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

Quintiles 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 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

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Belagavi-590 010,Karnataka
209

reasonable efforts to minimize further costs, and Quintiles 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, Quintiles 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:	Attention: Narendra Lalwani Name: Esperion Therapeutics, Inc. Address: 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108, USA Tel: 1-734-887-3903 e-mail: nlalwani@esperion.com
To Quintiles	Name: Quintiles Research (India) Private Limited Address: Quintiles Research (India) Private Limited, Natraj By Rustomjee, 6th Floor,194, M. V. Road Junction, Western Express Highway Metro Station, Andheri (East), Mumbai-400069, India Tel: +91 22 66774242
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. Kothiwale Veerappa Annasaheb

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Belagavi-590 010,Karnataka

210

	Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: +91-9448119899
To Research Company	Name. Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, 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 Quintiles and Sponsor.

Upon Sponsor's request, Quintiles may assign this Agreement to Sponsor or to a third party, and Quintiles 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

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Belagavi-590 010, Karnataka

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

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

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212

ACKNOWLEDGED AND AGREED BY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED:

By: Subashri Shivkumar

Title: Sr. Director and Head Clinical Development Services

Signature: Subashri Shivkumar

Date: 25/Sept/2017

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Kothiwale Veerappa Annasaheb

Title: Principal Investigator

Signature: _____

Date: 23 oct 2017

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

By: Dr. M. V. Jali

Title: Medical Director

Signature: _____

Date: 23 oct 2017

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: 26/oct/2017

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	GDD Experts India Pvt. Ltd., Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
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
Pan #	AADCG0363Q

In case of changes in the Payee's bank details, Site is obliged to inform Quintiles 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 Quintiles to the Payee.
Investigator acknowledges that if Investigator is not the Payee, Quintiles will not pay Investigator even if the Payee fails to reimburse Investigator

B. PAYMENT TERM

Quintiles 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 one Screening Failure per randomized subject 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 Quintiles 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 Quintiles and/or Sponsor, the return of all unused supplies to Quintiles, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Quintiles 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 Quintiles 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 Quintiles with an invoice, to be sent to Quintiles 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 _25____ 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 Quintiles may reconsider Site's suitability to continue participation in the Study.

E. DISCONTINUED OR EARLY TERMINATION
Reimbursement for discontinued or early termination subjects who continue in the study with visits will be paid as a normal subject. subjects who discontinue treatment and visits will be prorated based on the number of confirmed completed visits.

F. SCREENING FAILURE
Reimbursement for screen failures at Screening Visit 1 will be at a rate of **Sixteen Thousand Four Hundred and Forty Three Rupees (INR 16,443)** Reimbursement for screen failures at Screening Visit 2 will be the Screening Visit 1 Screen Fail rate plus an additional **Fifteen Thousand and Ninety Rupees (INR15,090).** Reimbursement for Screen failures at Treatment 1 Visit will be at a rate of Five Thousand Seven Hundred and Fourteen Rupees (INR 5,714) plus Screening Failure Visit1 plus Screeen Failure Visit2. Reimbursement of Screen Failures shall not to exceed one (1) screen failures paid per one (1) subject randomized.

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

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G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is Six Thousand Six Hundred and Fifty Rupees(INR 6,650). [which includes overhead]. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to Quintiles along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit.

H. ADDITIONAL UNSCHEDULED VISIT PROCEDURES

Additional Unscheduled Visit procedures costs that are not captured in the attached budget will be reimbursed on a pass-through basis upon receipt of invoice. To be eligible for reimbursement subject number, procedure, and date of service must be included on the invoice along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit procedure.

I. CONDITIONAL PROCEDURES

The following conditional procedures costs will be reimbursed on a pass-through basis upon receipt of invoice at amount indicated in the below table [which includes overhead]. Subject number and visit/dates must be included on the invoice for payment to be issued.

PROCEDURE	PROCEDURE AMOUNT (INR)
Blood draw, venipuncture, phlebotomy specimen collection with lab handling and shipping; simple (serology, serum Pregnancy, TSH, clinical safety lab, basic fasting lipids, HBA 1c, HsCRP)	725
12-lead ECG: Includes tracing, interpretation and report	665
Screen Failure S1	16,443
Screen Failure S2	15,090
Serious Adverse events (SAE)	1451

J. INVOICES

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

Quintiles Research India Private Ltd., Bangalore
Attention: Finance PSC – Accounts Payable (Investigator Payments)
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

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

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- **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 Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

- STUDY START-UP FEE

A one-time, non-refundable Study Start-Up payment of Thirty Six Thousand Nine Hundred and Twenty Two Rupees (**INR 36,922**), will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of an original invoice.

- Record Storage Fee/Archiving Fee

A record storage payment of Forty One Thousand Rupees (**INR 41,000**), will be made 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.

- Patient Travel Expenses

Patient travel expenses will be reimbursed upon receipt of original supporting invoices up to Eight Hundred Rupees (INR 800) per visit per patient per round trip and is included in the attached Budget. Invoices must contain the Patient number, amount paid, and visit number and visit date in which patient travel is being requested.

- **Meeting Attendance:**

Necessary travel and lodging expenses (including meals) incurred by the Site when attending Study start up meetings or other meetings necessary to provide information regarding the Study or Investigational Product will be reimbursed on a pass-through basis upon receipt of supporting invoices from a third party vendor

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts include all applicable taxes.

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

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K. BUDGET TABLE

Visit	Total Cost Per Visit With IOH & Travel
S1	26654
S2	24197
T1	14060
T2	10123
T3	11083
T4	11083
T5	3094
T6	11083
T7	3094
T8	11083
T9	3094
T10	11083
T11	3094
T12	11083
T13	3094
T14	11083
T15	3094
T16	11083
T17	3094
EOS	24405
PT1	3094
TOTAL	212855
Off Treatment scheduled Telephone Visit	544

*Treatment Telephone visits and in-clinic visits occurring beyond T17 will be reimbursed at the same rate as T16 and T17

Sub Registrar
Jayanagar, Bangalore

DEPT. OF STAMPS & REGISTRATION INDIA R.0000100 PB6946

STAMP DUTY KARNATAKA

INVESTIGATOR CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this **26th day of Sep, 2017** by and between

Biocad India Pvt. Ltd. Registered office address: #163/C, 3rd Cross, 3rd Phase, JP Nagar, Bangalore-560078, Karnataka, India., duly represented by Mr. Krishnamurthy Rao, Managing Director **(herein after referred to as "Biocad")**

AND

Dr Mahesh kumar V Kalloli, KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi -590010 Karnataka, India.(hereinafter referred to as the "**Principal Investigator**" or "**PI**")

AND

KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi -590010 Karnataka, India (hereinafter referred to as the **"Institution."**)

AND

Genesis Research, 4/22, Near Apoorva Hospital Jadhavwadi, Kolhapur, Maharashtra. India

in connection with conduct of clinical trial - **"International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients"** bearing the protocol/study ID: BCD-021-02.

PI, institution and Biocad hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company responsible for execution of a clinical trial in **India.**

2. Biocad India is the Indian subsidiary of CJSC "BIOCAD" (Sponsor) which is a Russian biotechnology company, established in 2001. CJSC Biocad has both research and development and full cycle manufacturing facilities. Biocad India desires to engage the services of the PI to conduct/assist in this clinical trial ;

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219

3. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

1. Provision of Services

1.1 The services to be provided by the PI to Biocad are described in detail in the statement attached hereto and incorporated herein by references as **Exhibit A** (hereinafter referred to as "**the Proposal**").

1.2 The Study will be conducted at the Institution under the supervision and direction of the Investigator, wherein Investigator shall control any individual performing any portion of the Study at the Institution. Site will carry out Study-related laboratory services and investigations as may be required for the Study.

1.3 The PI will conduct various activities with respect to the Clinical Trial (hereinafter referred to as "**activities**") in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B)**
- All applicable International Conference on Harmonisation (ICH) Good Clinical Practice (hereinafter referred to as **"GCP"**) guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.

1.4 Biocad will provide the PI with all the information, documents, and materials which, in Biocad's reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.5 Biocad transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.6 Biocad will appoint a representative (hereinafter referred to as the **"Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)"**) to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Biocad and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Biocad may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

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220

1.7 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Biocad.

2. **Term**

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

3. **Termination and Consequences of Termination**

Termination:

3.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

3.2 Either Party may terminate this Agreement by written notice of **forty five (45) days** to the other Party without assigning any reason thereof and **with no penalty on either side**.

3.3 Either Party may terminate this Agreement by written notice of **thirty (30) days** in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

3.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 3.3 above.

3.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

3.6 Upon expiry or termination of this Agreement, Biocad shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Biocad to the PI under this Agreement exceed the project costs as set forth in the study Budget.

3.7 Upon expiry or termination of this Agreement, the PI shall, at Biocad' option, either immediately transfer to Biocad or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4. Intellectual Property Ownership, Invention & Discoveries and Publication

4.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor (Biocad) which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor (Biocad).

4.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the PI may publish data generated at their (own) site:

- only upon getting written approval from Sponsor and
- only after the first publication of such data by the Sponsor.

5. Representations; Indemnification

5.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

5.2 The PI will be covered by a professional indemnity of sufficient value as decided by Biocad, which shall be in force through out the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

6. Conflict of Interests

Site warrants that neither Institution nor Investigator has any conflict of interest that would affect the conduct of the Study. PI shall notify Biocad promptly and within twenty four (24) hours, if a conflict of interest arises during the term of this Agreement

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222

7. Payment

7.1 The total fees and expenses payable by Biocad to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B**.

7.2 This study is non-negotiable and includes all costs associated with the conduct of the study, including pharmacy fees, laboratory fees, dry ice, procedure cost, study coordinator/investigator fees, patient payments, all overhead charges and administrative fees.

7.3 Non Payment:
Unless and otherwise agreed in writing, Biocad India shall make no payment for patients whom the investigator entered into the study in violation of protocol (i.e, the patient is not a qualified participant)

7.4 Biocad shall pay the PI for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

7.5 Payment shall be made by account payee Cheque / DD only.

8. Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9. Arbitration

9.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore**.

10. Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

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223

11. Record Keeping

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

12. Review of Work, Audit

12.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Biocad.

13. Headings

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

14. Notices & Service of documents

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Biocad shall be addressed to:

Biocad India Pvt. Ltd.
#163/C, 3rd Cross,
3rd Phase, JP Nagar,
Bangalore-560078
Phone No. 080-41699773
Fax No. 080-41699773

All the correspondence/ notices to be sent by Biocad to PI shall be addressed to:

Dr Maheshkumar V Kalloli,
KLES Dr Prabhakar Kore Hospital and MRC,
Nehru Nagar,
Belagavi -590010
Karnataka, India

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224

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Genesis Research**	**Dr Maheshkumar Kalloli**	**Dr M.V Jali**
Seal:	**Seal:**	**Seal:**	**Seal:**
Witness	**Witness**	**Witness**	**Witness**

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Exhibit A

RESPONSIBILITIES OF PI:

INVESTIGATOR'S AGREEMENT FOR THE CLINICAL TRIAL - **"International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients"** bearing the protocol/study ID: **BCD-021-02**

1. I have sufficient time, adequate staff, and appropriate facilities to conduct and complete the Clinical Study. I agree to make these resources available for the duration of the study and agree that other Studies will not divert essential subjects or facilities away from this trial.

   I assure Biocad India Pvt. Ltd., that no other Clinical Study conducted by me shall give rise to a conflict of interest or interfere with the Clinical Trial.

   I will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Biocad India Pvt. Ltd. will furnish me with copies of the Investigator's Brochure and the Study Plan or Protocol and I agree:

   a) to become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and

   b) To become well acquainted with the Study Plan before signing it.

3. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the Study.

4. I understand that I shall have primary responsibility for the accuracy, legibility, and security of all Study data, documents, and subject records both during and after the Study. I will be responsible for signing the Case Report Forms (CRFs). Any alteration of the raw/source data shall be signed and dated, without obliterating the original entry.

   I agree to abide by the following conditions governing my handling of the data associated with this Study.

   a) I am required to maintain adequate records regarding all investigational product received and used by me including batch numbers, dates, and quantities. If the Study is terminated, suspended, discontinued, or completed, I

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226

shall return to Biocad India Pvt. Ltd., any unused supplies unless other arrangements are made by Biocad India Pvt. Ltd.

b. I am required to prepare and maintain adequate and accurate subjects, case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the Clinical Study.

c. I understand I am to furnish my records of the Study to Biocad India Pvt.Ltd.

d. I will maintain records of the disposition of the investigational product and other records for the duration longer than the following periods:

i. the period defined by national or local law and rules
ii. five years after the Study is terminated or computed, or
iii. five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
iv. To avoid any possible errors I will contact Biocad India Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. I agree to provide accurate information to the Ethics Committee upon request. I also agree to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and my ethical obligations, as set forth below:

1. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, I will make records related to the Clinical Study available for inspection and copying.

2. The subject's identity will not be released except under the following limited circumstances.

i) Where data verification procedures demand inspection of subject's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person.

3 The subject's identity shall not be released to third parties without the Subject's or subject's legal representative's prior consent. Accordingly, the study subject's or subject's legal representative's consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. I agree to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Biocad India Pvt. Ltd.

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227

I shall not commence the Study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the subject or the Subject's legal representative.

I shall provide the Ethics Committee or Institutional Review Board with all required information.

6. I certify that the investigational products for clinical investigation will be provided only to subjects under my personal supervision or under the supervision of the following sub-investigators responsible to me (add any additional names on a separate sheet, if needed):

Sub-Investigator 1: Dr Jyothi Hattiholi

I further certify that the investigational products will not be supplied by me to any investigator, other than those listed above as sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. I agree to be responsible for the personal safety and well being of the subjects. To this end, I agree to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature.

a) I will ensure that subject / subject's legal representative or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the subject / subject's legal representative.

The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

b) I will ensure that the subject / subject's legal representatives are given the opportunity to inquire about the details of the Clinical Study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the Clinical Study at any time without any sanction. I will make an effort to ascertain the reasons for any withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

Dr. V.A.Kothiwale
Registrar
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Belagavi-590 010,Karnataka

c) I will ensure that the subject / the subject's legal representatives are provided adequate time to decide whether or not they wish to participate / wish their ward to participate in this clinical investigation.

9. I will ensure that complete Case Report Forms (CRF) provided by Biocad will be completed promptly and accurately within 5 working days after the visit occurs at site and also ensure that any queries arising will be resolved within 3 working days.

10. I will discuss with Biocad India Pvt. Ltd. any question of modification of the Study Plan and obtain Biocad India Pvt. Ltd. written agreement and also approval from the ethics committee prior to implementation of any modification. I will not precede with a non-emergency deviation from the Clinical Protocol without approval from Biocad India Pvt. Ltd. and as needed the Ethics Committee. It is my responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Biocad India Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. I will report all adverse events to Biocad.

a. I will promptly report:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study subjects.
   - Changes increasing the risk to subjects and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) that is both serious and unexpected
   - New information that may affect adversely the safety of the subjects or the conduct of the study.

b. All staff in contact with the subject should be aware of their responsibility to note and report all adverse events reported by the Subjects / subjects legally acceptable representative.

c. The Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d All serious adverse events (SAEs) should be reported to Biocad within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the study subjects rather than by the subjects' names, personal identification numbers and/or addresses.

229

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g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Biocad according to the reporting requirements and within the time periods specified by Sponsor in the Protocol.

h. I will personally be responsible for, or I will appoint a sub-investigator (who has signed an Investigator Agreement and has been added to the Institution's, Biocad India Pvt. Ltd. and the Study Monitor's Investigator List) to be responsible for all Study related medical decisions.

i. I agree to personally conduct and/or supervise the clinical trial at my site. I may delegate some of the activities to the study staff, However all delegated activities will be my responsibility.

12. I will report all deviations from the protocol to Biocad India Pvt. Ltd. and the study monitor.

13. I will notify Biocad India Pvt. Ltd., immediately, but in no event in more **than five working days**, about withdrawal of approval by the reviewing Ethics Committee of my part of the Clinical Study.

14. I will comply with any request by Biocad India Pvt. Ltd. to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. I understand that Biocad India Pvt. Ltd. is required by law to discontinue shipments of investigational product to me if I fail to comply with the Study Protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

15. I agree to permit personnel from Biocad India Pvt. Ltd. and/or the Study Monitor/auditor to visit me and/or the Study Site to monitor my compliance with the protocol and/or audit the investigational records. To facilitate Biocad India Pvt. Ltd., or the Study Monitor's audit, I further agree to make records related to the Clinical Study available for inspection and copying.

16. I agree to maintain confidentiality regarding all information generated in the course of this Clinical Study. I further agree to ensure that the confidentiality of all information about subjects and the information supplied by Sponsor is respected by all persons, with the limitations discussed above.

17. I agree to submit and sign a Final Report of the Clinical Study within three months after termination or completion of the Clinical Study or of my part in the Clinical Study to the Ethics Committee.

I agree to abide by this Investigator Agreement.

Investigator Signature: _____

Date Signed: 4 OCT 2017

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230

Exhibit B: Proposal (Budget)

Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Biocad India Pvt Ltd. offers to pay the PI **Rs.3,50,250 which** will be paid per subject as per Annexure I who completes full study (complete all study visits and procedures as required by the protocol)
   This payment is inclusive of all patient related cost as well as non patient related cost such as all Overhead expenses, completion of case report forms, audits, Hospitalization and infusion charges, pharmacy fees and lab costs for testing {for example CBC, ECG, USG, CT Scan(contrast), Biopsies, as per protocol requirement}, patient travel costs, including unscheduled visits as per protocol, study/site staff fees. (Subject to deductions as per point No.4 below):

3. For Screening Failure, Rs. 9000 per patient (Investigations are reimbursed as per actuals) will be paid to PI which includes institutional overhead charges.

   Reimbursement will be not be made for any additional testing, treatment or procedures not required by the protocol, unless such additional testing, treatment or procedures are pre-approved by the sponsor.

Terms of Payment.

- Payment will be made after verifying completed case report forms and completion of Resolution of Data Clarification Form/ Data queries raised by Data Management for that respective visit.

- In case the patient does not complete the milestone visits then the payment would be made as per the earliest milestone visit.

- Payment to the PI on the above milestones will be made on monthly basis only by a crossed A/C Payee Cheque in favour of Genesis Research. No payment shall be made in cash.

- The final payment will be subject to a final reconciliation, meaning after (i) all subjects have completed the study, and the database has locked, (ii) all study specific queries and issues (including data queries) has been satisfactorily resolved. (iii) The site close out visit has been completed (including the return of all study drugs) and (iv) Study records have been received by sponsor.

4. The following deductions will be made, if applicable:
   - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.

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- Any capital expenses for the site incurred by Biocad on behalf of PI will be deducted from the fee payable to PI.

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao Managing Director Biocad India Private Limited	Genesis Research	Dr. Mahesh Kumar Kalloli	Dr M.V. Jali
Seal:	Seal	Seal	Seal:
Witness	Witness	Witness	Witness

232

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The Deccan Merchants Co-op. Bank Ltd.

Authorised Signatory

THE DECCAN MERCHANT CO-OP BANK LTD. BYCULLA BL. 354/364-A, BHEMA SADAN DR. A.BORKAR ROAD, BYCULLA (EAST) MUMBAI - 400 027

D-5/STP(V)/C.R.1093/02/10/710-14/10

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INDIA STAMP DUTY MAHARASHTRA

CLINICAL TRIAL AGREEMENT

STUDY TITLE:	A randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD)
STUDY CODE:	CP/11/15
DATE OF AGREEMENT: ("Effective Date")	23/01/2018
SPONSOR	
Name:	**Cipla Limited**
Address:	Cipla House Cipla Limited, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra, India 400013
PRINCIPAL INVESTIGATOR	
Name:	Dr. Jyothi Virupaxi Hattiholi
Address:	Assistant Professer, KLE's Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belagavi, Karnataka, India.
Contact Details:	Contact: 9164012011 Email Id: pulmojyoti@gmail.com Fax No: 081-2493099
PAN No:	
INSTITUTION (Hospital)	
Name:	KLE's Dr. Prabhakar Kore Hospital & Medical Research Center
Address:	Nehru Nagar, Belagavi, Karnataka, India.
Contact Details:	Contact No: 0831-2470400 Fax No: 0831-2493099
PAN No:	AABTK0881E

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233

This clinical trial agreement ("**Agreement**") is made between Cipla Limited ("**Sponsor**"), Dr. Vineet Kumar Shukla ("**Principal Investigator**" or "**PI**") and KLE's Dr. Prabhakar Kore Hospital & Medical Research Center ("**Institution**") as described above.

RECITALS:

WHEREAS, Sponsor is engaged in research and development, developing, manufacturing and marketing of pharmaceutical products and desires to conduct the Study;

WHEREAS, Principal Investigator is an employee of the Institution;

WHEREAS, Institution is a research institute engaged in conducting clinical trials for various pharmaceutical companies; and

AND WHEREAS, Sponsor is willing to engage the PI and Institution to conduct the Study on non-exclusive basis and Institution and PI are willing to carry out the Study on the terms and conditions set out in this Agreement.

NOW THEREFORE, the Parties agree as follows:

1. **DEFINITIONS:**

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

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

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

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

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

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

1.7. **GCP** means good clinical practices guidelines issued by the Central Drugs Standard

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Belagavi-590 010,Karnataka

234

Control Organisation (CDSCO), Directorate General of Health Services, Govt. of India and under Applicable Law;

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

1.9. **ICH-GCP** shall mean International Council for Harmonisation of technical requirements for pharmaceuticals for human use – good clinical practice guidelines;

1.10. **IEC** shall mean independent ethics committee of the Institution;

1.11. **Investigational Product** shall mean a pharmaceutical or comparator product being tested or used as reference in the Study;

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

1.13. **Party** shall individually mean Sponsor or PI or Institution;

1.14. **Parties** shall collectively mean Sponsor and PI and Institution;

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

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

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

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

1.19. **Study Site** shall mean the Institution facility located at Nehru Nagar, Belagavi, Karnataka, India.

1.20. **Study** means a randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD).

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

1.22. **Study Materials** means study related essential documents, source files, source documents, protocol, investigational brochure/pack insert, case report form, inform consent forms, patient information sheet, subject diaries, UPT kits, etc; and

1.23. **Subject** means a healthy volunteer enrolled in the Study;

2. SCOPE AND CONDUCT OF THE STUDY

2.1 Sponsor hereby engages the PI and Institution to conduct the Study on non-exclusive basis.

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

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

2.4 Institution shall perform the Study under the direct supervision and control of PI. If PI is unwilling or unable to perform the Study, Institution shall refer alternative investigator to Sponsor as replacement of PI and based on Sponsor's written approval, such investigator shall be engaged as PI for the Study.

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

3. SUBJECT RECRUITMENT:

3.1 PI and Institution shall enroll the Subjects in the Study after IEC approval.

3.2 PI and Institution shall ensure that all Subjects comply with Protocol requirements.

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

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

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

3.6 If a Subject suffers Study injury, PI and Institution shall notify Sponsor within 24 hours, however, PI and Institution shall be responsible to provide complete medical treatment to

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Belagavi-590 010,Karnataka

236

the Subject. Sponsor will bear actual medical expenses incurred by the PI and Institution for the Subject as a result of Study injury. In case of death of Subject due to Study injury, PI and Institution shall immediately notify the Sponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. RESPONSIBILITY OF PARTIES:

4.1 PI and Institution:

4.1.1 PI and Institution shall be responsible to conduct the Study at the Study Site.

4.1.2 PI thoroughly familiarizes himself with the appropriate use of Study Materials and Investigational Product as described in the Protocol, product monograph (if applicable), informed consent documents, Case Report Form and IPR;

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

4.1.4 PI and Institution shall provide preliminary and final reports to Sponsor as per the timelines specified in the Protocol.

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

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

4.1.7 Institution is responsible to ensure that its Representatives and PI conducting the Study under this Agreement are not debarred by the Regulatory Authority or under Applicable Laws.

4.1.8 Institution is responsible to provide necessary facilities, equipment and any other resources reasonably required to complete the Study.

4.1.9 Institution will ensure that the Study is subject to the continuing oversight of the PI and IEC throughout the Study Completion.

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

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

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

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

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

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237

4.2 Sponsor:

4.2.1 Sponsor will provide Study Materials to the PI and Institution for the purpose of conducting the Study.

4.2.2 Sponsor will share relevant information of Study Materials and Investigational Product with PI and Institution.

4.2.3 Sponsor will nominate a project coordinator to coordinate with the PI and Institution for the Study.

5. REGULATORY AUTHORITY

5.1 PI and Institution shall obtain IEC approval and Regulatory Authority clearance under Applicable Law as specified in the Protocol.

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

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

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

6. REPRESENTATION AND WARRANTIES

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

6.2 PI and Institution represents and warrants that they have relevant skill, experience, expertise, licenses and facilities to conduct the Study as required by Sponsor from time to time.

6.3 Institution represents and warrants that the processes and clinical tools used by PI to perform the Study herein does not infringe any patent, copyright, trade secret or other proprietary right of any third party.

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

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

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

7. INTELLECTUAL PROPERTY

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

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

PI and Institution agrees that all inventions, data, works, discoveries, technology and

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238

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

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

8. FEES

8.1 In consideration of the Study, Sponsor will pay the Fees to the PI and Institution on completion of relevant milestones as specified in **Annexure I, II and III**

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

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

8.4 All payments made by Sponsor to Institution shall be subject to tax deduction at source. Service tax, at applicable rates, shall be paid extra by Sponsor

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

Payee details:

PAYEE NAME:	CMS Clinical Research Pvt Ltd.
PAYEE ADDRESS:	E- 285, First Floor Greater Kailash -2, M-Block Road, New Delhi- 110048
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAFCC8457M

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239

BANK ACCOUNT NUMBER	50200007478582
BANK NAME	HDFC Bank
BRANCH NAME	Hyderabad
SWIFT/IFSC CODE	HDFC0000368

9. **PUBLICATION:**

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

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

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

9.4 Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a journal without further obligation to the PI and Institution or discloser. All communications in relation to the Study such as press releases or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

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

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

10.3 In the event PI and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, PI and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek

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240

protective order or other appropriate remedy to minimize disclosure and PI and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

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

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

10.6 All obligations contained in Section 10 shall survive the expiry or early termination of this Agreement and the Parties shall remain bound by the same at all times.

11. INDEMNITY:

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

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

12. TERM

This Agreement shall commence from the Effective Date and shall be valid for a period of 1year or on Study Completion or unless sooner terminated by Sponsor in accordance with clause 13, whichever is earlier. Parties may renew this Agreement upon mutually agreed terms and conditions.

13. TERMINATION

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

a. without cause at any time by giving seven (7) days' prior written notice to the other.
b. in the event of breach by PI and Institution that is not cured within thirty (30) days from the date of written notice by Sponsor.
c. immediately, if PI and Institution fails to obtain Regulatory Authority clearance;
d. immediately, if Institution becomes insolvent or files for bankruptcy.
e. in the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

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241

13.2 If this Agreement is terminated by Sponsor and/or PI and Institution:

a. Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.
b. PI and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.
c. Should Sponsor retain a third party for completion of the Study, then PI and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

14 INSURANCE

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

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

15 NOTICE

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

15.2 Any such notices be deemed to have been received;
-if delivered personally at the time of delivery;
-in the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt to the address mentioned below.

The addresses and fax numbers of the Parties for any written notice are as follows:

Sponsor

Address: Cipla House, Cipla Limited, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra, India 400013

Attention: Dr. Jaideep Gogtay

Fax No: 022-24816910

PI

Address: Assistant Professor, KLE's Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belagavi, Karnataka, India.
Attention: Dr. Jyothi Virupaxi Hattiholi
Fax No: 0831-2493099

Institution

Address: KLE's Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belagavi, Karnataka, India.
Attention: 0831-2470400
Fax No: 0831-2493099

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242

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

16 GOVERNING LAW AND DISPUTE RESOLUTION

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

16.2 The Parties agree that any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which any dispute or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof shall be governed exclusively by the laws of India with exclusive jurisdiction of courts of Mumbai.

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

17 General Provisions

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

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

17.3 PI and Institution shall not assign this Agreement to any person, without prior written consent of Sponsor.

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

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

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

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

[Signature Page Follows]

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243

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

For Cipla Limited

Signature

Name: Dr. Jaideep Goglay

Title: Sr. Vice President, Global Chief Medical Officer

For Cipla Limited

Signature

Name: Mr. Saurabh Maheshwari

Title: Associate Director Finance

By PI

I, Dr. Jyothi Virupaxi Hattiholi, the PI, acknowledge that I have read and understood the terms and conditions of this Agreement and accept to be bound personally as agreed in this Agreement. I, also agree to use all reasonable endeavors to enable the Institution to comply with its obligations under this Agreement.

Signature: _____
Name: Dr. Jyothi Virupaxi Hattiholi

For Institution

Signature

Name:

Title: Medical Director & Chief Executive
KLES Dr Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

244

ANNEXURE - I
Project Timelines

Task	Tentative Periods
First Patient In	Within one week of initiation
Last Patient In	After two months of initiation
Last Patient Last Visit	After four months from last patient in
Data base lock	After 1 months from Last Patient Last Visit
Site Closeout Visit	Within one month of data base lock
Signing Of Study Report	Within two months of close out
Proposed Principal Investigator Involvement	10 to 12 months from initiation

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245

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ANNEXURE II

Payment Details

Investigators Fees

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Total
	SCR-1	SCR-2	Week 0	Week 2	Week 4	Week 8	Week 12	
Investigator	1500	1500	1000	1000	1000	1000	1500	8500
Co-Investigator	700	700	500	500	500	500	700	4100
CRC Fees	500	500	500	500	500	500	500	3500
Total	2700	2700	2000	2000	2000	2000	2700	16100

Pass-through Expense on actual								
Spirometry		800	800	800	800	800	800	4800
X-ray	350							350
ECG	200		200	200	200	200	200	1200
Patient TA	500	500	500	500	500	500	500	3500
Total	1050	1300	1500	1500	1500	1500	1500	9850

A	Investigator and Team Fees	16100
B	Institution Overhead 20% of investigator's fees	3220
C	Site Pass-through expense	9850
D	Internet & logistic expense	1500
D	Cost per subject (A+B+C)	30670

- Total cost for 20completed subjects: 20*D: Rs 6,13,400/- (Six lakh thirteen thousand four hundred Indian rupees only).
- GST will be applicable as per government of India tax laws (GST number/ Certificate will be provided by site)

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246

Additional payments

- For any screen failure of a Subject, Fees would be paid as per the actual cost incurred at the end of the study.
- Number of screen failures should not exceed 15% of the total number of patients recruited at the center.
- Institutional Ethics Committee of KLE's Dr Prabhakar Kore Hospital & Medical Research Center review charges: Rs 75000/- (GST 18%) will be paid in favor of **The Registrar KLE University, Nehru Nagar Belagavi-590010.**
- Overhead charge will be calculated based on enrolled subject and number of visit completed by the subjects and will be paid collectively at the end of the study
- Archival charges will be paid after generation of original Invoice up to maximum INR 5000 per year (after closeout of study).

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247

ANNEXURE III

Payment Schedule

Installment	Time of payment of the grant	% of Total Grant
First	Site initiation	10%
Second	10 Patient completed screening visit 2	10%
Third	07 patients randomized or 18 patient completed screening visit 2	10%
Fourth	15 patients randomized or 20patient completed screening visit 2	10%
Fifth	20 patients randomized	10%
Sixth	7 patients completed	10%
Seventh	15 patients completed	10%
Eighth	20 patients completed	15%
ninth	Data base lock	10%
tenth	CSR sign off	05%
Total		**100%**

For **Cipla Limited**

Authorized Signatory

Cipla Limited

Accepted and agreed to by the Principal Investigator

Signature: _____
Name: Dr. Jyothi Virupaxi Hattiholi

For Institution

Signature _____

Name: Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

Title:

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Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 30th day of Oct 2017 between **1) Dr. Jyothi Hatthioli ("Investigator"), Consultant Pulmonologist at KLE's Dr. Prabhakar Kore Hospital** and **2) KLE's Dr. Prabhakar Kore Hospital** ("**Institution**") both having its address at **KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India 3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business** ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

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

PROTOCOL NUMBER:	RLS/RES/2016/01
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022 / Xolair® in patients with moderate to severe persistent asthma.
STUDY PRODUCT:	*R-TPR-022 / Xolair®*
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Jyothi Hatthioli**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/RES/2016/01** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

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WHEREAS the Institution has engaged **Genesis Research** a Site Management Organization of **KLE's Dr. Prabhakar Kore Hospital & M.R.C.**, authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

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d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

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c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 **New findings.** Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization**:

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

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transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses.

The Investigator shall retain the Records of the Study, including either the original of all volunteer consent forms, for the longer of:

(i) two (2) years after the date of the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the Study Product in the indication being investigated.

(ii) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(iii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

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7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. **Subject Injury Reimbursement**

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 122 DAB of Drugs and Cosmetics Rules 1945 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. **Inspection and Debarment.**

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from

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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

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

iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

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

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or

(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or

(iii)any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,

(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or

(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;

b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.

c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and

d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and

e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

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Belagavi-590 010,Karnataka

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

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Belagavi-590 010,Karnataka

13. **Insurance:** Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts:** During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name:** Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

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

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and

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Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 30 Oct 2017

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Jyothi Hatthioli

Title: Consultant Pulmonologist

Date: 4th Nov 2017

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. M. V. Jali.

Title: KLE's Dr. Prabhakar Kore Hospital & M.R.C.

Date: 11 Nov 2017

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 14 Nov 2017

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Belagavi-590 010,Karnataka

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research** in Indian Rupees.

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

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory

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Belagavi-590 010,Karnataka

documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

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Belagavi-590 010,Karnataka

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/RES/2016/01**

Investigational Product: R-TPR-022

Clinical Trial Budget		
	Project Name:	Omalizumab
	Project Code	K068
	Name of PI	Dr. Jyothi
		Unit Cost/Visit
Investigator fees		
	Principal Investigator	4,000
	Clinical Research Coordinator	1,200
	Unblinded Pharmacist	300
	Phlebotomist	200
Patient related expenses		
	Travel reimbursement	300
	Hospitalization charges	10,000
	Consumables	100
Administrative overhead-20%		1,040
Laboratory Testing Charges		
	Name	Cost
	Investigation	
1	Skin Prick test	450
2	Lung Function Test	800
3	12 lead ECG	350
4	Chest X Ray	500
Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study. Skin Prick Test Charges are per patient and kits will be provided by Reliance		

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Belagavi-590 010,Karnataka

er Visit Payment schedule:

Budget for 2 weekly dosing schedule						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		5200	2100	300	1040	8640
Day 0/Week 1	0 hrs	5700	800	10400	1140	18040
	12hrs	200	0	0	40	240
	24 hrs	200	0	0	40	240
Day 2	48 hrs	200	0	300	40	540
Day 3	72 hrs	200	0	300	40	540
Day 4	96 hrs	200	0	300	40	540
Day 5	120 hrs	200	0	300	40	540
Day 7	168 hrs	200	0	300	40	540
Day 9	216 hrs	200	0	300	40	540
Day 12	288 hrs	200	0	300	40	540
Day 15	360 hrs	200	0	300	40	540
Day 22	528 hrs	200	0	300	40	540
Day 30	720 hrs	200	0	300	40	540
Week 2		5700	800	400	1140	8040
Week 4		5700	800	400	1140	8040
Week 6		5700	800	400	1140	8040
Week 8		5700	1150	400	1140	8390
Week 10		5700	800	400	1140	8040
Week 12		5700	800	400	1140	8040
Week 14		5700	800	400	1140	8040
Week 16		5700	1150	400	1140	8390
Week 18		5500	800	400	1100	7800
Week 20		5500	800	400	1100	7800
Week 22		5500	800	400	1100	7800
Week 24		5500	1150	400	1100	8150
Week 26		5500	1150	400	1100	8150
TOTAL		86400	14700	18900	17280	137280
					CGST (9%)	0
					SGST (9%)	0
					IGST (18%)	24710
					Total budget per subject	161990

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Belagavi-590 010,Karnataka

268

Budget for 4 weekly dosing schedule						
Visit	Sub visit	Investigator fees	Laboratory Tests	Patient related expenses	Administrative Overheads	TOTAL
Screening		5000	2100	300	1040	8440
Day 0/Week 1	0 hrs	5600	800	11200	1140	18740
	12hrs	200	0	0	40	240
	24 hrs	200	0	0	40	240
Day 2	48 hrs	200	0	300	40	540
Day 3	72 hrs	200	0	300	40	540
Day 4	96 hrs	200	0	300	40	540
Day 5	120 hrs	200	0	300	40	540
Day 7	168 hrs	200	0	300	40	540
Day 9	216 hrs	200	0	300	40	540
Day 12	288 hrs	200	0	300	40	540
Day 15	360 hrs	200	0	300	40	540
Day 22	528 hrs	200	0	300	40	540
Day 30	720 hrs	200	0	300	40	540
Week 4		5600	800	400	1140	7940
Week 8		5600	1150	400	1140	8290
Week 12		5600	800	400	1140	7940
Week 16		5600	1150	400	1140	8290
Week 20		5400	800	400	1100	7700
Week 24		5400	1150	400	1100	8050
Week 26		5400	1150	400	1100	8050
Total		51600	9900	17300	10520	89320
					CGST (9%)	0
					SGST (9%)	0
					IGST (18%)	16078
					Total budget per subject	105398

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Belagavi-590 010,Karnataka

269

: R-TPR-022
l No: RLS/RES/2016/01

Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll 10 patients. The payment schedule would be done as per the actual dosing regimen only i.e.02 weekly or 04 weekly to maximum of INR 161990 only.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

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CLINICAL TRIAL AGREEMENT STAMP DUTY KARNATAKA

PROTOCOL:

Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1 Infection

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

ECRON ACUNOVA LIMITED (FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED), a company incorporated under the Companies Act, 1956 having its Registered Office at Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore – 560 066, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Dnyanesh N Morkar, the **Principal Investigator** presently employed at **KLEs Dr Prabhakar Kore Hospital and MRC** (hereinafter referred to as the "Principal Investigator" which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

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

AND

Genesis Research situated at **4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005** (hereinafter referred to as the "SMO" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

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

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271

Whereas, **Mylan Pharmaceuticals Private Limited (MPPL)** (hereinafter referred to as the "**Sponsor**") through its representative CRO desires the Institution to study Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

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

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

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

1. THE STUDY AND THE PROTOCOL

The study of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) (the "**Study Drug**") shall be conducted, under the direction of the Principal Investigator, in the treatment of patients ("**Subjects**") in accordance with this Agreement and the protocol identified as Protocol ID No MYL -TLE 400 - 4001and entitled "Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1Infection" a copy of which is attached hereto as Exhibit A (the "**Protocol**"), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the "**Study**"). The Study will be monitored by the CRO as per the Protocol.

A. The Principal Investigator represents and warrants that he is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of the curriculum vitae and other relevant documents requested by the Sponsor, the Ethics Committee, CRO and the Regulatory Authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled throughout the duration of the Study. The Principal Investigator should also ensure that he does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

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272

B. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study services hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution and Principal Investigator. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study. In any event, if the Principal Investigator is unable to perform the obligations of Study or suspends or abandons or is unwilling to continue with the Study, CRO and Institution shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, in such case, the Study may be terminated at the option of the CRO for andon behalf of the Sponsor or by the Sponsor.

C. **Conditions precedent.** The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the Reference-listed Product with full prescribing information, and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Site under the supervision and direction of the Principal Investigator, who will be the Principal Investigator for the Study.

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

2. THE STUDY SCHEDULE

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

B. Enrollment. Principal Investigator shall be responsible for recruiting eligible Subjects to the Study. Principal Investigator shall use the best efforts to recruit the Subjects and ensure unbiased selection of suitable Subjects in accordance with the terms of Protocol. Principal Investigator will enroll minimum 10-12 Subjects (as per the randomization schedule) and not more than 40-50 Subjects (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the CRO, or the Sponsor's designee, that, in the sole determination of the CRO:

i. the Complete Study enrollment has been achieved; or

ii. the CRO and Sponsor have placed the Study on hold, for any reason; or

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

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under Applicable Laws and Requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. Study Documentation. Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three to five (3 to 5) working days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three to five (3 to 5) working days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three to five (3 to 5) working days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the CRO and Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. There will be no paper Data Clarification Forms Queries ("DCFs"). Site staff will have to enter the eCRF and resolve the same within **three (3) working days** of its receipt. Only in case of urgent requirement of safety data, safety vendor may contact the site to request the safety data which should be contacted as early as possible.

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

Study Completion. The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than five days after the last Subject visit. In any event, Institution and Principal Investigator shall not publish or present interim or preliminary results of the Study at any time without the prior written approval of CRO and Sponsor.

3. PAYMENT

A. Budget and Payment Schedule: In consideration of the Services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the **"Budget and Payment Schedule"**). Payment shall be made by cheque. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

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274

B. Payment of Costs outside Budget and Payment Schedule. Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

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

The foregoing notwithstanding:

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

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

The mailing address for checks shall be:

The further details for the payments should be provided as

1. **Cheque in the favor of: Genesis Research**
2. **PAN Number: CQJPP0528D**
3. **Name of Bank: State Bank of India**
4. **Branch: Market Yard, Kolhapur**
5. **Account No: 36599680134**
6. **Branch Code: 001887**
7. **IFS CODE : SBIN0001887**

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

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F. Payments for Screen Failure: CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 5:1 i.e. maximum one screen failure per five randomized Subjects.

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

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Goods and Service Tax (GST) will be paid, if applicable, on generation of valid tax invoice showing the amount of GST to be charged before any payment is made under this Agreement

The parties acknowledge that the designated Payee is authorized to receive all the payments for the services performed under this Agreement. Investigator acknowledges that if Investigator is not the Payee, CRO will not pay Investigator even if the Payee fails to reimburse Investigator.

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

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

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

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276

Agreement to any other individual or entity without the prior written consent of the CRO. The Principal Investigator shall be responsible for responding promptly, in writing, to all issues and questions raised by regulatory agencies relating to the performance of the Study

C. Patient consent and entry into Trial. As well as complying with the requirements of the Declaration of Helsinki, the principles of Good Clinical Practice [and other legislation appropriate to clinical trials, medical treatment, and the processing of personal and medical data], the Investigator shall, before entering a patient into the Trial:

i. exercise independent medical judgement as to the compatibility of each prospective Patient with the requirements of the Protocol;

ii. advise the CRO of all instances in which, in the Investigator's judgement, there is any question as to any prospective Patient's suitability for participation in the Trial, and abide by the Sponsor's decision as to whether or not to enrol that Patient;

iii. ensure that, before their participation in the Trial, the Patients are duly informed about all aspects of the Trial that are relevant to them, including:

iv. the purpose, duration, nature, significance, implications, and risks of the Trial; and

v. the processing, auditing, and monitoring of data (including personal data) under this Agreement.

vi. ensure that, before his or her participation in the Trial, each Patient has given his or her Informed Consent on the basis of the information described in Clause 2.5(c) by signing a consent form in accordance with the Protocol;

vii. acknowledge that the use of the consent form does not release the Investigator from his or her legal and contractual obligations relating to Informed Consent, and that it remains the Investigator's responsibility to ensure that those obligations are complied with;

viii. comply with the procedures described in the Protocol in relation to that Patient; and

ix. provide details of the proposed Patient to the CRO.

D. Key Personnel. The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the CRO and/or Sponsor's designee and the CRO and/or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the CRO may terminate this Agreement as set forth in Clause 12(B) below.

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

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277
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the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

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

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

G. Study Records, Reports, and Data.

i. *Study Records*. The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice

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("**Study Records**"). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of seven (7) years after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ Sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the Study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data. In no event, shall Institute and Principal Investigator remove any Study Records or destroy any Study Records without the prior written consent of CRO and Sponsor.

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

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

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

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of Study Records.Sponsor and CRO will help to find vendor for archival of study records.

H. Reporting of Serious Adverse Event.

- In 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.

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279

- In the event of a trial related injury or death, CRO (as a representative of the sponsor) on behalf of Sponsor shall provide financial compensation for the injury or death.

- Neither CRO nor Sponsor will be responsible for, and Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any loss, damage, liability, claim, cost (including reasonable attorney fees) or demand arising from any injuries or damages resulting from negligence, failure to adhere to the Protocol, failure to comply with Applicable Laws, failure to obtain informed consent, unauthorized warranties made by, breach of this Agreement or willful misconduct or omission of Site or any Site Personnel in performing their obligations under this Agreement.

- Sponsor will promptly inform Site, Site's Institutional Review Board/EC, and CRO, of any finding that could affect the safety of subjects or their willingness to continue participation in the Study, influence the conduct of the Study, or alter Site's IRB/EC approval to continue the Study. Site shall promptly, in accordance with Applicable Laws, advise Sponsor and CRO of any Adverse Event occurring during the conduct of the Study that it becomes aware of. In the event of the occurrence of any serious Adverse Event, Site shall notify CRO and Sponsor or its designee by fax and/or other electronic means within twenty-four (24) hours of the occurrence.

- The recording of Adverse Events is an important aspect of study documentation. It is the Investigator's responsibility to document all Adverse Events according to the detailed guidelines of the Protocol. The Investigator agrees to answer any questions of Sponsor/CRO's medical monitor concerning any Adverse Events.

- The Investigator must immediately report all Serious Adverse Events ("SAE") (as defined in the Protocol) (within 24 hours of occurrence of SAE) to the DCG (I), Sponsor and Ethics Committee which occur since informed consent is signed, during the course of the Study and up to the date of the subject's last visit.

- The Investigator shall forward a due analysis report to DCG (I), Ethics Committee and Head of the Institute within fourteen (14) days of occurrence of SAE including all initial information and follow-up information until stabilization/ resolution of the SAE.

5. CONFIDENTIALITY

A. Confidential Information. The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution, SMO or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution, SMO or the Principal Investigator as required by the Protocol

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280

and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

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

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

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

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

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

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

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of preventing any existing or anticipated breach of the terms of confidentiality under this Agreement.

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

Dr. V.A.Kothiwale
Registrar
281
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

requirements, or (ii) prevent Institution, SMO and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. Non-Disclosure and Non-Use. Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

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

E. The PI and Institution hereby acknowledge and agree that in accordance with the applicable laws and codes, and in particular with any transparency obligations contained therein, certain value transfers between pharmaceutical companies and healthcare professionals and/or healthcare or academic institutions or hospitals, are subject to mandatory publication. The Parties acknowledge that, in accordance with said obligations the Sponsor is responsible for the publication of the relevant information in the appropriate format and within the applicable timeframe. Such information shall at least include the amount, purpose and recipient of the value transfers. The PI and Institution hereby explicitly agree with such publication by Sponsor, provided the publication is in accordance and strictly limited to the requirements of the said laws and codes, and does not go beyond the requirements of the applicable privacy laws.

6. Protection. Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure

282

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

or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish information arising from his/her participation in the Study, the prior written approval from Sponsor is required.

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

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

B. Patents and Inventions.

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

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

iii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor. Institution and Principal Investigator shall assign and transfer to Sponsor without further consideration, the

283

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

entire right, title and interest globally in all Sponsor Intellectual Property of any New Inventions made or any process carried out in the name of Sponsor. Institution and Principal Investigator acknowledge that all original works of authorship made whether by Institution and Principal Investigator under this Agreement are "works made for hire" and assist Sponsor in obtaining patent or other intellectual property protection.

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

v. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

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

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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

284

criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

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

B. <u>Of the CRO.</u> The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms. CRO represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) CRO has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration of drugs and devices

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

285

under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular CRO shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

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

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

10. GOVERNING LAW

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

11. INDEMNIFICATION

A. CRO Indemnification.The CRO shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents harmless against all notices, claims, demands, action, suits or proceedings given, made or initiated against the CRO due to a) Breach of responsibility of the CRO; b) Willful negligence; c) Willfulmisconduct or misrepresentation d) breach of representation and warranties and confidentiality obligations under this Agreement (e) CRO's Negligence (f) Breach of Applicable Law.

B. Institution Indemnification. The Institution shall defend, indemnify, and hold harmless the CRO/Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**CRO Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the CRO Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the CRO concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner

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

286

required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnitee, or any other person on the Institution's property or under its control, exclusive of the CRO's employees and (iii) (a) breach of any terms of the Agreement and the representations and warranties made by Principal Investigator or Institution jointly and / or severally.

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

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

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

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

12. INSURANCE

A. Parties represent and warrant that they possess and shall maintain, for the duration of the Agreement and thereafter, at its own expenses, insurance coverage for their respective services in the performance of the Study. Each Party shall provide the other Party with proof of insurance upon request.

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

This Clause 12 shall survive termination of this Agreement.

287

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. TERM AND TERMINATION

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

B. Termination.

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

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

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

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

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

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

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

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

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

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

b. Reasonable non-cancelable obligations (as evidenced in writing) properly incurred for the Study by Institution prior to the effective date of termination.

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

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

vii. Effect of Termination. In the event this Agreement is expired or terminated prior to completion of the Study, for any reason, the Principal Investigator shall: a) notify the

IRB/IEC that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the CRO to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the CRO's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes and shall make no further use of, all Sponsor Confidential Information, and any other records, data, materials and information that are the property of Sponsor. The CRO shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement. Notwithstanding any termination or expiration of the Study or this Agreement, Institution shall remain responsible for compliance with all obligations under Applicable Laws and other requirements as per this Agreement with regards to disposition of the Study Materials.

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

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

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

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR

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

289

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

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

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

15. MISCELLANEOUS

A. Use of Names; Publicity. Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its staff/employees, agents in any advertisement or sales promotional material or in any publication, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Section 7 herein). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement even existence of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances and ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. Independent Contractors. The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and shall not to be considered as partner, agent, employee, or representative of CRO or the Sponsor. That neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. Limitation of Liability. In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.CRO expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product.

290

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

Any notice to Sponsor shall be addressed as follows:

Address	: **Mylan Pharmaceutical Private Limited, 7th-12th Floor, Prestige Platina Tech Park, Block 3, Kadubeesanahalli, Outer Ring Road, Bangalore-560087**
Attention	: **Dr Sanjeev Hegde**
Title	: **Associate Vice President**
Phone	: **+91 7349635726**
Fax	: **NA**

Any notice to Institution shall be addressed as follows:

Address	: **KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi 590010**
Attention	: **Dr M.V. Jali**
Title	: **Head of the Institution**
Phone	: **+91 9844032499**
Fax	: **+91 8312470732**

Any notice to Principal Investigator shall be addressed as follows:

Address	: **KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi. 590010**
Attention	: **Dr Dnyanesh N Morkar**
Title	: **Principal Investigator**
Phone	: **+91 9448231298**
Fax	: **+918312493099**

Any notice to SMO shall be addressed as follows:

Address	: **4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005**
Attention	: **Mr. Satyajit Patil**
Title	: **Manager**
Phone	: **+91 9762881140**
Fax	: **NA**

Any notice to CRO shall be addressed as follows:

Name of CRO	: **Ecron Acunova Limited (Formerly known as Manipal Acunova Limited)**
Address	: **Mobius Tower, SJR- I Park, EPIP, Whitefield, Bangalore-560066**
Attention	: **Dr. Ayaaz Hussain Khan**
Title	: **Managing Director**
Phone	: **080 6691 5700**

291

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

Fax : 080 6691 5719

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

F. Modification; Waiver. This Agreement may not be altered, amended or modified in any way except in writing signed by the CRO, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right. Parties shall not delegate or subcontract its duties under this Agreement without prior written consent of the CRO/Sponsor

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

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

I. Execution. The Institution's IRB/IEC shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile or other electronic signature.

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

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

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

FOR AND ON BEHALF OF INSTITUTE

By:

(Signature and Date)

NAME: DR M.V. JALI

FOR AND ON BEHALF OF SMO

By:

(Signature and Date)

NAME: MR. SATYAJEET PATIL

FOR AND ON BEHALF OF
ECRON ACUNOVA LIMITED
(FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED)

By: S. Nageswari 27 Dec 2017

(Signature and Date)

DR. NAGESWARI SANTOSH

NAME:

AND

By: Y R Sachin 27 Dec 2017

(Signature and Date)

Y. R. SACHIN KUMAR HOLLA

NAME:

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

293

ECRON ACUNOVA LTD Bangalore

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

PRINCIPAL INVESTIGATOR

By:_____

(Signature and Date)

NAME: DR. DNYANESH N MORKAR

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: PROTOCOL

As annexure 1

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Dr. V.A.Kothiwale 295
Registrar
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EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : **Dr. Dyanesh N Morkar**

Site Address : **KLES DR Prabhakar Kore Hospital and MRC, Nehru Nagar, belagavi-590010**

PAYMENT SCHEDULE

Payment Schedule for the total study Grant of **INR 990520** for **15** patients is as follows:

Overall Per Patient Budget

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Includes the following 1. Professional fees: PI and site team payment including Co- Investigator (s), Site coordinator(s), Nurse(s), as applicable	40800	612000
2. Procedural Charges	6400	96000
3. Institutional Over Head (IOH) charges 20% on Procedural Charges and Professional Charges	9440	141600
4. Patient Travel Reimbursement	3000	45000
Total Amount (INR)	59640	894600

Other payments includes

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Screen Failure	8240	24720 (Considering 3 subjects)
Study Start-up		40000
Archival Charges		30000
Digital Hygrothermometer		1200

Dr. V.A.Kothiwale 296
Registrar
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Investigator Site Budget estimate - TLE 400mg							
	Screening	Baseline	Week 4	Week 12	Week 24	Week 28	
Investigator fees	4000	5000	4000	4000	4000	5000	26000
Study Coordinator	1500	2000	1500	1500	1500	2000	10000
Phlebotomist	300	500	500	500	500	500	2800
Hospitalization for PK sampling	0	4000	0	0	0	0	4000
PK sampling-Professional fees	0	1000	0	0	0	0	1000
PK sampling-Phlebotomist	0	1000	0	0	0	0	1000
12 lead-ECG	300	0	0	0	0	300	600
PT and INR	250	250	250	250	250	250	1500
UPT	100	100	0	0	0	100	300
Total (Visit Wise)	6,450	13,850	6,250	6,250	6,250	8,150	47,200
IOH 20%							20%
IOH							9440
Patient Travel Reimbursement	500	500	500	500	500	500	3000
Grand Total/subject							59,640
No of subjects planned**	15	15	15	15	15	15	
Estimated Amount/ Total subjects	96,750	2,07,750	93,750	93,750	93,750	1,22,250	7,08,000
IOH 20%							1,41,600
Patient Travel Reimbursement	7,500	7,500	7,500	7,500	7,500	7,500	45,000
Grand Total/ Total subject/site							8,94,600

Summary of Budget/Payments:

Table A:

Details	Per Patient Grant	For 15 patients
Procedural Charges	6400	96000
Professional Charges	40800	612000
IOH 20% on Procedural Charges and Professional Charges	9440	141600
Patient Travel Reimbursement	3000	45000
Grand Total	**59640**	**894600**

Table B: Screening Failure

Details	Per Screen Failure	For 3 patients
Screening	6450	19350
IOH 20% on Screening	1290	3870
Patient Travel Reimbursement	500	1500
Total	8240	24720

Table C:

Details	Charges
Study start up	**40000**
Archival Charges	**30000**
Digital hygrothermometer	**1200**

Details	Grand Total	Total # of subjects	Per Patient grant
	990520	15	**66035**

Dr. V A Kothiwale 298
Registrar
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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. Non- Refundable Study startup cost INR. 40,000/- will be paid after SIV
2. CRO will pay only INR. 8240/- amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).
3. The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.
4. A Non- refundable amount of INR 30,000/- will be paid to the site as Archival fees after Site Close-out Visit. The duration of archival will be for 3 years after site close out visit. After completion of 3 years of archival, the PI is responsible to consult Mylan for further instructions to transfer the study documents from site to the Archival facility as per Mylan confirmation. Ecron will be responsible for arranging the pickup and ensure the delivery of these documents from Site to the Archival facility.
5. Discontinued or Early Termination Patients: Discontinued or early termination patient will be reimbursed based on the number of confirmed completed visits and the eCRF completion.
6. Reimbursement of Clinical Trial Subjects: Clinical Trial Subjects are reimbursed for their travelling to site either according to pertinent receipts or by paying them an expense flat charge of INR 500/- (in words: Five hundred only)

Payment Adjustments

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

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

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299

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

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

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

Invoices:

Invoices shall include the heading "study code (EA-CT-17-004) or Protocol ID (MYL -TLE 400 -4001)". They shall be sent from site to CRO on a regular basis and shall be addressed to
Send invoices to:

Contact Person: <<Name of the Study Project Manager>>
Address : Ecron Acunova Limited, Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore - 560 066. India .

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.
Payments under this Agreement shall be made upon receipt of an appropriate invoice.

Final Payment

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

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 screening, baseline, week 4, week 12, week 24 and end of study. 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. 50 % of the total amount of the last invoice 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.

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6. Payee represents that the services it provides under this Agreement are taxable service under the laws governing in India, and that it is required to charge taxes as per the applicable laws, as may be amended from time to time depending on the change in tax regulations.
7. 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.
8. Reimbursement of Meetings: The Sponsor shall reimburse the Investigator upon prior written approval for reasonable expenses on travelling and lodging which occurred through his/her participation in meetings on request of the Sponsor.

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CLINICAL TRIAL AGREEMENT STAMP DUTY KARNATAKA

PROTOCOL:

Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1 Infection

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

ECRON ACUNOVA LIMITED (FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED), a company incorporated under the Companies Act, 1956 having its Registered Office at Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore – 560 066, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Dnyanesh N Morkar, the **Principal Investigator** presently employed at **KLEs Dr Prabhakar Kore Hospital and MRC** (hereinafter referred to as the "Principal Investigator" which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

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

AND

Genesis Research situated at **4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005** (hereinafter referred to as the "SMO" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

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

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Belagavi-590 010,Karnataka

302

Whereas, **Mylan Pharmaceuticals Private Limited (MPPL)** (hereinafter referred to as the **"Sponsor"**) through its representative CRO desires the Institution to study Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

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

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

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

1. THE STUDY AND THE PROTOCOL

The study of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) (the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No MYL -TLE 400 - 4001and entitled "Multicenter, Open-Label, Randomized, Prospective Phase IV, Interventional, Non-Inferiority Study with Blinded Assessment, to Evaluate the Efficacy and Safety of Fixed Dose Combination (FDC) of Tenofovir/Lamivudine/Low dose Efavirenz (300/300/400mg) Vs FDC of Tenofovir/Lamivudine/Efavirenz (300/300/600mg) in Adult Indian Patients who have HIV-1Infection" a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored by the CRO as per the Protocol.

A. The Principal Investigator represents and warrants that he is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of the curriculum vitae and other relevant documents requested by the Sponsor, the Ethics Committee, CRO and the Regulatory Authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled throughout the duration of the Study. The Principal Investigator should also ensure that he does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

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Belagavi-590 010,Karnataka

303

B. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study services hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution and Principal Investigator. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study. In any event, if the Principal Investigator is unable to perform the obligations of Study or suspends or abandons or is unwilling to continue with the Study, CRO and Institution shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, in such case, the Study may be terminated at the option of the CRO for andon behalf of the Sponsor or by the Sponsor.

C. **Conditions precedent**: The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the Reference-listed Product with full prescribing information, and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Site under the supervision and direction of the Principal Investigator, who will be the Principal Investigator for the Study.

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

2. THE STUDY SCHEDULE

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

B. Enrollment. Principal Investigator shall be responsible for recruiting eligible Subjects to the Study. Principal Investigator shall use the best efforts to recruit the Subjects and ensure unbiased selection of suitable Subjects in accordance with the terms of Protocol. Principal Investigator will enroll minimum 10-12 Subjects (as per the randomization schedule) and not more than 40-50 Subjects (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the CRO, or the Sponsor's designee, that, in the sole determination of the CRO:

i. the Complete Study enrollment has been achieved; or

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304

ii. the CRO and Sponsor have placed the Study on hold, for any reason; or

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

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under Applicable Laws and Requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. Study Documentation. Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three to five (3 to 5) working days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three to five (3 to 5) working days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three to five (3 to 5) working days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the CRO and Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. There will be no paper Data Clarification Forms Queries ("DCFs"). Site staff will have to enter the eCRF and resolve the same within **three (3) working days** of its receipt. Only in case of urgent requirement of safety data, safety vendor may contact the site to request the safety data which should be contacted as early as possible.

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

Study Completion. The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than five days after the last Subject visit. In any event, Institution and Principal Investigator shall not publish or present interim or preliminary results of the Study at any time without the prior written approval of CRO and Sponsor.

3. PAYMENT

A. Budget and Payment Schedule: In consideration of the Services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

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Belagavi-590 010,Karnataka

305

B. Payment of Costs outside Budget and Payment Schedule. Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

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

The foregoing notwithstanding:

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

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

The mailing address for checks shall be:

The further details for the payments should be provided as

1. **Cheque in the favor of: Genesis Research**
2. **PAN Number: CQJPP0528D**
3. **Name of Bank: State Bank of India**
4. **Branch: Market Yard, Kolhapur**
5. **Account No: 36599680134**
6. **Branch Code: 001887**
7. **IFS CODE : SBIN0001887**

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

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306

F. Payments for Screen Failure: CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 5:1 i.e. maximum one screen failure per five randomized Subjects.

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

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Goods and Service Tax (GST) will be paid, if applicable, on generation of valid tax invoice showing the amount of GST to be charged before any payment is made under this Agreement

The parties acknowledge that the designated Payee is authorized to receive all the payments for the services performed under this Agreement. Investigator acknowledges that if Investigator is not the Payee, CRO will not pay Investigator even if the Payee fails to reimburse Investigator.

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

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

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

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307

Agreement to any other individual or entity without the prior written consent of the CRO. The Principal Investigator shall be responsible for responding promptly, in writing, to all issues and questions raised by regulatory agencies relating to the performance of the Study

C. Patient consent and entry into Trial. As well as complying with the requirements of the Declaration of Helsinki, the principles of Good Clinical Practice [and other legislation appropriate to clinical trials, medical treatment, and the processing of personal and medical data], the Investigator shall, before entering a patient into the Trial:

i. exercise independent medical judgement as to the compatibility of each prospective Patient with the requirements of the Protocol;

ii. advise the CRO of all instances in which, in the Investigator's judgement, there is any question as to any prospective Patient's suitability for participation in the Trial, and abide by the Sponsor's decision as to whether or not to enrol that Patient;

iii. ensure that, before their participation in the Trial, the Patients are duly informed about all aspects of the Trial that are relevant to them, including:

iv. the purpose, duration, nature, significance, implications, and risks of the Trial; and

v. the processing, auditing, and monitoring of data (including personal data) under this Agreement.

vi. ensure that, before his or her participation in the Trial, each Patient has given his or her Informed Consent on the basis of the information described in Clause 2.5(c) by signing a consent form in accordance with the Protocol;

vii. acknowledge that the use of the consent form does not release the Investigator from his or her legal and contractual obligations relating to Informed Consent, and that it remains the Investigator's responsibility to ensure that those obligations are complied with;

viii. comply with the procedures described in the Protocol in relation to that Patient; and

ix. provide details of the proposed Patient to the CRO.

D. Key Personnel. The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the CRO and/or Sponsor's designee and the CRO and/or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the CRO may terminate this Agreement as set forth in Clause 12(B) below.

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

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

308

the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

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

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

G. Study Records, Reports, and Data.

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice

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Belagavi-590 010,Karnataka

309

("**Study Records**"). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of seven (7) years after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ Sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the Study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data. In no event, shall Institute and Principal Investigator remove any Study Records or destroy any Study Records without the prior written consent of CRO and Sponsor.

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

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

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

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of Study Records.Sponsor and CRO will help to find vendor for archival of study records.

H. Reporting of Serious Adverse Event.

- In 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.

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Belagavi-590 010,Karnataka

310

- In the event of a trial related injury or death, CRO (as a representative of the sponsor) on behalf of Sponsor shall provide financial compensation for the injury or death.

- Neither CRO nor Sponsor will be responsible for, and Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any loss, damage, liability, claim, cost (including reasonable attorney fees) or demand arising from any injuries or damages resulting from negligence, failure to adhere to the Protocol, failure to comply with Applicable Laws, failure to obtain informed consent, unauthorized warranties made by, breach of this Agreement or willful misconduct or omission of Site or any Site Personnel in performing their obligations under this Agreement.

- Sponsor will promptly inform Site, Site's Institutional Review Board/EC, and CRO, of any finding that could affect the safety of subjects or their willingness to continue participation in the Study, influence the conduct of the Study, or alter Site's IRB/EC approval to continue the Study. Site shall promptly, in accordance with Applicable Laws, advise Sponsor and CRO of any Adverse Event occurring during the conduct of the Study that it becomes aware of. In the event of the occurrence of any serious Adverse Event, Site shall notify CRO and Sponsor or its designee by fax and/or other electronic means within twenty-four (24) hours of the occurrence.

- The recording of Adverse Events is an important aspect of study documentation. It is the Investigator's responsibility to document all Adverse Events according to the detailed guidelines of the Protocol. The Investigator agrees to answer any questions of Sponsor/CRO's medical monitor concerning any Adverse Events.

- The Investigator must immediately report all Serious Adverse Events ("SAE") (as defined in the Protocol) (within 24 hours of occurrence of SAE) to the DCG (I), Sponsor and Ethics Committee which occur since informed consent is signed, during the course of the Study and up to the date of the subject's last visit.

- The Investigator shall forward a due analysis report to DCG (I), Ethics Committee and Head of the Institute within fourteen (14) days of occurrence of SAE including all initial information and follow-up information until stabilization/ resolution of the SAE.

5. CONFIDENTIALITY

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution, SMO or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution, SMO or the Principal Investigator as required by the Protocol

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Belagavi-590 010,Karnataka

311

and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

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

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

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

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

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

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

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of preventing any existing or anticipated breach of the terms of confidentiality under this Agreement.

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

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312

requirements, or (ii) prevent Institution, SMO and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. Non-Disclosure and Non-Use. Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

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

E. The PI and Institution hereby acknowledge and agree that in accordance with the applicable laws and codes, and in particular with any transparency obligations contained therein, certain value transfers between pharmaceutical companies and healthcare professionals and/or healthcare or academic institutions or hospitals, are subject to mandatory publication. The Parties acknowledge that, in accordance with said obligations the Sponsor is responsible for the publication of the relevant information in the appropriate format and within the applicable timeframe. Such information shall at least include the amount, purpose and recipient of the value transfers. The PI and Institution hereby explicitly agree with such publication by Sponsor, provided the publication is in accordance and strictly limited to the requirements of the said laws and codes, and does not go beyond the requirements of the applicable privacy laws.

6. Protection. Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure

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Belagavi-590 010,Karnataka

313

or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish information arising from his/her participation in the Study, the prior written approval from Sponsor is required.

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

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

B. Patents and Inventions.

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

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

iii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor. Institution and Principal Investigator shall assign and transfer to Sponsor without further consideration, the

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Belagavi-590 010,Karnataka

314

entire right, title and interest globally in all Sponsor Intellectual Property of any New Inventions made or any process carried out in the name of Sponsor. Institution and Principal Investigator acknowledge that all original works of authorship made whether by Institution and Principal Investigator under this Agreement are "works made for hire" and assist Sponsor in obtaining patent or other intellectual property protection.

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

v. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

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

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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Belagavi-590 010,Karnataka

315

criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

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

B. Of the CRO. The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms. CRO represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) CRO has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration of drugs and devices

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Belagavi-590 010,Karnataka

316

under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular CRO shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

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

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

10. GOVERNING LAW

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

11. INDEMNIFICATION

A. CRO Indemnification.The CRO shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents harmless against all notices, claims, demands, action, suits or proceedings given, made or initiated against the CRO due to a) Breach of responsibility of the CRO; b) Willful negligence; c) Willfulmisconduct or misrepresentation d) breach of representation and warranties and confidentiality obligations under this Agreement (e) CRO's Negligence (f) Breach of Applicable Law.

B. Institution Indemnification. The Institution shall defend, indemnify, and hold harmless the CRO/Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**CRO Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the CRO Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the CRO concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner

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Belagavi-590 010,Karnataka

317

required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnitee, or any other person on the Institution's property or under its control, exclusive of the CRO's employees and (iii) (a) breach of any terms of the Agreement and the representations and warranties made by Principal Investigator or Institution jointly and / or severally.

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

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

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

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

12. INSURANCE

A. Parties represent and warrant that they possess and shall maintain, for the duration of the Agreement and thereafter, at its own expenses, insurance coverage for their respective services in the performance of the Study. Each Party shall provide the other Party with proof of insurance upon request.

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

This Clause 12 shall survive termination of this Agreement.

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Belagavi-590 010,Karnataka

318

13. TERM AND TERMINATION

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

B. Termination.

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

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

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

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

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

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

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

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

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

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

b. Reasonable non-cancelable obligations (as evidenced in writing) properly incurred for the Study by Institution prior to the effective date of termination.

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

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

vii. Effect of Termination. In the event this Agreement is expired or terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the

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

319

IRB/IEC that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the CRO to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the CRO's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes and shall make no further use of, all Sponsor Confidential Information, and any other records, data, materials and information that are the property of Sponsor. The CRO shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement. Notwithstanding any termination or expiration of the Study or this Agreement, Institution shall remain responsible for compliance with all obligations under Applicable Laws and other requirements as per this Agreement with regards to disposition of the Study Materials.

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

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

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

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR

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Registrar
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Belagavi-590 010,Karnataka

320

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

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

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

15. MISCELLANEOUS

A. Use of Names; Publicity. Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its staff/employees, agents in any advertisement or sales promotional material or in any publication, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Section 7 herein). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement even existence of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances and ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. Independent Contractors. The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and shall not to be considered as partner, agent, employee, or representative of CRO or the Sponsor. That neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. Limitation of Liability. In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.CRO expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product.

321

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

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

Any notice to Sponsor shall be addressed as follows:

Address	: Mylan Pharmaceutical Private Limited, 7th-12th Floor, Prestige Platina Tech Park, Block 3, Kadubeesanahalli, Outer Ring Road, Bangalore-560087
Attention	: Dr Sanjeev Hegde
Title	: Associate Vice President
Phone	: +91 7349635726
Fax	: NA

Any notice to Institution shall be addressed as follows:

Address	: KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi 590010
Attention	: Dr M.V. Jali
Title	: Head of the Institution
Phone	: +91 9844032499
Fax	: +91 8312470732

Any notice to Principal Investigator shall be addressed as follows:

Address	: KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi. 590010
Attention	: Dr Dnyanesh N Morkar
Title	: Principal Investigator
Phone	: +91 9448231298
Fax	: +918312493099

Any notice to SMO shall be addressed as follows:

Address	: 4/22, Near Apporva Hospital, Jadhavwadi, Kolhapur -416005
Attention	: Mr. Satyajit Patil
Title	: Manager
Phone	: +91 9762881140
Fax	: NA

Any notice to CRO shall be addressed as follows:

Name of CRO	: Ecron Acunova Limited (Formerly known as Manipal Acunova Limited)
Address	: Mobius Tower, SJR- I Park, EPIP, Whitefield, Bangalore-560066
Attention	: Dr. Ayaaz Hussain Khan
Title	: Managing Director
Phone	: 080 6691 5700

322

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

Fax : 080 6691 5719

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

F. Modification; Waiver. This Agreement may not be altered, amended or modified in any way except in writing signed by the CRO, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right. Parties shall not delegate or subcontract its duties under this Agreement without prior written consent of the CRO/Sponsor

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

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

I. Execution. The Institution's IRB/IEC shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile or other electronic signature.

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

323

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Belagavi-590 010,Karnataka

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

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

FOR AND ON BEHALF OF INSTITUTE

By:

(Signature and Date)

NAME: DR M.V. JALI

FOR AND ON BEHALF OF SMO

By:

(Signature and Date)

NAME: MR. SATYAJEET PATIL

FOR AND ON BEHALF OF
ECRON ACUNOVA LIMITED
(FORMERLY KNOWN AS MANIPAL ACUNOVA LIMITED)

By: 27 Dec 2017

(Signature and Date)

DR. NAGESWARI SANTOSH

NAME:

AND

By: 27 Dec 2017

(Signature and Date)

Y.R. SACHIN KUMAR HOLLA

NAME:

Confidential

324

ECRON ACUNOVA LTD Bangalore

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

PRINCIPAL INVESTIGATOR

By:_____

(Signature and Date)

NAME: DR. DNYANESH N MORKAR

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EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : Dr. Dyanesh N Morkar

Site Address : KLES DR Prabhakar Kore Hospital and MRC, Nehru Nagar, belagavi-590010

PAYMENT SCHEDULE

Payment Schedule for the total study Grant of INR 990520 for 15 patients is as follows:

Overall Per Patient Budget

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Includes the following 1. Professional fees: PI and site team payment including Co- Investigator (s), Site coordinator(s), Nurse(s), as applicable	40800	612000
2. Procedural Charges	6400	96000
3. Institutional Over Head (IOH) charges 20% on Procedural Charges and Professional Charges	9440	141600
4. Patient Travel Reimbursement	3000	45000
Total Amount (INR)	59640	894600

Other payments includes

Reimbursement	Amount in Indian rupees per patient	Amount in Indian rupees for total patients
Screen Failure	8240	24720 (Considering 3 subjects)
Study Start-up		40000
Archival Charges		30000
Digital Hygrothermometer		1200

326

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Investigator Site Budget estimate - TLE 400mg							
	Screening	Baseline	Week 4	Week 12	Week 24	Week 28	
Investigator fees	4000	5000	4000	4000	4000	5000	26000
Study Coordinator	1500	2000	1500	1500	1500	2000	10000
Phlebotomist	300	500	500	500	500	500	2800
Hospitalization for PK sampling	0	4000	0	0	0	0	4000
PK sampling-Professional fees	0	1000	0	0	0	0	1000
PK sampling-Phlebotomist	0	1000	0	0	0	0	1000
12 lead-ECG	300	0	0	0	0	300	600
PT and INR	250	250	250	250	250	250	1500
UPT	100	100	0	0	0	100	300
Total (Visit Wise)	6,450	13,850	6,250	6,250	6,250	8,150	47,200
IOH 20%							20%
IOH							9440
Patient Travel Reimbursement	500	500	500	500	500	500	3000
Grand Total/subject							59,640
No of subjects planned**	15	15	15	15	15	15	
Estimated Amount/ Total subjects	96,750	2,07,750	93,750	93,750	93,750	1,22,250	7,08,000
IOH 20%							1,41,600
Patient Travel Reimbursement	7,500	7,500	7,500	7,500	7,500	7,500	45,000
Grand Total/ Total subject/site							8,94,600

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Belagavi-590 010,Karnataka

327

Summary of Budget/Payments:

Table A:

Details	Per Patient Grant	For 15 patients
Procedural Charges	6400	96000
Professional Charges	40800	612000
IOH 20% on Procedural Charges and Professional Charges	9440	141600
Patient Travel Reimbursement	3000	45000
Grand Total	**59640**	**894600**

Table B: Screening Failure

Details	Per Screen Failure	For 3 patients
Screening	6450	19350
IOH 20% on Screening	1290	3870
Patient Travel Reimbursement	500	1500
Total	8240	24720

Table C:

Details	Charges
Study start up	40000
Archival Charges	30000
Digital hygrothermometer	1200

Details	Grand Total	Total # of subjects	Per Patient grant
	990520	15	**66035**

328

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

Payment Schedule for the advance payment is as follows:

1. Non- Refundable Study startup cost INR. 40,000/- will be paid after SIV
2. CRO will pay only INR. 8240/- amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).
3. The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.
4. A Non- refundable amount of INR 30,000/- will be paid to the site as Archival fees after Site Close-out Visit. The duration of archival will be for 3 years after site close out visit. After completion of 3 years of archival, the PI is responsible to consult Mylan for further instructions to transfer the study documents from site to the Archival facility as per Mylan confirmation. Ecron will be responsible for arranging the pickup and ensure the delivery of these documents from Site to the Archival facility.
5. Discontinued or Early Termination Patients: Discontinued or early termination patient will be reimbursed based on the number of confirmed completed visits and the eCRF completion.
6. Reimbursement of Clinical Trial Subjects: Clinical Trial Subjects are reimbursed for their travelling to site either according to pertinent receipts or by paying them an expense flat charge of INR 500/- (in words: Five hundred only)

Payment Adjustments

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

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

329

Dr. V.A.Kothiwale
Registrar
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Belagavi-590 010,Karnataka

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

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

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

Invoices:

Invoices shall include the heading "study code (EA-CT-17-004) or Protocol ID (MYL -TLE 400 -4001)". They shall be sent from site to CRO on a regular basis and shall be addressed to
Send invoices to:

Contact Person: <<Name of the Study Project Manager>>
Address : Ecron Acunova Limited, Mobius Towers, SJR i-Park, EPIP, Whitefield, Bangalore - 560 066. India .

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.
Payments under this Agreement shall be made upon receipt of an appropriate invoice.

Final Payment

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

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 screening, baseline, week 4, week 12, week 24 and end of study. 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. 50 % of the total amount of the last invoice 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.

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Belagavi-590 010,Karnataka

330

6. Payee represents that the services it provides under this Agreement are taxable service under the laws governing in India, and that it is required to charge taxes as per the applicable laws, as may be amended from time to time depending on the change in tax regulations.
7. 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.
8. Reimbursement of Meetings: The Sponsor shall reimburse the Investigator upon prior written approval for reasonable expenses on travelling and lodging which occurred through his/her participation in meetings on request of the Sponsor.

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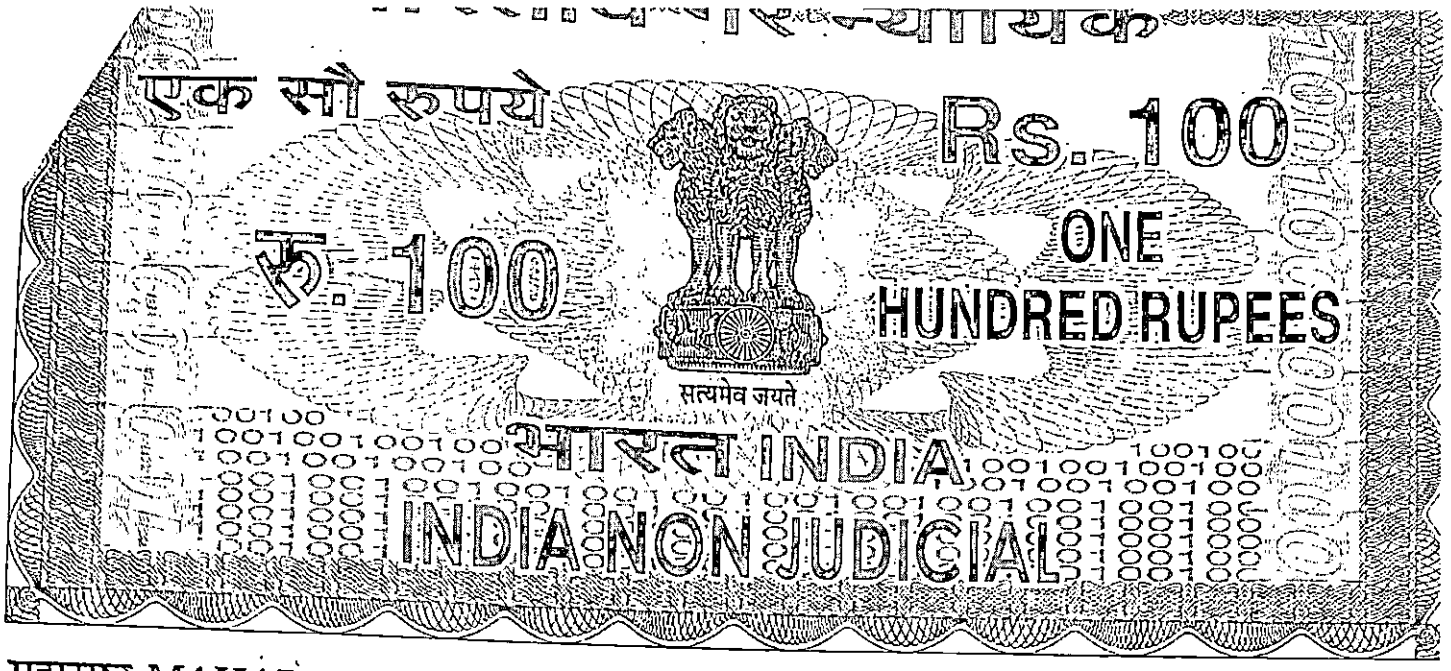
331



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SS 234592

जिल्हा कोषागार कार्यालय,
ठाणे
- 2 NOV 2017
मुद्रांक प्रमुख लिपीक / लिपीक

2/11/2017

CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is made and entered into this 13/Nov/2017 by and between:

Principal Investigator,
Dr. Siddalingeshwar Ishwarappa Neeli
KLE's Dr. Prabhakar Kore Hospital & MRC,
Nehru Nagar,Belagavi-590010

And

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

332

INSTITUTION: The CRO has approached the INSTITUTION on behalf of the SPONSOR, as the SPONSOR desires the INSTITUTION to perform the study in regards to the said Investigational Product in accordance with the following standards:

(a) The current World Medical Association Declaration of Helsinki titled "Ethical Principles for Medical Research involving Human Patients";

(b) The current ICH Harmonized Quadripartite Guideline for Good clinical Practice

(c) The current Indian Ministry of health and Family Welfare Guidelines for good clinical practice titled, "Good Clinical Practices for Clinical Research in India";

(d) The current Indian Council of Medical Research on Human Patients;

(e) The written requirements of all reviewing institutional ethics committees;

(f) The Principal Investigator requirements;

(g) All policies and procedures of the INSTITUTION;

(h) All current and applicable permission, licenses, approvals, federal wide assurance and certifications and (1) all current and applicable laws and regulations (such as standards set forth in Sections 2(a) – (i) collectively referred to hereafter as the Standards) and;

(i) In accordance with the final protocol, patient information sheet, informed consent documents and case report forms for the above-referenced clinical study (collectively, the Clinical Trial Protocol, a current version of which is attached hereto, which attachment shall be replaced in the final version and all amended versions, if any).It is understood and agreed that, in the event of a conflict among any of the standards, the most stringent standard shall apply.

2. PERFORMANCE:

a) Protocol and Standards: Principal investigator who will supervise and direct the work of the INSTITUTION and the Dean of the INSTITUTION, hereby confirm that they have read and understood the Clinical Trial Protocol for the Study to be conducted in 399 patients and further confirm that their research team is properly trained concerning the clinical trial Protocol and Standards. All amendments have also been read and understood. The Principal Investigator and the INSTITUTION agree to the final Clinical Trial Protocol and to perform the study in strict accordance with this Agreement.

b) Subcontracting: Services of Principal Investigator: The INSTITUTION shall not subcontract the performance of any or all of its obligations under this Agreement to any third party (including to any affiliate). The services of the Principal Investigator are considered essential for the performance of this Agreement. If for any reason the Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, INSTITUTION shall promptly notify the CRO/SPONSOR. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by the CRO.

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

333

this Agreement, that subject enrollment will be completed approximately in four months from the date of Site Initiation Visit, and that the Clinical Study will be completed as per the study schedule, unless otherwise terminated in accordance with Section 7.

Recruitment: The Principal Investigator understands and agrees that the CRO/SPONSOR requires at least 339 evaluable patients at the conclusion of the Study from approximately 9-12 sites, hence it will be necessary for the INSTITUTION to enroll 35-40 patients (considering a drop-out rate of 15%) to achieve the targeted number of patients who satisfy all enrollment criteria specified in the Clinical Trial Protocol, within a period of 2-3 months approximately after the SPONSOR authorizes commencement of the study.

Confidentiality:

i. Definition: During the term of this agreement (period of five years thereafter), the INSTITUTION and Principal Investigator may have access to information, know-how, knowledge and data in oral, written, electronic, graphic or other tangible form, confidential or proprietary to SPONSOR or to SPONSOR's other collaborators (other than the INSTITUTION) and is, therefore of a confidential nature (confidential information). Confidential information shall include the Clinical

Trial Protocol, SPONSOR's Investigator's Brochure concerning the Investigational Product data, all Study Data, all documents maintained in the Clinical Trial Record Binder (site documentation), any other data emerging out of the protocol, any other information supplied by SPONSOR/CRO during the course of the study and clinical development plan, except the information already existing in the public domain, and all results and reports obtained, collected, conceived, processed and developed pursuant to this Agreement.

ii. Use: The INSTITUTION shall hold all confidential information and shall disclose confidential information only to its Principal Investigator, Co-Investigators, hospital staff and employees who have a need to know such confidential information for the purpose of this agreement and who agree in writing to keep such confidential information, confidential under terms substantially similar to those set forth herein. The INSTITUTION shall use confidential information for the sole purpose of providing services under this Agreement and shall not use confidential information for the INSTITUTION's own benefit at any time. No right or license under any patent application, trade secret or other proprietary right now or hereafter owned or controlled by the SPONSOR or other collaborators is granted to the INSTITUTION from the provision of confidential information hereunder. The INSTITUTION shall comply with the Study Data Confidentiality conditions.

iii. Provision to CRO/SPONSOR: The INSTITUTION agrees that, at any time upon CRO/SPONSOR's request, it shall promptly provide to the CRO/SPONSOR respectively, copies of all Confidential Information under this Agreement. The INSTITUTION further agrees that upon any termination or expiration of this Agreement, it shall at CRO/SPONSOR's election, return to the CRO/SPONSOR or destroy all copies of all Confidential Information; however, that the INSTITUTION may retain two (2) archival copies, with obligation to maintain the confidentiality of such confidential information.

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Belagavi-590 010,Karnataka

334

Work Product:

i. Definition: The Parties agree that all work performed by the INSTITUTION hereunder including, without limitation, all study data, results, reports, inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice by Principal Investigator or the INSTITUTION's other hospital staff or employees pursuant to this Agreement (collectively, work product) shall be the property of the SPONSOR.

ii. Disclosure, Assignment and Provision to CRO/SPONSOR: The parties agree that the INSTITUTION shall promptly disclose to the CRO/SPONSOR any and all work related to the product comprising inventions, discoveries, new uses or know-how obtained. As per the agreement, the CRO/SPONSOR can review and obtain copies of all work related to the product including and without limitation, all study data, in an agreed–upon format and with a complete glossary of terms used for such data.

iii. Materials: The study medication, blood samples from patients under the study and all other tangible material provided to or obtained by the INSTITUTION under this Agreement (Collectively the Materials) shall be the property of the SPONSOR and/or SPONSOR's other collaborators (other than the INSTITUTION). The INSTITUTION shall use the Materials forthe sole purpose of providing services under this agreement and shall not use the materials for its own benefit at any time. No right or license, any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by SPONSOR or SPONSOR's other collaborators is granted to the INSTITUTION from the provision of materials hereunder. Upon any remaining Investigational Product and other Materials received or obtained hereunder in accordance with the Protocol, standards and the directions of CRO/SPONSOR.

g) Human Patients: The INSTITUTION shall be responsible for safeguarding the rights and welfare of patients in the study. The INSTITUTION shall ensure (i) the rights and welfare of each such patient are protected, (ii) informed consent of each such patient is freely and knowledgeably given: (A) to participate in the study and (B) for the collection by, processing by and disclosure to and between the CRO representatives of SPONSOR, Principal Investigators and Researcher, Study Monitors, Study Laboratory Personnel, Study Data Analysts, members of the Independent Ethics Committees and representatives of governmental and inter-governmental agencies in India; (iii) the balance between risk and potential benefit from participating in the study has been assessed and deemed acceptable; and (iv) the SPONSOR/CRO has made appropriate arrangements to eliminate, mitigate and/or compensate for the consequences to such patients and their families in case of any death, injury or illness which has causal relationship with the Erectile Dysfunction and Premature Ejaculation treatment for which the SPONSOR/CRO has agreed to assume liability. Such arrangements shall include medical treatment and financial relief as per the Policy provided by Sponsor.

Ethical Approval: The INSTITUTION shall petition for written certification of ethical approval of the Study from its Institutional Ethics Committee. The INSTITUTION shall keep the CRO/SPONSOR fully advised of the progress of such submission and shall

335

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

upon request, provide the CRO/SPONSOR with all correspondence relating to such submission. The INSTITUTION shall obtain such certification prior to screening any patients for the Study, annually after obtaining such certification, and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the INSTITUTION shall promptly provide a copy to the CRO/SPONSOR.

h) Case Report Form Handling: The Principal Investigator shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

i. 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.

ii. 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 CRO/SPONSOR for data management and biometric analysis.

iii. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to the CRO/SPONSOR.

iv. 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.

v. If CRFs are not complete the Principal Investigator shall be obliged to complete them on request of CRO/SPONSOR.

j) Drug Safety: 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 CRO/SPONSOR Medical Monitors concerning any AEs. 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. The Principal Investigator must immediately report all Serious Adverse Events (as defined in the Protocol), which occur during the course of the Study and up to the date of the patient's last visit, to the addressee given below. The SAE Report Form will be used for documentation and reporting. Initial and follow up SAE reports are to be sent to **CRO** for onward transmission to SPONSOR:

Name: Dr. Neeta Nargundkar
Telephone Numbers: (022) 41006794
Cell Number: +91-9029025200
E-mail: drneeta@biospherecro.com

Dr. V.A.Kothiwale 336
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010,Karnataka

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication CRO shall be informed immediately by telephone and followed immediately by majl. CRO will be responsible to notify on-time the health authorities in India.

k) Source Data: The Principal Investigator shall be responsible for providing the Source Data according to the following regulations. Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically, but not limited to they comprise:

i. Signed Informed Consent Form
ii. Patient hospital file and individual clinical notes
iii. Laboratory Reports
iv. Pharmacy Records
v. Study specific source documents
vi. Appropriate sections of the CRF, where data are recorded directly onto specific forms
vii. Other reports and records of any procedure performed in accordance with the Protocol

l) 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 5 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 CRO/SPONSOR.

m) Investigator Study File and Archiving: The INVESTIGATOR 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:

i. Signed Protocol and Amendments
ii. Investigator's Brochure and Updates
iii. EC Composition, approval(s)/opinion correspondence/reporting
iv. Notifications of regulatory authorities
v. CVs and signature sheet for key study personnel (e.g. Investigators, Study Nurses)
vi. Signed study agreements including financial agreement.
vii. Trial Initiation Report
viii. Approved and signed Informed Consent Forms
ix. Patient Insurance Certificate
x. CRFs (Investigator's copy)
xi. Data Clarification Forms (copies)
xii. SAE documentation and related correspondence/reporting
xiii. Shipping/accountability/destruction records for investigational product
xiv. Certificate of Analysis
xv. Instructions for handling of investigational product
xvi. Laboratory accreditation/certification and up-to-date reference ranges of normal values q Screening, enrollment and monitoring logs and subject identification code list

337

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

xvii. Appointment diaries
xviii. Study related correspondence with CRO/SPONSOR

n) Documentation and Material (Supplies): All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

n) The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of unused material for the Study, supplied by the CRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to the CRO/SPONSOR. In the latter case, *the identification and quantity of each unit of study medication and the person in charge* must be documented.

o) Monitoring, Quality Assurance and Inspection by Authorities: The Study will be monitored by the CRO. 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. CRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring and remote monitoring throughout the Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence
ii. to verify the data in the CRFs against source documents (SDV)
iii. to check progress of the study and to motivate, if necessary
iv. to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs
vi. to review signed informed consent forms for signatures and date of consent
vii. to ensure accurate record of drug accountability
viii. to ensure adequate storage of study supplies
ix. to collect completed CRFs
x. to discuss and help resolve any problems

p) 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.

q) 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 is allowed for monitoring visits. Follow-up correspondence between the Site and the CRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both CRO and the Site.

r) 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 CRO.

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

...study and according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the CRO/SPONSOR.

t) For monitoring visits and in case of audits and inspections by authorities, the Principal Investigator must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additional background data. Furthermore, access to Study related facilities must be ensured.

u) Confidentiality of Patient Records: The INSTITUTION and the Principal Investigator must assure that Study patients' anonymity will be maintained, and that their identities will be protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION, patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full name and date of birth together with the corresponding patient identification number to allow revealing identity of any subject.

v) The Principal Investigator agrees that representatives of CRO/SPONSOR, of the responsible IEC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and CRO guarantee for their representatives that patient data will be treated confidentially. Monitors and Auditors are further bound to secrecy.

4. **AMENDMENTS:** The CRO, on behalf of the SPONSOR, may 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.

5. **INSPECTIONS:**

a) By Representatives of CRO/SPONSOR: The INSTITUTION agrees that CRO/SPONSOR's representatives and clinical monitors for the Study will have free access to the INSTITUTION's facilities and all documents pertaining to the Study during normal business hours, after provision of prior written notice, as is necessary to ensure that the Study is conducted in accordance with this Agreement. In the event any such representative or monitor observes non-compliance with this Agreement, incomplete, illegible or inaccurate recording of Study data, or other matters of concern relating to the Study, the INSTITUTION shall, in cooperation with such representative or monitor, promptly remedy such non-compliance, Study data recording problems or matters of concern and shall promptly notify such representative or monitor of such remedial actions taken.

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

339

representatives: The INSTITUTION agrees that representatives of the government will have access to its facilities and such documents pertaining to the study as may be legally requested by such representatives. The INSTITUTION shall not disclose individually- identifiable personal information, individually-identifiable health care information or other Confidential Information to such governmental representatives except as required by law, and if the INSTITUTION discloses such individually-identifiable information or other Confidential Information to such governmental representatives, the INSTITUTION shall seek an appropriate, written agreement of confidentiality from such governmental representatives prior to making such disclosure. The INSTITUTION shall promptly provide copies to the CRO/SPONSOR of any notices, correspondence and other documentation received or prepared by or on behalf of the INSTITUTION in connection with any governmental inspection, action; inquiry or correspondence relating to or that may affect the INSTITUTION's activities under the Study. The INSTITUTION shall take all actions necessary to remedy any non-compliance cited by governmental authorities and shall promptly notify CRO/SPONSOR of such remedial actions taken.

6. **WARRANTIES AND DISCLAIMER OF WARRANTIES:** INSTITUTION warrants that all services provided under this Agreement will be provided in a professional and workmanlike manner, in compliance with the Standards and the terms of this Agreement.

7. **AGREEMENT TERM AND TERMINATION:**

a) This Agreement is effective as of beginning of the study, and shall continue until 5 (five) years after completion of study, unless terminated sooner in accordance with this Article 7 or unless extended for a defined period by a signed written amendment in accordance with Article 14.

b) The Study and this Agreement may be terminated by written notice from the SPONSOR/CRO to the INSTITUTION for any of the following reasons:

i. Notification to CRO/SPONSOR from applicable regulatory authorities to terminate this Study.
ii. Determination by CRO/SPONSOR that the INSTITUTION is not performing the Study as required in the Agreement and/or is not meeting the agreed upon patient enrollment requirements set forth in Section 7(c) herein.
iii. Failure of the Principal Investigator and/or the INSTITUTION to provide access to the SPONSOR monitors or SPONSOR representatives to the INSTITUTION's facilities and all original medical records and Study-related documents necessary to verify entries on Study Case Report Forms and the INSTITUTION's compliance with this Agreement.
iv. Failure of the Principal Investigator or associated staff or any other person engaged in the Study (excluding patients) to be available, upon reasonable notice and by prior mutually convenient time appointment by CRO/SPONSOR, to meet with the CRO/SPONSOR monitors or CRO/SPONSOR representatives during the course of the Study as necessary to discuss information relevant to the Study.
v. Unauthorized replacement of Principal Investigator, in accordance with Section 7(b) herein.
vi. Determination by SPONSOR that business or scientific considerations require termination.

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

340

vii. Case Report Forms provided to the Principal Investigator by the CRO/SPONSOR for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to the CRO/SPONSOR's designated representative, as appropriate, within one (1) week of each patient's visit date.

c) The INSTITUTION may terminate this Agreement by written notice from the INSTITUTION to the CRO/SPONSOR for any of following reasons:

i. SPONSOR does not comply with the Clinical Trial Protocol provisions related to supply of Investigational Product for the Study, or the CRO/SPONSOR does not supply other agreed-upon study related material.
ii. The Principal Investigator reasonably suspects an adverse reaction/adverse event related to the Study procedure and of serious nature, after informing the Institutional Ethics Committees and the CRO/SPONSOR.

d) In case of any termination or expiration of this Agreement:

i. Responsibility for treatment of enrolled patients will be as specified in the Standards;
ii. The INSTITUTION shall cooperate with the SPONSOR/CRO for an orderly wind-down of activities, with due regard for patient safety and welfare;
iii. The INSTITUTION shall return or destroy all Confidential Information to CRO/SPONSOR, at the CRO/SPONSOR's election, in accordance with Section 7(d)(iii) herein;
iv. The INSTITUTION shall promptly provide all Agreement deliverables due to the CRO/SPONSOR and, if requested by the CRO/SPONSOR, provide copies of all Work Product (including without limitation all Trial Data) to CRO/SPONSOR, in accordance with Section 7(d) (ii) herein;
v. The INSTITUTION shall return and/or dispose off all remaining Investigational Product or other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of CRO/SPONSOR, in accordance with Section 7(d) herein;
vi. The INSTITUTION shall, within thirty (30) days after such termination or expiration, provide a final invoice to the CRO; and
vii. The INSTITUTION shall, notwithstanding such termination or expiration, remain responsible for compliance with all Standards.

e) The provisions of Articles 5, 6, 7, 8, 9, 10, 12 and 13 herein shall survive any termination or expiration of this Agreement, as shall such other provisions as, by their context, are intended to survive such termination or expiration.

Effect of Termination

The Institution shall comply all the standard procedures required for study close out

8. RECORDS: The INSTITUTION shall maintain in the English language (a) all Work Product; and (b) complete, accurate and legible scientific and clinical documents, books and records pertaining to all activities performed and all Materials provided or obtained under this Agreement. The other Study materials will be archived at the INSTITUTION for the period set forth in the Clinical Trial Protocol and originals given to the CRO for

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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

341

a) Both the INSTITUTION and CRO shall treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication.

b) It is hereby expressly made clear that all Intellectual Property Rights in the final test report as well as in the material generated during the process of Clinical trial will reside with the SPONSOR. CRO.

10. FINANCE:

a) The expenses of the Study, as set forth in the total projected budget, shall be paid by the CRO and are estimated not to exceed the amount mentioned in the total projected budget, in case it exceeds it will be mutually agreed upon on reasonable grounds and documented appropriately. The CRO's payment to INSTITUTION is contingent upon the CRO receiving payment from the SPONSOR. Funds shall be paid by the CRO to the INSTITUTION for the satisfactory and timely performance under this Agreement, as per the payment details, terms and conditions laid out in

b) ***Annexure A.***

All payments will be based on actual patient visits for every 3 months.

Method of payment

CRO, on behalf of the Sponsor shall pay the relevant cost and fee as set out in Annexure A to the Institution and Institution will pay Principal Investigator.

Details of Payee are:

Trial Payment

Payee Name: CMS Clinical Research Pvt. Ltd.
PAN Number: AAFCC8457M

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 and CRO will deduct the tax at the time of making payments unless a valid Certificate) from tax authority is made available.

c) An insurance policy, as relevant, for the participating patients covering any injury or illness suffered as a direct result of their participation in this Clinical Study shall be taken out by the SPONSOR/CRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

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

11. PUBLICITY, PRODUCT PROMOTING ACTIVITY AND COMMUNICATION GUIDELINES:

a) The SPONSOR shall not identify or use the names, trademarks, trade names or symbols of the institution, Principal Investigator or his research team under the study without the prior written permission of the Principal Investigator and head of the institution for claims, publicity or any product promoting activity. because the SPONSOR is a publicly funded organization that must maintain a certain level of transparency about its collaborations, SPONSOR may disclose the identity of the INSTITUTION, publicly available information about the INSTITUTION and the broad purpose of the collaboration under this Agreement to third parties such as a Court of Law, regulatory agencies, governmental or legal agencies, other collaborators, other investigators involved in the project and the organization (profit or non-profit) funding the development of theInvestigational Product. Also such details can be shared in scientific forums and with other medical professionals, if questioned.

b) The INSTITUTION shall not identify or use the names, trademarks, trade names or symbols of the SPONSOR, the SPONSOR's employees or affiliates, SPONSOR, SPONSOR's employees, donors or affiliates or any other author of the primary collaborative publication described in Section 11(b) herein for publicity or product promoting activity.

c) Prior to the beginning of the Study, the CRO/SPONSOR shall develop external communication guidelines for use by the INSTITUTION. The INSTITUTION agrees to comply with such guidelines. The INSTITUTION shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of SPONSOR.

12. LIMITATION OF LIABILITY: The parties expressly agree that there shall be no limitation on either Party's liability for any claims, damages, losses or liabilities arising out of *or related to this Agreement or the services performed hereunder.* IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE PATIENT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK. Any disputes that arise during the study between SPONSOR/CRO and Principal Investigator will be under the jurisdiction of Mumbai courts.

i. 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. The parties shall share equally the costs of the Arbitration unless *determined otherwise.*

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

AMENDMENTS: This Agreement may only be amended by and to such degree as specified by the mutual written consent of the parties hereto.

14. ENTIRE AGREEMENT: This Agreement, contains the entire understanding of the parties with respect to the subject matter hereof and except as expressly set forth herein, all express or implied agreements, representations and understandings, either oral or written, made prior to this Agreement are hereby expressly superseded by this Agreement. In the event there is a conflict between the Clinical Trial Protocol and the terms in the body of this Agreement, the terms in the body of this Agreement will govern with respect to commercial and contract terms, but such Protocol will govern with respect to the conduct of the Study and with respect to serving the welfare of patients of the Study. This Agreement may only be amended by a written instrument executed by the parties hereto, and CRO must approve any such amendment in writing prior to such amendment becoming effective.

16. SEVERABILITY: The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

17. ASSIGNMENT: The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of the CRO. The CRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

18. WAIVER: No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Agreement.

19. 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:

Dr. V.A.Kothiwale
Registrar
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
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344

WHEREOF, the parties hereto have executed this Agreement in quadripartite by proper persons thereunto duly authorized.

If to Principal Investigator:	If to INSTITUTION:
Dr. Siddalingeshwar I. Neeli M.S.,DNB (GEN.SURGERY),DNB (URO) Consultant Urologist KLES Dr. Prabhakar Kore Hospital & MRC Belgaum-10 Dr. Siddalingeshwar Ishwarappa Neeli KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar,Belagavi-590010	Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. Dr. M. V. Jali Medical Director and Chief Executive KLE's Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010
If to SMO:	**If to CRO:**
CMS Clinical Research Pvt. Ltd. Ms. Nidhi Singh Head- Clinical Operation CMS Clinical Research Pvt. Ltd. Newbridge Business Centre, Inox Tower-B, Plot No. 17, Sector-16A, Film city, Noida, India	BIOSPHERE CLINICAL RESEARCH PVT. LTD. MUMBAI 13 NOV 2021 Dr. Neeta Nargundkar Managing Director, Biosphere Clinical Research Pvt. Ltd.,20/21, Gr. Floor, Lake City Mall, Kapurbawadi Naka, Thane (W) - 400 607, Mumbai, Maharashtra.

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Belagavi-590 010 Karnataka

Annexure A

Name of the Site: KLE's Dr. Prabhakar Kore Hospital & MRC

Provisional Investigator Site Payment-Per Patient cost is as follows:

Visit Number	Payments INR
Visit 1- Screening visit/Baseline	2830
Visit 2- Randomization visit	2000
Visit 3- Follow-up visit	1800
Visit 4- Follow-up visit	1800
Visit 5- Follow-up/End of Study visit	2830
Total	**11200 INR**

Note 1: The above payments are inclusive of Investigator Fees, Sub-Investigator Fees, Institutional Overheads and Administrative Charges, applicable for this study.

Note 2: Lab Charges excluding Penile Doppler for Visit 1 and Visit 5 will be INR 2210/- and INR 730/- respectively. Penile Doppler charges of INR 1300/- per test will be paid at actual.

Note 3: Subject Travel Reimbursement charge will be INR 500/- per visit.

Note 4: Clinical Research Site Coordinator Fees 10,000/- Per Month will be paid from Site Initiation Visit to Site Close-out Visit.

Note 5: The above payments are applicable only for randomized completed subjects.

Note 6: For Screen Failure subject charges will be paid INR 2830/- per subject. Lab Charges of INR 2210/-and Penile Doppler charges of INR 1300/- as applicable; this will be paid only to 10% of the total randomized completed subjects at the site.

Note 7: For drop-out subjects payment will be made per completed visit on pro-rated basis.

Note 8: SMO and PI will share the profit.

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

346

NAME :_____
ADDRESS :_____
THROUGH :_____
SIGNATURE :_____
RECEIPT NO. :_____
FOR W.M.D.C. LTD.

AUTHORISED SIGNATORY

Western Maharashtra Development Corporation Ltd. 2nd Floor, Kubera Chambers, Dr. Rajendra Prasad Road, Shivajinagar, Pune 411 005. D-5/STP(W)/CR.1016/01/08/205-208/08

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Amendment – I to the Clinical Trial Agreement

This Amendment Agreement (**"Amendment – I"**) is made as of 18th December, 2017 (**"Effective Date"**) by and between:

Lupin Limited, a company incorporated as under the Companies Act, 1956 and having its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway, Santacruz East, Mumbai 400098 (hereinafter **"Lupin"**); and

Dr. Mallikarjun Karishetti, an Indian citizen/ resident, with his address at A14/8, Staff Quarters, J.N. Medical College Campus, Belgavi, Karnataka and having PAN: ADRPK2096A (hereinafter **"Principal Investigator"**); and

KLES Dr. Prabhakar Kore Hospital and MRC, with its address at, Nehru Nagar, Belgavi 590010, Karnataka (hereinafter **"Institution"**).

Lupin, Principal Investigator and Institution may hereinafter collectively be referred to as the **"Parties"** and individually as **"Party"**.

WHEREAS

A. Lupin and the Principal Investigator and the Institution entered into a Clinical Trial Agreement dated 14th September, 2017 (hereinafter **"Agreement"**) whereby the Principal Investigator agreed to conduct the Study under the Protocol at the Institution subject to terms and conditions contained in the Agreement.

B. The Parties are desirous of amending certain provisions of the Agreement and hence have agreed to enter into this Amendment – I.

NOW THEREFORE, THIS AMENDMENT WITNESSETH AND THE PARTIES HERETO AGREE AS FOLLOWS:

1. This Amendment – I shall be effective from 18th December, 2017 (**"Effective Date"**).

2. The Parties hereby agree that with effect from the Effective Date, Attachment – B of the Agreement shall stand deleted in its entirety and shall be replaced by Attachment – B of this Amendment – I.

3. The Parties hereby agree that with effect from the Effective Date, Attachment – D of the Agreement shall stand deleted in its entirety and shall be replaced by Attachment – D of this Amendment – I.

4. All other provisions of the Agreement shall remain binding on the Parties with full force and effect.

Dr. V.A.Rothiwale
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. Terms used that are not specifically defined herein shall have the same meaning ascribed to it in the Agreement. The Parties expressly agree and acknowledge that the Agreement shall stand amended to the extent specifically set out in this Amendment – I, and this Amendment – I shall form an intrinsic part of the Agreement and all the other terms and conditions of the Agreement shall continue to be valid and unchanged and binding on the Parties.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the day, month and year first hereinabove written.

Accepted and Agreed
For Lupin Ltd.

By: Dr. Dhananjay Bakhle
Its: EVP & Head – Medical Research

Accepted and Agreed
by the Principal Investigator

Name: **Dr. Mallikarjun Karishetti**

Dr. M. S. Karishetti (Trumpet),
[illegible] Physiology
Chief Consultant [illegible]
KMC Registration [illegible]
KLE's Dr. Prabhakar Kore Hospital and MRC
Belgaum-590010

Accepted and Agreed
For KLES Dr. Prabhakar Kore Hospital and MRC

By:
Its: Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

LUPIN LIMITED MUMBAI LUPIN OK LEGAL

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

RESEARCH GRANT PAYMENT TERMS

B-1. General Terms. Principal Investigator("Payee") will be paid the per patient grant amount as outlined on Attachment-D (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. Payment Terms. Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted.Invoices will be issued by Payee upon notice delivered by Lupin. Payments will be made in accordance with eCRFs submittedand monitored, and in accordance with Attachment D "Research Grant Worksheet".Monitoring will occur based on site enrollment and completion of data entry. Payments will be made in quarterly installments on a pro-rata basis. Undisputed invoices will be paid by Lupin within 60 (sixty) days of such invoice issue date. .

B-3. Non-Procedural Costs. Payee will be paid for additional non-procedural costs that are pre-approved by Lupin, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Lupin or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Lupin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Lupin Drug is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial.Lupin or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any.Payee will promptly reimburse Lupin amounts overpaid within thirty (30) days of notification by Lupin or designee.

B-5. Taxes.

(1) All payments to Payee by Lupin will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") regime ("GST Law"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Lupin harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Lupin. The Payee shall fully co-operate with Lupin to respond to the relevant tax authorities' demands, and to resolve any mismatch of Lupin and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Lupin will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

Dr. V.A.Kothiwale
Registrar

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349

B-6. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. Patient travel reimbursement. Lupin, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Lupin approval. Any payment will be based on the invoice together with supporting documentation (i.e. receipts) submitted to Lupin.

B-8. Administrative Start-up Fees. Within sixty (60) days of execution of this Agreement and receipt of a valid invoice, Lupin, will pay a non-refundable start-up payment in the amount listed in the Attachment D for the work performed to prepare for site activation and enrolment (including but not limited to, feasibility study, initial training of Protocol, briefings, advance talks, provisions of room for the monitoring, initiation of the Study at the Center, training of the future Members of the Study Team, participation in Investigator 's meetings, contract review activities, the cost for purchasing small equipment, set-up costs for equipment and all other preparation).This amount will be adjusted from final payment(s) for the Trial.

B-9. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Lupin in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Lupin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Lupin will be notified as soon as practicable after the fact.

B-10. Payee. The research grant payments will be made to the following payee and address:

Payee Name: **Dr Mallikarjun S. Karishetti**
Payee GST Number: **NA**
Payee PAN No.: **ADRPK2096A**
Payee Bank Account Details: **Savings**
Bank Name: **Canara Bank**
Bank Address: **KLES Hospital Branch, Nehru Nagar, Belgaum-10**
Bank Account Number: **85151010001000**
IBAN Number: **NA**
IFSC Code: **CNRB0008515**
Email address for remittance information: **DrmallikarjunK@hotmail.com**

In case of changes in the Payee's bank account details, Payee is obliged to inform Lupin in writing, but no amendment to this Agreement shall be required.

B-11. Invoices. All invoices must be issued and forwarded to the following as instructed:

Lupin Limited (Research Park),
Survey. No. 46A/47A,
Village Nande,Taluka Mulshi,
Pune – 412115, Maharashtra, India
Attn.: Dr Rajesh Kumawat

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Each invoice must contain: (1) Lupinname, (2) Protocol number. (3) Project code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (3) the GST Registration Number. (4) if GST reverse charge mechanism applies, the note "GST reverse charge applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

LUPIN LIMITED MUMBAI

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Attachment – D

RESEARCH GRANT WORKSHEET

Grant Worksheet

Principal Investigator: Dr. Mallikarjun Karishetti
Protocol No.: LRP/LNP1892/2016/007

Main Study	
Investigator Grant Per Patient	***Cost (INR)[1]***
Screening (All activities per protocol)	8,000
Day 1 (All activities per protocol)	10,000
Day 8 (All activities per protocol)	3,500
Day 15 (All activities per protocol)	3,500
Day 30 (All activities per protocol)	10,000
Day 60 (All activities per protocol)	10,000
Day 90 (All activities per protocol)	10,000
Day 97 (All activities per protocol)	8,000
Total per patient amount - Main Study	**63,000**
PK PD Study	
Investigator Grant Per Patient	***Cost (INR)[1]***
Screening (All activities per protocol)	8,000
Day 1 (All activities per protocol)	5,000
Day 2 (All activities per protocol)	3,000
Day 8 / EOT (All activities per protocol)	5,000
Day 9 (All activities per protocol)	2,000
Day 10 (All activities per protocol)	2,000
Day 15 / FU Visit (All activities per protocol)	2,000
Total per patient amount - PK PD Study	**27,000**
TOTAL PER PATIENT GRANT AMOUNT (Main Study & PK PD STUDY)	**90,000**

Additional Study Related Costs	***Cost (INR)[1]***
Screen Failures[2]	8,000
Patient travel reimbursement	500
12 Lead ECG (Only at Protocol scheduled time points)	400
Ultra-Sonography (USG) Neck (Only For Main study, Parathyroid Gland size assessment at protocol scheduled time points)	1,500
Hospital Per day charges (Night stay) (As per PK PD protocol schedule only)	2,000
Hemodialysis cycle (Post randomization per cycle cost, Only for patients randomized on hemodialysis arm)	2,500
Institutional Overheads[3]	20%

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Invoiced Charges[4]	*Cost (INR)*[1]
Administrative Start Up Fees	50,000
Archival Fees (For 15 Years) (includes onetime set up charge)	41,000
TOTAL Invoiced Charges	**91,000**

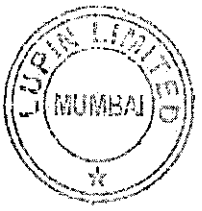
Notes:

[1]Total Costs are inclusive of indirect cost.

[2]Ratio: 1:1 (One (1) Screen Failure for every one (1) subject randomized into the Study. Screen Fails are

[3]Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.

[4]Invoiced Charges to be paid upon receipt of invoice from Principal Investigator, Administrative Start up fees at the time of site initiation, Archival fees before site close out



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