MOU Between clinzone Clinical research services , Pvt.Ltd. Pune

AND

Krishna Institute of medical sciences Deemed University, Karad

Clinical trials conducted

1) ODYSSEY OUTCOMES- EFC11570- A randomized, double blind, placebo controlled, parallel- group study to Evaluate the effect of SAR236553/REGN727 on the occurrence of cardiovascular events in patients who have recently Experienced an acute coronary Syndrome.

Sponsor: Sanofi

PI: Dr.Aparna patange

2) Evaluation of Efficacy and safety of fixed dose combination of losartan, Amlodipine and Hydrochlorothizide in the treatment of essential hypertension : An open label , multicentric trial

Sponsor: Sunpharma

PI: Dr. Aparna Patange

Memorandum of Understanding (MOU)

This **Memorandum of Understanding (MOU)** signed & executed from Thursday the 6th November 2014.

BETWEEN

Krishna Institute of Medical Sciences Deemed University, (KIMSDU) located at Central, Near Dhebewadi Road, Malkapur, Tal. – Karad Pin – 415 539, Dist. – Satara, (Maharashtra) hereinafter referred to as KIMSDU (which expression shall, unless repugnant to the context, mean and include his executors, administrators and assigns) of the **FIRST PART**

And

Clinzone Clinical Research Services Private Limited, a company incorporated under The Indian Companies Act, 1956, having its registered office at 106/8A Parvati Darshan Pune. Maharashtra India. Hereinafter referred to as **Clinzone** (which expression shall unless repugnant to the context mean and include its executors, administrators and assigns) of the **SECOND PART**

WHEREAS

Clinzone (with its headquarters in Puné, India) is essentially a Consulting & Knowledge Management Organisation offering a range of Enterprise Intelligence services especially to the Healthcare and Clinical Research Industry. **Clinzone**'s Mission is 'Serving People through Care'. CARE represents its main areas of operations viz. (a) Clinical Trial Management Services (CTMS) (b) **C**onsulting & Content Development (c) **A**ssociate Services, (d) **R**esearch and (e) **E**ducation & Management Training

Clinzone has since 2014 been actively involved in select Allied Health Initiatives and has decided to focus on Clinical Trial Management Services (CTMS) as a strategic area for growth

Clinzone has developed an excellent network of relationships with the Hospitals, Clinic, Pharmaceutical Industry, Sponsors and Clinical Research Organisations (CROs) and Research Institutions both in India and abroad.

AND WHEREAS

Clinzone presented a Proposal to **KIMSDU** for a Clinical Trial & Strategic Alliance wherein the two Parties would work in concert in the emerging area of Clinical Trial Management Services.

Add. Director of Research
KIMSDU, Karad

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प्रधान मुद्रांक कार्यालय, मुंबई
प. रु. वि. क. ८०००११
24 MAR 2015
सक्षम अधिकारी

श्री. विनोद नंदुरकर

PRODUCT CODE: (SAR236553/REGN727)

STUDY CODE: EFC11570 STUDY NAME: ODYSSEY OUTCOMES

INVESTIGATOR/INSTITUTION CONTRACT

Add. Director of Research
KIMSDU, Karad

This Contract (hereinafter "the Contract") is made as of the 1st *June 2015* (hereinafter "the Effective Date"), by and among:

DR. (MRS.) APARNA PATANGE having *her address at Medicine Department,* Krishna Institute of Medical Sciences Deemed University, Karad Pune-Bangalore Highway, 4 Malkapur, Karad, District- Satara 415110
Hereinafter the "**INVESTIGATOR**",
AND
KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY *having its address at* Karad Pune-Bangalore Highway, 4 Malkapur, Karad, District - Satara 415110 represented for the purposes hereof by *Dr. M. V. Ghorpade (Registrar)*
Hereinafter the "**INSTITUTION**"
AND

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

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

WITNESSETH:
WHEREAS, the SPONSOR is to perform a clinical trial ODYSSEY OUTCOMES-EFC11570 (hereinafter the « Study ») to evaluate Sanofi drug SAR236553/REGN727- Alirocumab (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled ODYSSEY OUTCOMES, EFC11570 and its amendments (hereinafter collectively the «Protocol»), and

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

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

ARTICLE 1. PROTOCOL.

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATOR and the INSTITUTION, as such Protocol is submitted to the relevant Independent Ethic Committee (« IEC/IRB »)/Health Authority («HA»)/ Competent Authority (« CA ») for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.
Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.
To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

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ARTICLE 2. STUDY SITE.

The Study shall be performed at Krishna Institute of Medical Sciences Deemed University situated at Karad Pune-Bangalore Highway, 4 Malkapur, Karad, Disrict- Satara 415110 (hereinafter the «Study Site»). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

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

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

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

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

ARTICLE 3. COMPLIANCE.

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

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

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR. The INVESTIGATOR and any Collaborator (as such term is defined at article 5.2) will be trained by SPONSOR with respect to the use of eCRFs.

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

ARTICLE 4. TERM.

This Contract is being entered into force from the Effective Date as mentioned above and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately *[64 Months]* months from the first visit of the first Subject to the last visit of the last Subject.

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ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

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

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

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

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

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

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

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

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

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

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

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of 25 Subjects (the « Subjects »), within 12 months. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g. x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3)

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months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

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

ARTICLE 7. CONSENT OF THE SUBJECTS.

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

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

ARTICLE 8. MONITORING OF THE STUDY.

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

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

ARTICLE 9. DUTY OF INFORMATION.

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

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

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

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within forty-five (45) days of receipt by the SPONSOR of an itemized invoice.

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10.3 The INVESTIGATOR and/or the INSTITUTION will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees they will receive hereunder.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR and the INSTITUTION agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.
Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.
11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.
11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

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

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).
-
- The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

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

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's

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

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

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

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.
As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.
However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.
The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

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

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

ARTICLE 15. PROPERTY RIGHTS.

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

15.2 The INVESTIGATOR and INSTITUTION shall not and shall cause the Collaborators not to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

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

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

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

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1(A) In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:
(1) In the case of an injury occuring to the Subject, during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier;
(2) In case the injury occuring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;
In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the Subject;
(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;
(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;
(5) Any injury or death of the Subject occuring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :
(a) adverse effect of the Investigational Medicinal Product;
(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;
(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;
(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;
(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;
(f) for injury to a child in-utero because of the participation of parent in the Study;
(g) any clinical trial procedures involved in the Study.»
The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.
16.2 The insurance subscribed by the SPONSOR does not release neither the INVESTIGATOR nor the INSTITUTION from their obligation to maintain their own liability insurance policy.
16.3 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:
(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or
(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or
(3) the negligence or wilful malfeasance of the Indemnities.
The SPONSOR shall have no obligation under this Section, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling

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thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and the INSTITUTION shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities. The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

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

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

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

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

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

ARTICLE 18. TERMINATION OF THE CONTRACT.

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

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

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

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

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

The INVESTIGATOR shall immediately notify the SPONSOR should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or

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restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

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

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

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

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

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

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

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

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR and the INSTITUTION represent and warrant that they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

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

ARTICLE 22. MISCELLANEOUS

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

Add. Director of Research
KIMSDU, Karad

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

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

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

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

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

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

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

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

Add. Director of Research
KIMSDU, Karad

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

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED

[Signature]

[Dr. Chirag Trivedi]
[Clinical Study Unit- Director]

In the Presence of:

(Y. J. Cama)

THE INVESTIGATOR

A.P. Patange

[Signature]

[Dr.(Mrs.) Aparna Patange]
[Principal Investigator]
In the Presence of:

(Dr Aditya C. Andhalkar)

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY

[Signature]
[Dr. M. V. Ghorpade]
[Registrar]
In the Presence of:

(Mr. Aniket A. Jadhav)

Add. Director of Research
KIMSDU, Karad

EXHIBIT 1

Study Name : Odyssey Outcomes Study Code : EFC11570

CONDITIONS OF PAYMENT

1. The SPONSOR will pay **Rs.2,71,788/-** per Subject included in accordance with the Protocol and who has completed the Study.

Such amount is divided as follows :

Subject Visits	Cost per visit including 30% overheads
Visit 1 - Screening(incl. run-in period)- Onsite Visit	INR 19,522
Visit 2 - Screening(incl. run-in period)- Onsite Visit	INR 11,903
Visit 3- Wk 0- Onsite Visit	INR 19,760
Visit 4-Wk 4- Onsite Visit	INR 11,109
Visit 5-Wk 8- Onsite Visit	INR 12,396
Visit 6- Wk 16- Onsite Visit	INR 12,396
Visit 7-Wk 32	INR 3,260
Visit 8- Wk 48- Onsite Visit	INR12,396
Visit 9-Wk 56	INR 3,260
Visit 10- Wk 64- Onsite Visit	INR 14,112
Visit 11- Wk 72	INR 3,260
Visit 12- Wk 80- Onsite Visit	INR 8535
Visit 13- Wk 88	INR 3,260
Visit 14-Wk 96- Onsite Visit	INR 8535
Visit 15-Wk 104	INR 3,260
Visit 16- Wk 112- Onsite Visit	INR 14,112
Visit 17-Wk 124	INR 3,260
Visit 18-Wk 136- Onsite Visit	INR 8535
Visit 19-Wk 148	INR 3,260
Visit 20-Wk 160- Onsite Visit	INR 14,155
Visit 21-Wk 172	INR 3,260
Visit 22-Wk 184- Onsite Visit	INR 8,578
Visit 23-Wk 196	INR 3,260
Visit 24-Wk 208- Onsite Visit	INR 14,155
Visit 25-Wk 220	INR 3,260
Visit 26-Wk 232- Onsite Visit	INR 8535
Visit 27-Wk 244 .	INR 3,260
Visit 28-Wk 256- Onsite Visit	INR 14,155
Visit 29-Wk 264	INR 3,260
Visit 30 Final visit - Wk 272- Onsite Visit Or Visit 70 Early End of Treatment Visit EOT	INR 16519
Visit 31 Follow-up – Wk 280	INR 3,260
Total maximum per patient	**INR 2,71,788/-**

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2. The SPONSOR will pay all screen failure Subjects as per actuals up to the maximum amount of Rs.19,522/- at Visit 1 and/or to the maximum amount of Rs.11,903/- at Visit 2 and for combined visit V1 plus V2 i.e. a sum total of V1+V2 equivalent to a maximum amount of Rs.31,425/- (Rupees Thirty One Thousand Four Hundred Twenty Five only).

   A screen failure is defined as a subject who meets the following three criteria:

   - From whom an informed consent is obtained;
   - That has completed screening procedures (as defined in the protocol) and
   - Is not included in the study

   Payment for screen failures will be made by the SPONSOR, after documentation of per protocol assessments is completed and all CRFs have been completed, as required.

3. The SPONSOR shall reimburse additional Rs.2,000/- (Rupees Two Thousand only) per screened Subject to the INVESTIGATOR/ INSTITUTION towards the efforts for identification of Subjects for screening.

4. Patient travel reimbursement is included in the per visit costs at INR 1200 per patient, per onsite visit.

5. A Close out fees of Rs.10,000/-(Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit is conducted.

6. Ethics Committee fees (Based on actuals)

7. SPONSOR agrees to provide and/or reimburse the statin medication to the Subject for the duration of Study subject to their participation in the Study, as required. Such reimbursement shall be done by the SPONSOR at actuals and against the receipt of original invoice/bills.

8. Amount of Rs.5000/- (Rupees Five Thousand only) per year will be paid for archiving study documents. The documents will be archived for a period of 15 years after study close-out.

9. Any cost of additional fee (Such as ECG cost, laboratory tests, subject trasnportation & meals) regarding unscheduled visit if any; and repeat local laboratory tests in emergency cases will be reimbursed within 30 days upon presentation of the invoice.

10. For the actual costs under Clause 6 & 7 the INSTITUTION/INVESTIGATOR shall provide the neces-ary documentation in support to SPONSOR.

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

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

Add. Director of Research
KIMSDU, Karad

11. The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION on monthly basis upon presentation of the invoices in INR by bankwire transfer within 30 days on the following account:

- Bank – **HDFC Bank**
- n°-**01651000036454**
- in the name of – **Dr.(Mrs.) Aparna Patange**
- PAN Number – **AMCPP6280B**
- The final payment will occur only after:
- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis ;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Section 5).

Add. Director of Research
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Sun Pharma Laboratories Limited
Regd. Office : Sun House, Plot No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai - 400 063, Maharashtra, INDIA.
Tel. : (91-22) 4324 4324
Fax : (91-22) 4324 4343
CIN : U25200MH1997PLC240268

SUN PHARMA

CLINICAL STUDY AGREEMENT

This clinical study agreement (**"Agreement"**) is executed as of this the [01] day of [Apr] 2015(**"Effective Date"**) by and between:

Sun Pharma Laboratories Limited(**"Sponsor"**), a company registered under the Companies Act, 1956 having its registered office at Acme Plaza, Andheri Kurla Road, Andheri (E), Mumbai 400059, India, through its authorized signatory which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the **"Sponsor"**).

AND

Krishna Institute of Medical Sciences Deemed University, Karad, Dist: Satara, Maharashtra. Pin: 415110 (hereinafter referred to as the **"Institution"**)

AND

Dr. Aparna Patange, Hospital, **Krishna Institute of Medical Sciences Deemed University, Karad, Dist: Satara, Maharashtra. Pin: 415110** (hereinafter referred as the **" Investigator"**)

(each a "Party" and collectively, the "Parties")

WHEREAS:

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

B. Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans and has developed a **"FDC Losartan, Amlodipine and Hydrochlorothiazide"** which will be used for treatment of **"Essential hypertension"**. Sponsor represents that it has applied for the necessary permissions and licenses required under the provisions of relevant Acts and Rules which are required for use of the same on patients

C. Sponsor desires Institution to study the safety and/or efficacy of **"FDC Losartan, Amlodipine and Hydrochlorothiazide"** and Institution is willing to perform a clinical study of the Study Drug.

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

1. SCOPE

1.1 The Study is of mutual interest and benefit to Sponsor and Institution, and will further the Institution's instructional and research objectives in a manner consistent with its status as a not-for-profit tax-exempt educational institution.

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KIMSDU, Karad

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1.2 The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol **"Evaluation of efficacy and safety of fixed dose combination of Losartan, Amlodipine and Hydrochlorothiazide in the treatment of essential hypertension: an open label, multi-centric trial"**, which has been provided prior to signing of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. The Study shall be conducted under the direction of Investigator in accordance with this Agreement, subject to review and prior approval by the institution's ethical committee.

2. CONDUCT OF THE CLINICAL TRIAL

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

2.2 It is explicitly agreed and acknowledged by the Parties that the Protocol for clinical trial/Study be reviewed and approved by the Institution's Ethical Committee ("IEC") before the commencement of the Study. The Investigator shall obtain and deliver a copy of such approval to the Sponsor. The approval must indicate the date of issuance and bear the name and signature of the Chairperson or Secretary of the IEC. If any such committee do not exist in the Institution, then the approval granted to a protocol by the ethical committee of another institution will be applicable to use of that protocol in the Institution.

2.3 During the Term of this Agreement, Institution and Investigator shall conduct study in accordance with the Protocol , as may be modified from time to time in writing, and as set forth in a Clinical Trial Request Form ("CTRF"). The terms and conditions of this Agreement shall apply to any CTRF entered into prior to the end of the Agreement period . The Investigator for each clinical trial/Study shall indicate assent by signature on the relevant CTRF.

2.4 The Institution and Investigator agree that the Sponsor or its designee as clinical monitor may conduct routine clinical practice audits at mutually convenient times and upon reasonable advance notice to the Investigator. The clinical monitor will have free access to all documents pertaining to the study to ensure that the study is conducted in accordance with the Protocol and in terms of this Agreement.

2.5 It is explicitly agreed and acknowledged by the Parties that in case Investigator is unable to perform the study in accordance with this agreement, the Institution shall appoint another Investigator in consultation with the Sponsor. The Institution shall take written consent from the Sponsor prior to such appointment. The Sponsor retains the right to suggest Investigator(s) for appointment to conduct and perform the Study.

2.6 If any clinical Biological Samples required to be tested during the course of the clinical Study , these are to be tested in accordance with the Protocol and at a central laboratory approved by

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Sponsor and with the Clinical Trial Subject's informed consent. It is explicitly agreed and acknowledged by the Parties that Collection, Retention, Use and Destruction of Biological Samples by Institution or Investigator or Sponsor or either of the parties shall be in accordance with the applicable Protocol, acceptable clinical trial practices, applicable patient privacy and informed consent laws and in compliance with all applicable laws and regulations.

3. OBLIGATIONS, REPRESENTATIONS & WARRANTIES OF THE PARTIES

3.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the appropriate IEC for the conduct of the clinical Study and from time to time the Investigator shall inform Sponsor about the progress of IEC submissions and directions, and provide Sponsor and the Institution with all correspondences relating to such submissions. The institutions shall ensure the proper conduct of trials.

3.2 The Investigator shall be responsible for obtaining a signed informed consent form from each Clinical Study Subject prior to the Clinical Study Subject's participation in the Clinical Study .For clarity **"Clinical Trial Subject"** means a person recruited to participate in the Clinical Trial. The investigator shall comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles in obtaining and documenting informed consent. Prior to the beginning of the Study, the Investigator must have the IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to Clinical Trial Subject. Neither the investigator, nor the trial staff, should coerce or unduly influence a Clinical Trial subject to participate or to continue to participate in a trial.

3.3 The Investigator shall use commercially reasonable efforts to recruit the agreed upon number of Clinical Trial Subjects on a timely basis and the Parties shall use reasonable efforts to conduct the Clinical Study in accordance with the agreed time period. It is agreed and acknowledged by the Investigator and the Institution that when a clinical trial (therapeutic or non-therapeutic) includes Clinical Trial Subjects who can only be enrolled in the trial with the consent of the Clinical Trial Subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the Clinical Trial Subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

3.4 The Institution and Investigator shall not permit the use of Study drug for any purpose (whether directly or indirectly) other than the conduct of the clinical Study and upon termination or expiration of this Agreement, all unused investigational drug shall, at Sponsor's option, either be returned to Sponsor or disposed of/ destroyed in accordance with the Protocol or Sponsor's written instructions.

3.5 It is explicitly agreed and acknowledged by the Parties that the Study may involve the participation of multiple sites and recruitment and in such event, when the enrolment goal for the clinical Study as a whole is reached, enrolment will be closed at all sites, including the trial Site, regardless of whether the Institution has reached its individual enrolment goal.

3.6 To the extent permitted by law, the Institution and the Investigator shall immediately inform Sponsor of :

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

3.6.2 any queries by State or Central Information Commission under Right to Information Act (amended up to date)

in connection with the clinical Study and forward promptly to Sponsor copies of any correspondence from any such authority.

The Institution or Investigator shall use its best efforts to obtain the consent of the regulatory authority to have a representative of Sponsor present during any such visit. If a representative of Sponsor is unable to be present during a visit, the Institution and the Investigator shall provide Sponsor with a detailed written report of the visit promptly following the visit.

3.7 The Institution and the Principal Investigator shall keep complete and accurate records of the conduct of the clinical Study and of all clinical Study data in accordance with generally accepted industry standards and practices and applicable Law. The Institution and the Investigator agree to retain all such records for a period of not less than three (3) years from the date of termination or expiration of this Agreement (the "Retention Period"). The Institution shall use reasonable efforts to give Sponsor written notice before destroying the Clinical trial documentation and clinical trial data.Any such destruction is subject to prior written consent of the Sponsor.

3.8 The Investigator undertakes to document all Adverse Events (AE) and Adverse Reactions (AR) and promptly notify to the Sponsor in writing. Any Serious Adverse Events (SAE) shall be reported immediately (within 24 hours) to the Sponsor together with the detailed report. For clarity, SAE means "any untoward medical occurrence" where the result is:

- Fatal.
- A threat to life.
- In inpatient hospitalization.
- Extension of an existing hospital stay.
- Persistent or significant disability/incapacity.
- Congenital anomalies or birth defects.

3.9 The Sponsor shall pay all medical expenses pertaining to Study subject in the event of any SAE, unless it has arisen due to non-adherence to the terms of the Protocol or Sponsor's written instructions relative to use of the Drug as agreed by Investigator and IEC and/or the same has resulted from the negligence or willful malfeasance or malpractices by Investigator and /or any trial staff or the Institution.

3.10 Investigator warrants and represents that:

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3.10.1 She is free to participate in the clinical trial/ Study and there are no rights, which may be exercised by, or obligations owed to any third party, which might prevent or restrict her performance of the obligations detailed in this Agreement;

3.10.2 where the Institution is not the Investigator's principal employer, She has notified her principal employer of her proposed participation in the clinical trial/Study and, where relevant, her supervision of trial site team members. She has obtained all necessary consents from her principal employer relating to this;

3.10.3 She is not involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Ministry of Health, the General Medical Council or other regulatory authorities;

3.10.4 She is qualified to provide clinical Study services based on the skills and experiences and has reviewed information regarding the Sponsor's Study Drug and the Protocol for the proposed clinical Study and wishes to conduct the trial and to supervise the team members at the trial site; and

3.10.5 during the Clinical Trial, She will not serve as an investigator or other significant participant in any clinical trial/study for another sponsor or any CRO companies if such activity might adversely affect her ability to perform her obligations under this Agreement.

3.11 Institution certifies that neither Institution nor any person (including Investigator) employed or engaged by Institution in the conduct of the Study has been debarred pursuant to applicable provisions of law (whether state or federal) and that no debarred person will in the future be employed or engaged by Institution in connection with conduct of the Study. Institution further certifies that it will notify Sponsor immediately in the event of any debarment or threat of debarment of any person employed or engaged by Institution in the conduct of the Study occurring during the period of this Agreement.

3.12 Sponsor, Institution and the Investigator represent and warrant that it has the right to enter into and fully perform this Agreement and, by entering into this Agreement it is not in violation of any law, statute, agreement or any other statue.

4. FINANCIAL ARRANGEMENTS

4.1 SPLL, as Sponsor, has agreed to provide financial support for the project. The Sponsor shall pay fees for the services of the Investigator in accordance with the budget as per **Exhibit-A**. For the purpose of administrative convenience and smooth functioning of the clinical Study, if any reasonable investigation expenses to be incurred that initially shall be spent by the Institution on behalf of the Sponsor. However, the Sponsor shall reimburse the same to the Institution upon receipt of the valid supporting documents.

4.2 The parties estimate that the payments provided for in the budget will be sufficient to support the Study, but Institution may submit to Sponsor a revised budget requesting additional funds in the event that costs may reasonably be projected to exceed the Budget. Except as otherwise provided in this Agreement, Sponsor will not be required to make any payment in excess of the Budget without Sponsor's prior written approval.

4.3 Sponsor shall make payments to Institution in accordance with the payment schedule set forth in Exhibit A and incorporated herein. Cheque(s) shall be made payable and sent to the :

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Fax : (91-22) 4324 4343
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Payee Name - Krishna Institute of Medical Sciences Deemed University, Karad
Address- Karad, Dist: Satara, Maharashtra. Pin: 415110

4.4 All laboratory investigations will be conducted at a central laboratory identified by sponsor. If any investigations are required to be conducted at the local laboratory and/ or site, the expenses will be reimbursed as per actuals, subject to production of the original invoices and corresponding receipts for the same.

4.5 The Investigator agrees to make every effort to supervise and lead the project to completion as planned and in time. Should any circumstances beyond her control delay the project or make it impossible to complete it, the Investigator shall give due notice to the Sponsor so as to minimize the delay or the loss, and return unutilized funds to the sponsor.

4.6 The Institution shall raise invoice on the Sponsor and separately specify Service Tax payable, if applicable on the services rendered and shall also show other necessary details such as Service Tax registration no. etc. so as to enable Sponsor to claim credit for the same as per law. The Sponsor shall verify the invoice and make the payment within 30 days from the receipt of the invoice submitted by Institution. However, if, upon verification by Sponsor, the invoice is found to be incorrect or inappropriate, the same shall be returned by Sponsor to the Institution for correction and revision. No other costs, payments and expenses would be borne by Sponsor unless specifically mentioned in this agreement. or mutually agreed in writing in advance. Notwithstanding the foregoing, any payment under this Agreement is subject to deduction of applicable Tax-deduction-at-source (TDS). Sponsor shall deduct the amount and pay balance amount to the Institution.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective date and will continue for a period of 3 years from the Effective Date or upon completion of the Clinical Study, whichever is earlier.

5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. Notwithstanding to the above, the Investigator may terminate the Study, if the Investigator suspects an adverse drug reaction / adverse drug event related to the Study related procedure and of serious nature to take its cognizance, after informing Institution, IEC and Sponsor in writing. In case of termination of study, responsibility of treatment of enrolled patients will be as specified in Protocol. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by Sponsor to Principal Investigator, Institution or any other person under this agreement.

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

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

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5.4.1 if the Investigator is not performing the Study as required in the protocol and/ or is not meeting the agreed upon enrollment;

5.4.2 in case of failure of the Investigator and/ or Institution to provide access by Sponsor representatives /Clinical monitor all original medical records necessary to verify entries on study case report forms;

5.4.3 in case of failure of the Investigator associated staff or any other person engaged in the study (excluding Subjects) to be available, upon reasonable notice and by prior mutually convenient time appointment by Sponsor, to meet with Sponsor monitors during the course of the study as necessary to discuss information relevant to the Study;

5.4.4 in case of an unauthorized replacement of Investigator;

5.4.5 if Sponsor determine that business or scientific considerations require termination of this Agreement (either full or in part);

5.4.6 if Case report forms provided to Investigator by Sponsor for use in the study are not legibly and accurately completed and forwarded the same to Sponsor or its designated representative within two (2) weeks of each Subject's visit date; or

5.4.7 if any malpractices adopted either by Investigator or Institution or both.

5.5 Within thirty (30) days after the termination of this Agreement, the Investigator shall deliver to Sponsor in writing a final accounting of:

a) all clinical trial Subjects that participated in the Clinical Study;
b) the clinical trial Subject visits completed in accordance with the Protocol during the term of this Agreement; and
c) all reasonable direct costs incurred in connection with any transfer of the Clinical Study to another trial site.

6. INDEMNIFICATION

6.1 The Sponsor hereby confirms that Sponsor shall pay all medical expense to study subjects in the event of any serious, immediate or delayed Adverse Drug Reaction or Adverse Drug Event unless it has arisen due to non-adherence to the terms of the protocol or sponsor written instructions relative to use of the study Drug as agreed by investigator and institutional Ethics Committee and/or the same has resulted from the negligence or willful malfeasance by investigator and/or its employee/consultants and/or the same has resulted from the negligence or willful malfeasance by the Study Subject himself/herself.

6.2 The Sponsor to indemnify and hold harmless the investigator, Institution and their trustees , officers, agents and employees from any and all liability, loss or damage they may suffer as the result of claims, demands, costs or judgment against them arising out of the activities to be carried out pursuant to the protocol designated, except to the comparative extent that Claims result from

6.2.1 Failure to adhere to the terms of the protocol or sponsor's written instruction relative to use of the study Drug as agreed by Investigator and institutional Ethics Committee

Add. Director of Research
KIMSDU, Karad

Sun Pharma Laboratories Limited
Regd. Office : Sun House, Plot No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai - 400 063, Maharashtra, INDIA.
Tel. : (91-22) 4324 4324
Fax : (91-22) 4324 4343
CIN : U25200MH1997PLC240268

6.2.2 Negligence or willful acts of an indemnified party.

6.3 Investigator and institution agrees to notify Sponsor as soon as they become aware of a claim or action and to co-operate with and to authorize sponsor to carry out the sole management and defense of such claim or action. Sponsor agrees , at its own expense to provide attorneys to defend against any actions brought or filed against Investigator or Institution, their trustees, officers, agents and employees with respect to the indemnity contained herein, if such claims or actions are rightfully brought or filed.

Neither Investigator nor Institution shall compromise or settle any claim or action without the prior written approval of sponsor.

7. CONFIDENTIALITY.

"Confidential Information" means all information (including, without limitation, Study Protocol(s), case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of Sponsor or Sponsor's Affiliates that are: (1) provided to Institution or Investigator in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

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

7.2 Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose Sponsor Confidential Information to any third party. Institution and Investigator agrees not to disclose Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Investigator shall safeguard Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to IEC is "Confidential and Privileged"

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

8. PUBLICATION

Add. Director of Research
KIMSDU, Karad

Sun Pharma Laboratories Limited
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Western Express Highway, Goregaon (E),
Mumbai - 400 063, Maharashtra, INDIA.
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Fax : (91-22) 4324 4343
CIN : U25200MH1997PLC240268

8.1 The Parties acknowledge that inadvertent publication of the results arising under the study/project may jeopardize patent protection. In the event Institution or Investigator wants to publish or present any or all of the technical developments, it shall submit to Sponsor the manuscript, abstract or other proposed publication at least thirty (30) days prior to submission, and in the case of poster boards or other presentations, at least forty-five (45) days prior to the presentation itself . Sponsor shall timely review the proposed publication, and may revise the manuscript or other proposed publication to ensure protection of Sponsor's Confidential Information.

8.2 Any publication or disclosure by the Investigator contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7) & (8), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

9. INTELLECTUAL PROPERTY RIGHTS

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

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

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

9.4 The Institution and the Investigator shall promptly disclose to Sponsor any Clinical Trial IP generated pursuant to this Agreement and shall treat the Clinical Trial IP as Confidential Information.

10 . MISCELLANEOUS

10 .1 All notices required to be given by one Party to the other shall be deemed to have been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement.

10 .2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

10 .3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing

Add. Director of Research
KIMSDU, Karad

Sun Pharma Laboratories Limited
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Tel. : (91-22) 4324 4324
Fax : (91-22) 4324 4343
CIN : U25200MH1997PLC240268

under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

10 .4 The Institution and Investigator will be responsible for payment to its employees and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the employees or agents may be entitled to receive for performing services. Investigator will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions ,benefits, dues etc. that may be payable to its employees and/or agents.

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

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

10.7 Neither the Investigator nor the Institution may assign this Agreement without the prior written consent of Sponsor. Sponsor may assign any or all of its rights and obligations under this Agreement at any time, provided that Sponsor ensures the assignee is bound by the terms hereof.

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

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

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

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

Add. Director of Research
KIMSDU, Karad

Subject to normal Force Majeure clauses. Both Parties shall make their best endeavour & shall take all reasonable care to complete the assignments within the time line specified by respective CTA to be execute for each specific assignment.

16. Termination of Agreement:

1. This Agreement shall be terminated by mutual agreement by giving [illegible] days prior written notice by either party after the completion of any ongoing [illegible].

17. Governing Law:

This Agreement shall be governed by and construed in accordance with the laws of India, under PUNE jurisdiction.

FOR KIMSDU

By :

Title : Registrar

Date : 6/11/2014

Witness: Smt. Nandini [illegible] Chavan
119, Ranjeeth Plaza, Karad

1 Bharat

FOR Clinzone Clinical Research Services Private Limited

By : **Dr. Jayshri Pachange .**

Title : **Director**

Date :

Witness: Dr. Umesh Dumbre.

6/Nov/2014

Clinzone Clinical Research Services Pvt. Ltd.

Director / Authorised Signatory

Clinzone Clinical Research Services Pvt. Ltd.

Add. Director of Research
KIMSDU, Karad

MOU Between CROM Clinical research services , Pvt. Ltd. Goa

AND

Krishna Institute of medical sciences Deemed University, Karad

Clinical trials conducted

1) A phase IV , Non- inferiority, observe Blind, Randomized Clinical study comparing safety and Immunogenicity of measlesMumps-rubella (MMR) subcutaneous Vaccination by Disposable- syringe Jet Injector.

Sponsor: Serum Institute of India Ltd., Pune

PI: Dr. C.D. Aundhkar

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2015 ◑ MU 479324

16 OCT 2015

14 OCT 2015

STAMP HEAD CLERK
TREASURY OFFICE,
KOLHAPUR (M.S.)

Memorandum Of Understanding

This AGREEMENT (this "**Agreement**") is made on this day the 01/10/2015.

BETWEEN

CROM Clinical Research PVT LTD

UGH VINTAGE Premises. Building No 2 Second Floor.

St Inez. Panaji Goa Pin 403001

AND

Krishna Institute of Medical Sciences Deemed University, Karad.

Near Dhebewadi road, Malkapur. Tal- Karad, Pin- 415539, Dist- Satara, Maharashtra

For CROM CLINICAL RESEARCH PVT. LTD.

DIRECTOR

Add. Director of Research
KIMSDU, Karad

This AGREEMENT (this "**Agreement**") is made on this day the _01/10/2015.

BETWEEN CROM Clinical Research Pvt. Ltd., an SMO set up as a company incorporated under the Companies Act, 1956 and having its address at UGH-VINTAGE Premises Building no 2, Second Floor St Inez Panaji Goa. Pin - 403001hereinafter referred to as "**CROM**" (which expression shall, unless it be repugnant to the context or meaning thereof be deemed to include its successors in business and assigns) of the One Part

AND

Krishna Institute of Medical Sciences Deemed University, Karad. havingits address at Near Dhebewadi Road, Malkapur. Tal- Karad, Pin- 415539, Dist- Satara, Maharashtra (which expression shall unless repugnant to the context or meaning thereof be deemed to include the which expression shall, unless the context otherwise requires, and to the extent provided in this Agreement, be deemed to include the partners' heirs, successors, administrators and permitted assigns) of the Other Part:

WHEREAS:

A. **Krishna Institute of Medical Sciences Deemed University, Karad**isa fully equipped super-specialty hospital set up as per international standards in the State Maharashtra with modern infrastructure and facilities to handle all healthcare needs.
B. CROM is a site Management Organization (SMO) set up in Kolhapur, Maharashtra with Dr. Dhananjay Lad being the Managing Director.
C. CROM having its office in UGH-Vintage Premises ST Inez Panaji Goa. is engaged in the business of conducting clinical research related services for various Clinical Research

For CROM CLINICAL RESEARCH PVT. LTD.

DIRECTOR

Add. Director of Research
KIMSDU, Karad

Organizations (CROs) & conducts clinical trials for testing of new drugs and treatments in India on behalf of Pharmaceutical companies and Contract Research Organizations.

D. CROM is presently having 10 Research Sites in India and 5 sites in Thailand.

   a. CROM has now approached **Krishna Institute of Medical Sciences Deemed University, Karad** for the purpose of conducting clinical trials in its premises on behalf of various Contract Research Organizations (CROs) in India.

E. "Clinical Trial" to be conducted under the direction and supervision of the CROM using the facilities of the Hospital.

Scope of Krishna Institute of Medical Sciences Deemed University, Karad

1) To provide Separate area/space for the Research department
2) To enter into tripartite agreement between Pharma Sponsor, CROM and Krishna Institute of Medical Sciences Deemed University, Karad
3) To provide doctors/consultants who will be appointed as the Principal Investigator (PI) for the respective studies.

Scope of CROM

1) To get clinical trials sanctioned for Krishna Institute of Medical Sciences Deemed University, Karad (business development).
2) Toprovide sufficient Clinical Research coordinators (CRC). The salaries will be borne by CROM.
3) To conduct clinical trials according to International Conference of Harmonization for Good Clinical Practice guidelines and Documentations, as prescribed by USFDA, EMEA and Japan regulatory authority.

For CROM CLINICAL RESEARCH PVT. LTD.
DIRECTOR

Add. Director of Research
KIMSDU, Karad

4) To conduct clinical trials under the guidelines of the Drug Controller General of India (DCGI), New-Delhi.

5) To negotiate and fix budgets with CRO for clinical trials.

6) To supervise all clinical trials from Pre site selection visit to the close out visit.

7) Krishna Institute of Medical Sciences Deemed University, Karad patients can take part in research with prior permission of PI and hospital. However, the counseling of patients to take part in clinical research is responsibility of CROM.

Confidentiality

Confidentiality of the Research Projectand patients will be maintained by both the parties.

Financial terms:

1) CROM will pay 60 % of sanctioned budget from Pharma Sponsors to Krishna Institute of Medical Sciences Deemed University, Karad for the services used for research patients. This includes PI (Doctors Fees) Institutional Overhead Charges, room/ward charges, Lab and radiological investigations, ICU, pharmacy, etc

2) All office expenses including Staff Salary, stationary, printing, Xerox, scans, Telephone bills, International Fax and call bills, courier charges etc will be paid by CROM.

CROM required 50 sq meter space to accommodate 10 CRC staff.

This Agreement is valid for a period of **1** year from date of signing of both parties.

IN WITNESS whereof parties have executed this deal on the day and place herein above mentioned through their authorized representatives.

For CROM CLINICAL RESEARCH PVT. LTD.

DIRECTOR

Add. Director of Research
KIMSDU, Karad

For and on behalf of Registrar

Krishna Institute of Medical Sciences

Deemed University, Karad.

Name:

Title:

For and on behalf of

For CROM CLINICAL RESEARCH PVT. LTD.

CROM Clinical Research (P) Ltd

DIRECTOR

Name: Dr. Dhananjay Lad

Title: Director

WITNESSES:

For & on behalf of For and on behalf of

Krishna Institute of Medical Sciences

Deemed University, Karad.

CROM Clinical Research (P) Ltd

Mr. Ratnadeep Fatil [CRC]

Name:

Name:

Add. Director of Research
KIMSDU, Karad

For CROM CLINICAL RESEARCH PVT. LTD.

DIRECTOR

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (Agreement) is executed on this ___ day of _____, 2015

BY and AMONG

Serum Institute of India Limited, a Company incorporated under the Companies Act, 1956 and having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411 028, India **(Serum Institute)** which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its executors, successors, legal representatives and permitted assigns);

AND

DiagnoSearch Life Sciences Private Limited, with its principal office at 702, Dosti Pinnacle, E-7, Road 22, Wagle Estate, Thane- 400604, Maharashtra, India **(DiagnoSearch)** the contract research organization to the clinical study sponsored by Serum Institute,

AND

Dr. Chandrashekhar D. Aundhakar, Adult, in his personal capacity (**Principal Investigator**) and with an office located at **Department of Pediatrics, Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra**

AND

Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra **(Institution)**

for the conduct of a clinical trial titled " A Phase IV, Non-Inferiority, Observer Blind, Randomized Clinical Study Comparing Safety and Immunogenicity of Measles-Mumps-Rubella (MMR) Subcutaneous Vaccination by Disposable-Syringe Jet Injector to Vaccination by Needle and Syringe for the Administration in Healthy Children in India aged 15 to 18 months" (the **Study**).

Institution, Principal Investigator, Serum Institute and DiagnoSearch, sometimes may be referred to herein individually as a "Party" or collectively as the "Parties."

1) Study vaccine administration using Disposable Syringe Jet Injector (DSJI): Serum Institute's Measles-Mumps-Rubella (MMR) vaccine would be administered by DSJI to demonstrate its non-inferiority of seropositivity to that due to vaccine administration by needle and syringe (N-S) for all three components of the vaccine. The investigational device Stratis® to be used in the study is from Pharmajet® and is developed, tested and validated in accordance with the FDA regulations, WHO-POS

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KIMSDU, Karad

specification and globally Harmonized ISO standards All the necessary permissions and licenses required under the provisions of relevant acts and rules have been obtained by Serum Institute prior to it's authorization to Institution for comparing safety and immunogenicity of MMR subcutaneous vaccination by disposable- Syringe Jet Injector (DSJI) to vaccination by disposable-syringe needle in healthy children in India aged 15-18 months in accordance with the protocol as defined in the Study.

2) Institution: Serum Institute and DiagnoSearch have approached the Institution, as they desire the Institution to perform the Study in regards to the said vaccine administration using DSJI in accordance with the following standards: (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees); (f) the Principal Investigator Requirements set forth in Appendix A attached hereto; (g) all policies and procedures of the Institution; (h) all current and applicable permissions, licenses, approvals, and (i) all current and applicable laws and regulations (such standards set forth in Sections 3(a) – (i) collectively referred to hereafter as the Standards and in accordance with the final protocol, subject information sheet, informed consent document and case report forms for the above-referenced clinical study (collectively, the Clinical Trial Protocol / Protocol, a current version of which is attached hereto as Appendix B, which attachment shall be replaced with 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.

3) Performance:

a) Protocol and Standards: Dr. Chandrashekhar D. Aundhakar, who will supervise and direct the work of the Study at the Institution as Principal Investigator, hereby confirms that he/she has read and understood the Clinical Trial Protocol for the Study to be conducted in healthy children aged 15 to 18 months, and further confirms that the research team is properly trained concerning the Clinical Trial Protocol and Standards. All amendments and appendices 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 to the performance of this Agreement. If for any reason the

Add. Director of Research
KIMSDU, Karad

Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, the Institution shall promptly notify in writing to DiagnoSearch and Serum Institute. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by DiagnoSearch and Serum Institute by giving 15 days written notice.

c) Recruitment: The Principal Investigator understands and agrees that Serum Institute requires at least three hundred and ten (310) completed subjects at the conclusion of the Study from across all the participating sites, and that, based on estimated drop-out rates and enrollment rates provided by the Investigator/(s) and the number of subjects already recruited, it is expected from the Investigator to enroll a minimum of 50 human subjects to achieve this number of completed subjects. Recruitment is competitive across all the participating sites.

d) Confidentiality:

i) Definition: During the term of this Agreement, 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 Serum Institute or to Serum Institute's other collaborators (other than the Institution) and is, therefore, of a confidential nature (collectively referred as Confidential Information). Confidential Information shall include, the Clinical Trial Protocol, Serum Institute's clinical investigator's brochure concerning the MMR vaccine, Pharmajet's Stratis® device, all Study Data (as such term is defined in Appendix C, attached hereto), all documents maintained in the Investigator Site File (site documentation), any other data emerging out of the protocol, any other information supplied by Serum Institute or Serum Institute's representatives during the course of the Study and clinical development plan, all results and reports obtained, collected, conceived, processed, developed, improved or reduced to practice pursuant to this Agreement except the information already in the public domain and information requested by government authorities or as required to be submitted by the law and other statutory requirements.

ii) Use: The Institution shall hold all Confidential Information confidential and shall disclose Confidential Information to only its Principal Investigator, hospital staff and employees who have a need to know such Confidential Information for the purposes 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, patent application, trade secret or other proprietary right now or hereafter owned or controlled by DiagnoSearch, Serum Institute or Serum Institute's other collaborators is granted to the Investigator and the Institution from the provision of Confidential Information hereunder. The Institution shall comply with the Study Data Confidentiality Conditions set forth in Appendix C, attached hereto. In the event that

Add. Director of Research
KIMSDU, Karad

the Institution or any of the Institution's representatives is requested in any proceeding to disclose any of the Confidential Information, the Investigator and the Institution will provide Serum Institute with prompt prior written notice so that Serum Institute may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement. In the event that such protective order or other appropriate remedy is not obtained, the Institution will (i) furnish only that portion of the Confidential Information which the Institution is advised by legal counsel is required, (ii) will give Serum Institute written notice of the information to be disclosed as far in advance as practicable.

iii) Provision: The Institution agrees that, at any time upon Serum Institute's and/or DiagnoSearch's written request, it shall promptly provide to the requesting Party copies of all Confidential Information under this Agreement. The Institution further agrees that, upon any termination or expiration of this Agreement, it shall, at Serum Institute's discretion either return to Serum Institute or destroy all copies of all Confidential Information; provided, however, that the Institution may retain one (1) archival copy of Confidential Information for regulatory purposes, subject to the Institution's ongoing obligation to maintain the confidentiality of such Confidential Information.

e) 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 Serum Institute.

ii) Disclosure, Assignment and Provision to Serum Institute: The Parties agree that the Institution shall promptly disclose to Serum Institute any and all Work Product comprising inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice arising under or relating to this Agreement. The Institution hereby assigns to Serum Institute all of the Institution's rights and interests in all Work Product. At Serum Institute's request, the Institution shall execute, and shall require the Principal Investigator and other hospital staff and employees of the Institution to execute those documents as Serum Institute may reasonably require in order to fully and effectively vest all Work Product in Serum Institute. Serum Institute shall have the right, at any time, including upon any termination or expiration of this Agreement, to review and obtain copies of all Work Product (including without limitation all Study Data, in an agreed-upon format and with a complete glossary of terms used for such Data).

f) Materials: The Tresivac® (MMR vaccine), Stratis® (DSJI device), Needle-Syringe, blood samples from human subjects under the Study and all other tangible materials

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KIMSDU, Karad

provided to or obtained by the Institution under this Agreement (collectively, the Materials) shall be the property of Serum Institute and/or Serum Institute's other collaborators (other than the Institution), including but not limited to Serum Institute, the manufacturer of the Tresivac® and the manufacturer of the study device. The Institution shall use the Materials for the 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 under any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by Serum Institute or Serum Institute's other collaborators is granted to the Institution or Principal Investigator from the provision of Materials hereunder. Upon any termination or expiration of this Agreement, the Institution shall return / ship and/or dispose of all remaining Tresivac® (MMR vaccine), Stratis® (DSJI device) and other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of Serum Institute.

g) Human Subjects: The Institution shall be responsible for safeguarding the rights and welfare of human subjects in the Study. The Institution shall follow the study procedures as mentioned in the latest approved study protocol attached as Annexure B: The Institution shall ensure

(i) the rights and welfare of each such human subject are protected;

(ii) informed consent of each such human subject is freely and knowledgeably given: (A) to participate in the Study; and (B) for the collection of data by, processing by and disclosure to and between the DiagnoSearch, representatives of Serum Institute, Principal Investigators and researchers at the Study site, Study monitors, Study laboratory personnel, Study data analysts, members of Institutional Ethics Committees and representatives of 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 Institution has made appropriate arrangements to provide adequate support and medical care to such human subjects in case of any, injury, or illness or their families in the case of any death for which the Institution has agreed to assume liability, in accordance with Sections 6(b) and 6(e) herein.

h) Ethical Approval: The Institution shall petition for written certification of ethical approval of the Study from its Institutional Ethics Committee [hereinafter also referred as IEC]. The Institution shall keep DiagnoSearch fully advised of the progress of such submission and shall, upon request, provide DiagnoSearch with all correspondence relating to such submission. The Institution shall not consent to any change in the Clinical Trial Protocol requested by its Institutional Ethics Committee without the express, prior written consent of Serum Institute. The Institution shall obtain such certification of IEC prior to screening any human subjects for the Study

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and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the Institution shall promptly provide a copy to DiagnoSearch and Serum Institute.

i) Adverse Event Reporting: The Institution shall comply with the adverse event evaluation, investigation, treatment, reporting and follow-up obligations set forth in the Clinical Trial Protocol, Standards and the serious adverse event management standard operating procedures of Serum Institute. All Adverse Events shall be treated as per the current Good Medical Practices and applicable laws & regulatory requirements.

4) Amendments: The Principal Investigator, the Institutional Ethics Committees and Serum Institute must approve any alteration in or amendment to the Final Clinical Trial Protocol prior to such alteration or amendment becoming effective.

5) Inspections:

a) By Representatives of Serum Institute or Monitors of DiagnoSearch The Institution agrees that Serum Institute's representatives and DiagnoSearch's clinical monitors and third party auditors appointed by Serum Institute, if any, 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.

b) By Governmental 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 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 DiagnoSearch and Serum Institute 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

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any non-compliance cited by governmental authorities and shall promptly notify DiagnoSearch and Serum Institute of such remedial actions taken.

6) Indemnification:

a) Serum Institute agrees to pay:

(i) all the medical management expenses to the clinical trial subject in case of an injury occurring to him /her irrespective of it is arising out of or related to clinical trial or not;

(ii) for the financial compensation over and above the expenses referred in above clause 6 (a)(i) granted by the competent authorities, in the event of any claim arising out of any adverse reaction which is a trial related injury (defined as any adverse reaction causally related to the study procedures and/ or study drug) in a human subject in the Study in accordance with the Clinical Trial Protocol, (except to the extent the Institution or DiagnoSearch are liable for such expenses under this Agreement or any other agreement.)

b) Notwithstanding clause 6 (a) above, Serum Institute shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

i) A failure to adhere to the terms of this Agreement, Serum Institute's written instructions relating to the Study (including the Clinical Trial Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Serum Institute and DiagnoSearch.

Negligent acts or omissions or intentional, reckless or willful malfeasance by Principal Investigator, the Institution, or the Institution's trustees, officers, agents, hospital staff and employees, and the Institution hereby agrees to stand to pay all directly related medical expenses for such adverse reactions and adverse events.

c) Consistent with the information set forth in the subject information sheet, Serum Institute shall not stand to pay any medical expenses in the event of any pre-existing chronic illness or condition (including without limitation HIV status or AIDS) of any human subject in the Study. The Institution and the Principal Investigator will ensure during the informed consent process positive confirmation from the subject, that he/ she is required to disclose all pre-existing medical illness that he/she is aware of. Failure by the subject to do so would mean that the Serum Institute / Institution would not be liable for any resulting medical expenses.

d) DiagnoSearch hereby indemnifies and holds harmless the Serum Institute, Principal Investigator, the Institution and the Institution's trustees, officers, agents, hospital staff and employees from any and all third party liability, loss or damages they may suffer as the result of claims, demands, actions, costs or judgments including claims under the Indian Consumer Protection Act against them arising out of DiagnoSearch's

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failure to comply with the Clinical Trial Protocol, applicable Standards or this Agreement; or DiagnoSearch's negligent acts or omissions or intentional, reckless or wilful misconduct; provided, however, that DiagnoSearch shall not be liable for any such liability, loss or damage arising out of or resulting from:

i) A failure by Principal Investigator or Institution to adhere to the terms of this Agreement or Serum Institute's written instructions relating to the Study including the Clinical Trial Protocol; or

ii) Negligent acts or omissions or intentional, reckless or willful malfeasance by Principal Investigator, the Institution, or the Institution's trustees, officers, agents, hospital staff and employees who are excluded from this indemnification and the Institution hereby agrees to be liable for any such liability, loss or damages excluded from indemnification by DiagnoSearch.

e) Institution hereby indemnifies and holds harmless Serum Institute and DiagnoSearch, its officers, affiliates, agents, and employees from any and all third party liability, loss or damages they may suffer as the result of third party claims, demands, actions, costs or judgments including claims under the Indian Consumer Protection Act against them arising out of Institution's failure to comply with the Clinical Trial Protocol, applicable Standards or this Agreement; or Institution's negligent acts or omissions or intentional, reckless or willful misconduct; provided, however, that the Institution shall not be liable for any such liability, loss or damage arising out of or resulting from Serum Institute and DiagnoSearch's failure to adhere to the terms of this Agreement or Serum Institute's written instructions relating to the Study including the Clinical Trial Protocol.

f) In the event a human subject in the Study suffers from physical injury or illness related to the Study or from any long term irreversible adverse effects caused by the study vaccine or study device, the Institution shall take all reasonable measures to ensure that such subject contacts Serum Institute as soon as possible in order to initiate the process of evaluating such subject's rights and to make a liability claim for compensation.

g) The Institution agrees to notify Serum Institute and DiagnoSearch as soon as it becomes aware of a claim, demand, action, liability or loss hereunder and to co-operate with and to authorize Serum Institute &/or DiagnoSearch to carry out the sole management and defense of such claim, demand, action, liability or loss. Serum Institute/DiagnoSearch agrees, at its own expense, to provide attorneys to defend against any claims or actions brought or filed against Principal Investigator, the Institution, and/or the Institution's trustees, officers, agents, hospital staff and employees with respect to the subject of Serum Institute's / DiagnoSearch's indemnity contained herein, whether such claims or actions are rightfully brought or filed.

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h) Neither the Institution, nor its trustees, nor the officers, agents, hospital staff or employees of the Institution, shall compromise or settle any claim or action subject to indemnification hereunder without the prior written approval of Serum Institute and DiagnoSearch.

7) Insurance:

a) At all times during the Study, Serum Institute shall maintain clinical trials liability insurance for the Study and shall have its insurance company provide to DiagnoSearch or the Institution a certificate of such insurance upon the request of DiagnoSearch or the Institution.

b) At all times during the term of this Agreement, Serum Institute shall provide professional liability insurance adequate for the activities under this Agreement to Principal Investigator.

c) The Institution shall also maintain sufficient levels of all legally mandated insurance, if any including professional liability insurance for itself. DiagnoSearch shall be given notice prior to any material changes to or lapse in coverage.

8) 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.

9) Agreement Term and Termination:

a) This Agreement is effective for 2 (two) years from the date of signing of this Agreement, by the last party unless terminated sooner in accordance with this Article 9 or unless extended for a defined period by a signed writing in accordance with Article 20.

b) The Study and this Agreement may be terminated by written notice from DiagnoSearch and / or Serum Institute to the Institution for any of following reasons:

i) Intimating that Serum Institute has received a notice / intimation from applicable regulatory authorities to terminate said Study.

ii) Determination by DiagnoSearch and Serum Institute that the Institution is not performing the Study as required in the Agreement and/ or Protocol and/or is not meeting the agreed upon human subject enrollment requirements set forth in Section 3(c) herein.

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iii) Failure of the Principal Investigator and/or the Institution to provide access to DiagnoSearch monitors or Serum Institute representatives or third party auditors, if any, 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 subjects) to be available, upon reasonable notice and by
prior mutually convenient time appointment by DiagnoSearch or Serum Institute, to meet with DiagnoSearch monitors or Serum Institute representatives during the course of the Study as necessary to discuss information relevant to the Study.

v) Unauthorized replacement of Principal Investigator, other than in accordance with Section 3(b) herein.

vi) Determination by Serum Institute that business or scientific considerations require termination.

vii) Case report forms provided to Principal Investigator by DiagnoSearch for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to DiagnoSearch or Serum Institute's designated representative, as appropriate, within a reasonable time of each subject's visit date.

c) The Institution may terminate this Agreement by written notice from the Institution to DiagnoSearch for any of following reasons:

i) Serum Institute does not comply with the Clinical Trial Protocol provisions related to supply of study vaccine or study device for the Study, or DiagnoSearch does not supply other agreed-upon study related material.

ii) Principal Investigator reasonably suspects an adverse reaction related to the Study procedure and of serious nature, after informing the Institutional Ethics Committees and DiagnoSearch.

d) In case of any termination or expiration of this Agreement:

i) Responsibility for treatment of enrolled human subjects will be as specified in the Standards;

ii) The Institution shall cooperate with DiagnoSearch for an orderly wind-down of activities, with due regard for human subject safety and welfare;

iii) The Institution shall destroy or return all Confidential Information to Serum Institute, at Serum Institute's election, in accordance with Section 3(d) (iii) herein;

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iv) The Institution shall promptly provide all Agreement deliverables due to DiagnoSearch and, if requested by Serum Institute, provide copies of all Work Product (including without limitation all Trial Data) to Serum Institute, in accordance with Section 3(e) (ii);

v) The Institution shall return/ ship and/or dispose of all remaining Tresivac® (MMR vaccine), Stratis® (DSJI device), and other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of Serum Institute, in accordance with Section 3(f) herein;

vi) The Institution shall, within sixty (60) days after such termination or expiration, provide a final invoice to DiagnoSearch. The total sums payable to the Institution pursuant to this agreement shall be equitably prorated for actual work performed to the date of termination, with any advance funds previously paid to the institution being refunded to DiagnoSearch.

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 and Sections 3(d), 3(e) 3(f) and 3(g) 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.

10) 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 filled out case record forms (CRF) and all other Study materials will be archived by the Principal Investigator at the Institution for a period of at least five years set forth in the Clinical Trial Protocol. The CRF will be in NCR format. The original white copy will be retrieved during monitoring visit by the monitor and submitted to data management for data analysis. The yellow copies will remain at site as stated above and will be archived by site for a period of at least 5 years.

11) Publication of Results:

a) Both the Institution and Serum Institute 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) Serum Institute intends to publish and/or present the results of the Study with its collaborators and the Institution performing the Study and/or other authors, subject to the provisions contained in this Agreement.

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c) Institution shall not make any publication, press release, presentation without obtaining prior written approval of Serum Institute.

12) Finance:

a) The expenses of the Study, as set forth in the total projected budget, attached hereto as Appendix D, shall be paid by DiagnoSearch and are estimated not to exceed the amount mentioned in Appendix D. In case it exceeds, it will be mutually agreed upon on reasonable grounds and documented appropriately. Funds shall be paid by DiagnoSearch to the Institution for the satisfactory and timely performance under this Agreement, as follows:

i) Upon signature of all the Parties to this Agreement and the Institution's provision of the written certification of approval of the Study from the Institution's Institutional Ethics Committee, in accordance with Section 3(h) herein, DiagnoSearch will make payment on a monthly basis as per the attached site budget herewith as Appendix D for per completed subjects once their data is source verified and CRF pages are retrieved.

ii) The cost for treatment for adverse events will be paid on actuals in the month the cost is incurred provided all documentation related to the adverse event is completed by the site and reviewed by the Diagnosearch.

iii) All the payments will be released after deducting TDS at the source as per Income Tax regulations.

iv) The site budget is based on the completed subjects. Therefore, the investigators will be paid for the completed subjects only except the patients withdrawn because of safety reason. Such withdrawn subjects will be considered as completed subject and the investigator will be paid for such subjects.

b) DiagnoSearch shall forward to Serum Institute all invoices submitted by Institution. DiagnoSearch shall remit payment to Institution within forty-five (45) days of DiagnoSearch's receipt of payment from Serum Institute. DiagnoSearch will be solely responsible if the payments remain outstanding for a period exceeding forty five (45) days.

13) Publicity, Product Promoting Activity and Communication Guidelines:

a) DiagnoSearch and Serum Institute shall not identify or use the names, trademarks, trade names or symbols of the Institution, Principal Investigator or his/her research team under the Study without the prior written permission of the Principal Investigator and Head of the Institution for publicity or product promoting activity. Serum Institute 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 regulatory agencies, governmental legal agencies, other collaborators, and media.

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b) The Institution shall not identify or use the names, trademarks, trade names or symbols of DiagnoSearch, DiagnoSearch's employees or affiliates, Serum Institute, Serum Institute's employees or affiliates, Serum Institute's collaborators or any other author of the primary collaborative publication described in Section 10(b) herein for publicity or product promoting activity.

c) The Institution shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of Serum Institute.

14) Limitation of Liability IN NO EVENT SHALL ANY 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 ANOTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE SUBJECT MATTER OF THIS AGREEMENT.

15) Dispute: Any dispute that arises during the Study among the Parties to the Agreement will be subject to the jurisdiction of Mumbai courts. Any dispute will be attempted to be settled amicably.

16) Stamp Duty: All cost, expenses and other charges for preparation of this Agreement including stamp duty shall be borne and paid by Serum Institute.

17) Force Majeure

Each Party shall not be responsible for losses or damages to other Parties occasioned by delays in the performance or nonperformance of any of its obligations when caused directly or indirectly by acts of God, acts of government, casualty, riots, acts of other Parties, strikes or other labor difficulties, shortages of labor, supplies and transportation, or any other cause beyond its control. In such event Serum Institute may discontinue this Agreement or allow Institution and DiagnoSearch to adjust the schedule in accordance with the impact of any such delay or postponement and the revision in the compensation shall be decided mutually by the Parties.

18) Waiver

Failure by any Party/ies to enforce any provision of this Agreement shall not be deemed a waiver or future enforcement of that or any other provision.

19) Independent Contractors:

Institution, Serum Institute and DiagnoSearch shall perform this Agreement in the capacity of, independent contractors.

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20) Entire Agreement: This Agreement, including the Appendices attached hereto, 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 human subjects of the Study. This Agreement may only be amended by a written instrument executed by the Parties hereto.

21) Headings:-
Headings used in this Agreement are provided for convenience only and shall not be used to construe meaning or intent.

22) Notices:-
Any notice or report required or permitted to be given or made under this Agreement shall be in writing, delivered personally or by facsimile (and properly confirmed by personal delivery or courier) or courier, postage prepaid, addressed to the other Parties at their addresses indicated below, or to such other addresses as the addressee shall have last furnished to the addresser and shall be effective upon receipt by addressee.

If to Institution	Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra
and Principal Investigator:	Kind Attn: Dr. Chandrashekhar D. Aundhakar Department of Pediatrics, Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra
If to DiagnoSearch:	Kind Attn: Mr. Mandar Vaidya 702, Dosti Pinnacle, E-7, Road 22, Wagle Estate, Thane (W) – 400 604, India
If to Serum Institute:	Serum Institute of India Ltd. Kind Attn: - Dr Prasad Kulkarni 212/2, Off Soli Poonawalla Road, Hadapsar, Pune – 411028, India

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KIMSDU, Karad

With a copy to: Dr Rajeev Dhere

Any Party listed above may change its mailing address for purposes of notices under this Agreement by giving the other Parties notice of such change in accordance with this section.

23) Counterparts:

This Agreement is executed in 4 counterparts, each of which shall be deemed an original. Each Party and Principal Investigator, retain one copy.

This Agreement includes the following Appendices:-

Appendix A: -	Principal Investigator Requirements
Appendix B: -	Clinical Trial Protocol
Appendix C: -	Study Data Confidentiality Conditions
Appendix D: -	Total Projected Budget

DiagnoSearch Life Sciences Private Ltd

Signature of authorized signatory

Name: Mr. Mandar Vaidya

Designation: Director, Operations

Place: THANE

Date: 02/JUNE/2015

Department stamp:

Diagnosearch Life Science Pvt. Ltd. Thane

Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra

Signature of authorized signatory

Name: Dr. M. V. Ghorpade

REGISTRAR

Krishna Institute of Medical Sciences Deemed University, Karad

Designation:

Place: KARAD.

Date: 08/06/2015

Department stamp:

Krishna Institute of Medical Sciences, Deemed University, Karad

Add. Director of Research
KIMSDU, Karad

Serum Institute of India Limited

Signature of authorized signatory

Name: Dr. Rajeev Dhere

Designation: Executive Director

Place: Pune,

Date: 5/6/2015

Department stamp:

Serum Institute Of India Ltd. ★ Pune-411 028. INDIA ★

Department of Pediatrics, Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra

Signature of authorized signatory

Name: Dr. Chandrashekhar D. Aundhakar

Designation: Principal Investigator

Place: KARAD

Date: 9/6/2015

Department stamp:

DR. C. D. AUNDHAKAR
MD,DNB (Paed)
PROFESSOR & HEAD
DEPARTMENT OF PEDIATRICS
KIMSU, KARAD

Add. Director of Research
KIMSDU, Karad

APPENDIX D

Visit break up	Amount in Indian Rupees (INR)	
	Investigator (PI)	Institute Overhead (OH) @ 25%
Visit 1/Day 0	1700	425
Visit 2/ Day 14	1000	250
Visit 3/Day 35	1700	425
Query Resolution & DB Lock (10%)	550	137.5
Close Out Visit (10%)	550	137.5
Total grant/completed subject	5,500	1375
A. Total Grant for 50 completed Subjects*	**275000**	**68,750**
Pass-through		
Subject Compensation for Travel Allowance per completed subject (@ Rs. 300/ visit* 3 visits)	900	
Subject Compensation for Travel Allowance 50 completed subjects	45000	
Ethics Committee Fees**	25,000	
B. Total Pass Through	**70000**	
Total Site Budget (A + B)	**413,750**	

PAYMENT SCHEDULE

In connection with the Study, DiagnoSearch will pay Department of Pediatrics, Krishna Institute of Medical Sciences Deemed University, Malkapur, Karad-415539, Maharashtra in accordance with the terms set forth in the Budget (schedule D).

1. The payments to the site will be made on a monthly basis for completed subject visits in that month once their data is source verified and CRF pages are retrieved.
2. Payment of Institutional Charges at the rate of 25% on total investigator grant may vary depending on number of subjects recruited.
3. *Recruitment is competitive. Any additional recruitment would be paid pro rata as per the executed site budget.
4. **Additional payment may be applicable in case of any amendment submission to ethics committee as per the EC SOPs.
5. An amount of 10% of PI grant per subject will be kept on hold for query resolution and database lock and will be released after database lock is confirmed by the data management.
6. An amount of 10% of PI grant per subject will be released post close out visit.
7. Reimbursement for any investigation performed for safety evaluation, outside the scope of protocol and deemed necessary for subject safety will be on actuals on submission of bills.
8. All payments shall be subject to tax Deduction at Source regulations of the Income Tax Act

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Payments are expected to be made by, DiagnoSearch Life Sciences Pvt Ltd, by cheque payable as follows:

Payee name for cheque preparation: KRISHNA INSTITUTE OF MEDICAL SCIENCES UNIVERSITY

PAN details: AAATK1255H

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MOU Between Unique Clinical research services , Pvt. Ltd. Pune

AND

Krishna Institute of medical sciences Deemed To Be University, Karad

Clinical trials conducted as follows

1) Metastatic breast Cancer: 0927-17

PI: Dr.Anand Gudur

2)Triple negative breast cancer: 0063-17

PI: Dr.Anand Gudur

3) Onco tissue collection study: MBT –TB-70

PI: Dr.Anand Gudur

4) Hepatic Encephalopathy: EPDI067

PI : Dr.Sandeep Patil

5) Age related Macular degeneration: LRP/RBZ/2015/002

PI : Dr.Gaurav Paranjpe

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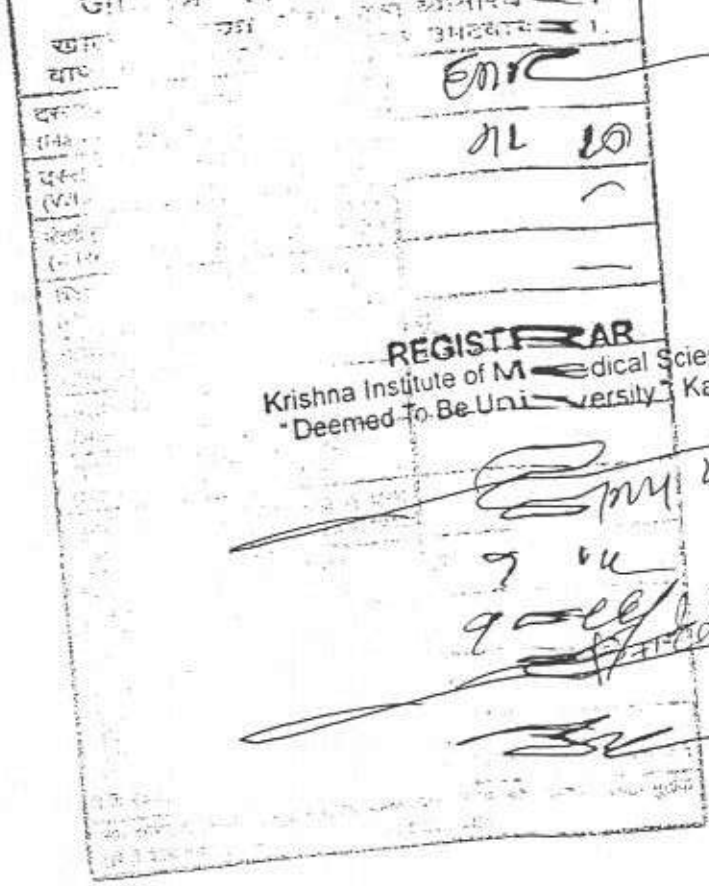

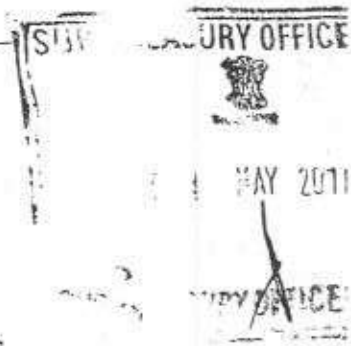

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

MEMORANDOM OF UNDERSTANDING BETWEEN UNIQUE CLINICAL RESERCH SERVICES, PUNE AND KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

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MEMORANDOM OF UNDERSTANDING BETWEEN UNIQUE CLINICAL RESERCH SERVICES, PUNE AND KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD

Objective: Setting up an Clinical Research Unit (CRU) at KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD

Version Number: 01
Version Date: June 20, 2018

This agreement made at Pune on 20th day of June of 2018 between, **UCRS** and **KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY"** having its registered office at Malkapur, Tal. Karad Dist. Satara 415 539 and represented by **Dr. M. V. Ghorpade, Registrar** (herein after referred to as the management for the sake of brevity) of the FIRST PARTY and Unique Clinical Research Services. Shriprasad Block Number D/2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, represented by **Dr. Sunil Chaudhary / Deepak Bagde**, to start Clinical Research Unit at KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", Karad on the following terms and conditions.

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Krishna Institute of Medical Sciences 'Deemed To Be University', Karad

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Krishna Institute of Medical Sciences "Deemed To Be University", Karad ★

1.0 BACKGROUND

UCRS is an initiative by experts and professionals inspired by the idea of providing quality services in the clinical research and allied areas. **Unique Clinical Research Services** is an SMO & Spin off of our ongoing unit - **Pentagon Research & Life point Research** and is also equipped to provide various vocational training options to Life Science, Pharmacy and Medical graduates.

UCRS also provides consulting services in setting up research departments in hospitals, data management services, Statistical analysis services, Medical and regulatory writing etc. We are clinical research professionals with total domain experience of nine years with headquarters based in Pune, Maharashtra.

Body of work of Unique Clinical Research Services -

We have successfully completed close to 300 plus trials at different sites with variety of indications. We have closely worked with all the domestic & Global players like Novartis, Sanofi aventis among others. We have also successfully completed site audit by eminent regulators like USFDA, not to mention DCGI.

In the hospitals that we have agreements with to conduct clinical trials, we have experienced oncologists, cardiologists, physicians, oncosurgeons, Dermatologists, psychologists, endocrinologists, Nephrologists, among others to conduct trials in all indications possible.

It is our vision to streamline and smoothen the "last mile connectivity" in clinical research in India. We are currently a proven and credible research outfit in Western India, with capability to conduct studies in all indications. It is our mission to provide professional, timely, effective and above all authentic clinical research services to our clients, across the country.

A brief about our directors –

Dr Sachin Mane is healthcare professional with 22 years' experience in various operational areas of hospitals including clinical research. He has worked in Senior Leadership Roles for India's leading healthcare providers like Wockhardt Hospitals and Sahyadri Hospitals.

Dr Sunil Chaudhary is a Medical professional with a decade's experience in Clinical research and trials management. He has handled Phase II, III and IV studies, investigator initiated studies and bioequivalence studies in patients. Having worked in research dept with Sanofi India, he has deep understanding of regulatory and statutory requirements by regulatory authorities.

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Mr. Deepak Bagde has 11 years' experience in healthcare and hospital administration. He has executed development of Regenerative Therapy Module and established stem cell banking business. Mr. Bagde has established a CRO for product development of generic molecules and he has established a Bioavailability and Bioequivalence Study Center in Pune. He has worked extensively in the development of new molecules for Phase I and Phase II studies.

Dr. Sunil Chaudhary is a healthcare professional with 10 years' experience in clinical trials management.

2.0 BUSINESS PROPOSAL

UCRS is pleased to extend collaboration MOU to KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD. As per the terms of the MOU, UCRS will offer services to KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD.

A Memorandum of Understanding is being signed herewith by both parties as per the mutually acceptable terms and conditions.

3.0 RESPONSIBILITIES OF PARTIES

3.1 UCRS RESPONSIBILITIES

UCRS (Activities)	UCRS (Financial liabilities)
Setting up an EC	Paying EC members meeting fees
Training EC members	Accreditation fees to be paid to the govt. agency
NABH accreditation process facilitation for EC	Paying fees to the liaison in Delhi
EC registration	Paying salary to CRC and QA executive (all staff members on the payroll of UCRS
Hiring and training coordinators required for site operations.	
Marketing and bringing feasibilities to the site	
Overseeing and maintaining quality at the site	
Patient recruitment policies and implementation	
Ensuring all regulatory requirements	

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

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1. All the payment made by the sponsor will be in the name of UCRS & UCRS in turn will disburse the payment to KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD as per mutual agreement.

2. UCRS will be responsible for legal & financial aspects of all MLC (medico legal cases) Pertaining to the clinical trial related drugs and procedures/ investigational drugs.

3. Clinical trial insurance policy will be provided by Sponsor Company and individual indemnity of medical professionals comes under the scope of hospital/ PI.

4. Institutional Ethics Committee will be approached by UCRS for review of study protocol.

5. Securing & initiating of projects in compliance with International Conference on Harmonization, Good clinical practices, Schedule Y and study protocol.

6. UCRS will put maximum efforts to get more number of projects at KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD.

7. Designee from UCRS will responsible for maintaining regulatory & financial documentation and will take decision related to that. UCRS will be one of the signatory on clinical trial related documents.

8. All record of study will be kept confidential & will have limited access over it, only for the purposes of Monitoring, Audits, and Inspection.

9. Appointment of onsite qualified well experienced and dedicated staff for research projects (Coordinator, Project managers, Quality Assurance managers, etc)

3.2 HOSPITAL'S RESPONSIBILITIES

Provide for an infrastructure and space required for carrying out studies.
Making nursing staff or lab technician available for sample collection
Making special storage conditions available as per the trial requirement (e.g. refrigerator, deep freezer, AC etc)
Making training room available for trainings/monitoring visits/inspections and audits as and when required.
Storage facility for archiving clinical trial documents

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Krishna Institute of Medical Sciences "Deemed To Be University", Karad ★ Krishna

1. KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD management will provide a dedicated space and storage facility with access control for Clinical Research Unit (CRU) operations.

2. Both UCRS and KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will appoint one person as a single point of contact from each side. These individuals will communicate with each other on a regular basis to sort out administrative issues and review progress.

3. KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD management will cooperate during site qualification visit, audits and monitoring visit of a site.

4. Both UCRS and KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will abide by mutually agreed payment terms/ profit sharing terms.
5. Access to required departments of the hospital for Clinical research staff, sponsors/CRO representatives, Auditors, Monitors, and Inspectors pertaining to clinical research activities only.

4.0 FINANCIAL ARRANGEMENT

UCRS will invest for all required items listed in *Table in Article 3.1*above.
Whereas KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will facilitate the operations by making the required space available.

UCRS will share 50% of PI Grant (quantum of the PI grant is generally well defined in Quadra party clinical trial agreement) with KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD. It will be responsibility of KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD to disburse PI grant as and when applicable. This amount shall be disbursed by UCRS to KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD on the settlement of payment with Sponsor Company.

All the investigations charges like radio and pathology will paid by UCRS to KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD on a periodic basis as per rate contract.
Hospital may avail other benefits like admission of clinical trial participants / patients and charges of the same shall be paid by UCRS as per predefined rate contract.
SEPARATE RATE CONTRACT WILL BE FRAMED BY BOTH PARTIES TO AVAIL HOSPITAL SERVICES FOR THE RESEARCH PURPOSE AND SAME WILL BE CONSIDERED AS ANNEXURE TO THIS MOU

Add. Director of Research
KIMSDU, Karad

5.0 BENEFITS OF COLLABORATION

From this arrangement, KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will get the following benefits:

- KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will not only emerge to be a prominent clinical research site, and it will attract new patient pool.
- In addition to above KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will gain prominence in the hospital industry due to NABH accredited EC

6.0 This agreement will remain effective till one of the parties decides to withdraw from agreement. In that case, the existing studies will be completed in their assigned period and only then the agreement will become null and void. In the meantime after termination, KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", KARAD will be at liberty to sign up with new Clinical Research Unit (CRU).

7.0 Arbitration

Any dispute arising in violation to or in connection with this MOU between the parties shall be resolved by mutual negotiations, In case of any unresolved dispute, the parties shall refer the said dispute for arbitration to the sole arbitrator appointed by the Hon. Vice-Chancellor of the University and the Director UCRS, and the decision of the arbitrator shall be final and binding on both the parties. The provision of Arbitration and Conciliation Act 1996 shall apply to such arbitration. Such arbitration proceeding shall be held at Karad.

Add. Director of Research
KIMSDU, Karad

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

Dr. M. V. Ghorpade, Registrar
For
KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY, KARAD

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

Dr Sunil Chaudhary, Director
For
Unique Clinical Research Services, Pune

WITNESSES:

For & on behalf of
KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY, KARAD

Signature
Name Dr ARUN RISBUD

For & on behalf of
Unique Clinical Research Services, Pune

Signature
Name+ Deepak Bagde

Add. Director of Research
KIMSDU, Karad

भारतीय गैर न्यायिक

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INDIA NON JUDICIAL

गुजरात गुजरात GUJARAT

नंबर 81821 रु.

BN 284646

तारीख : 12 SEP 2018

नाम : LAMBDA THERAPEUTIC RESEARCH LTD.

ठेकाणुं : Plot No. 38, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad-380 061.

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Clinical Trial Agreement

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota,
Ahmedabad 382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Engaged by:
Celerity Pharmaceuticals, LLC
9450 Bryn Mawr, Avenue, Suite 640,
Rosemont, IL 60018
(Hereinafter referred to as the "Sponsor")

04/10/2018

AND:

Dr. Anand K Gudur, Karad

LAMBDA Research Accelerated

Add. Director of Research
KIMSDU, Karad

AND:
Dr. Anand K. Gudur,
Krishna Institute of Medical Sciences Deemed University - Karad,
Pune - Bangalore Highway-4, Malkapur Road, Karad- 415110
Taluka – Karad, Dist – Satara, Maharastra, India
(Hereinafter referred to as the "Investigator")

AND:

Krishna Institute of Medical Sciences Deemed University - Karad,
Pune - Bangalore Highway-4, Malkapur Road, Karad- 415110
Taluka – Karad, Dist – Satara, Maharastra, India
(Hereinafter referred to as the "Institute")

AND:

Unique Clinical Research Services
Block No D-2, Sai Prakash, Prakash Housiág Society , Kalewadi Phata, Thergaon, Pune 411033, Maharastra, India
(Hereinafter referred to as the "SMO")

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

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota,
Ahmedabad 382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

AND:
Dr. Anand K. Gudur,
Krishna Institute of Medical Sciences Deemed University - Karad,
Pune - Bangalore Highway-4, Malkapur Road, Karad- 415110
Taluka – Karad, Dist – Satara, Maharastra, India
(Hereinafter referred to as the "Investigator")

AND:

Krishna Institute of Medical Sciences Deemed University - Karad,
Pune - Bangalore Highway-4, Malkapur Road, Karad- 415110
Taluka – Karad, Dist – Satara, Maharastra, India

Add. Director of Research
KIMSDU, Karad

LAMBDA
Research Accelerated

(Hereinafter referred to as the "Institute")

AND:

Unique Clinical Research Services
Block No D-2, Sai Prakash, Prakash Housing Society , Kalewadi Phata, Thergaon, Pune 411033, Maharastra, India

(Hereinafter referred to as the "SMO")

WHEREAS:

LAMBDA was engaged by Sponsor to serve as a Contract Clinical Research Organization (CRO) engaged in the design, implementation, and management of clinical trials of pharmaceutical products under a Service Agreement on behalf of Sponsor.

Sponsor has engaged LAMBDA to negotiate and execute site Agreements on its behalf;

PI has engaged SMO to oversee the clinical trial activities. PI is responsible to oversee the SMO activities as per the study protocol and applicable law.

Institution has appointed Dr. Anand K Gudur / SMO, an employee of Institution, to serve as principal investigator ("Investigator"), and as an employee the Institution has the authority to ensure the Investigator complies with the terms and conditions of this Agreement;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial involving the investigational drug **Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10 mL (2 mg/mL)**, according to the protocol entitled "**A Multicentre, Open Label, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over, Study to Test for Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10 mL (2 mg/mL) and Reference product, Caelyx® [Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10 mL (2 mg/mL)] in Patients with Metastatic Breast Cancer**" ("Clinical Trial") to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institution, having reviewed sufficient information regarding the Compound(s) and Protocol, agree to conduct the Clinical Trial to evaluate the Compound(s) under the terms and conditions set forth hereinafter and,

The Investigator is authorized to conduct the Clinical Trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 **Definitions**

1.1 In this Agreement, the following terms shall have the following meanings:

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Term	Meaning
Applicable Law	all applicable national, federal, state and local law, rules, regulations and guidelines governing the conduct of the Clinical Trial, including but not limited to the DCGI regulations, the U.S. Food and Drug Administration ("FDA") regulations, the Declaration of Helsinki and ICH GCP (collectively, "Applicable Law")
"Compound"	Celerity Pharmaceutical's Doxorubicin hydrochloride (pegylated liposomal), 20 mg/10 mL (2 mg/mL). Celerity Pharmaceuticals, LLC, Rosemont, Illinois, USA.(Test) ; or CAELYX® (Doxorubicin hydrochloride (pegylated liposomal)), 20 mg/ 10 mL (2 mg/mL)
"CRF"	Case Report Form
"Declaration of Helsinki"	The 1996 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee" or ("EC"))	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICF" or "Informed Consent Form"	Form of informed consent approved by the Ethics Committee and signed by the Clinical Trial Subject and/or his/her legal guardian, where applicable, providing consent for Subject's participation in the Clinical Trial and for the collection, use, storage and processing of information and data collected in the Clinical Trial.
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"Regulatory Authority(ies)"	Any regulatory or health authority in the United States, India or other countries having jurisdiction over the conduct of clinical research studies and/or the oversight or approval of pharmaceutical products, including without limitation, the FDA and DCGI and any successor entities thereto.
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.

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"Subjects" All individuals enrolled in the Clinical Trial

2 Investigator/Institution responsibilities

2.1 Institution agrees that it is responsible for compliance with the terms and conditions of this Agreement by any individual who performs services on behalf of Institution in connection with the Clinical Trial, including but not limited to Investigator. Institution will cause Investigator to comply with all relevant portions of this Agreement. Further, Institution acknowledges and agrees that any breach by Investigator of his obligations under this Agreement (regardless of whether such obligations are express obligations of Investigator or are obligations to act in a manner consistent with the obligations of Institution) will be deemed a breach by Institution.

2.2 The Investigator shall be responsible for direct supervision of the Clinical Trial Subjects. The Institution acknowledges that the Investigator's work is essential to the Trial to be conducted under this Agreement.

2.3 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol, this Agreement, and general acceptable clinical practices for the conduct of the Clinical Trial.

2.4 The Protocol is considered final after it is signed by Sponsor and the Investigator and approved by the Ethics Committee. Thereafter, the Protocol may be amended only by written agreement between Institution and Sponsor, and, any such amendments must be approved by the Ethics Committee. Institution shall not enroll any Subjects in the Clinical Trial until such time as the Ethics Committee approves the Clinical Trial.

2.5 The Investigator and Institution shall fully cooperate with Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.6 The Investigator is responsible for submitting the Protocol, the ICF and any Subject recruitment materials to the Ethics Committee and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Clinical Trial supplies may not be delivered until LAMBDA has received a copy of such Ethics Committee approval. The Ethics Committee approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.7 Institution shall ensure that all Clinical Trial Subjects and/or their legal acceptable representative, as applicable, sign an ICF prior to screening for participation in the Trial. Unless waived by the Ethics Committee in compliance with local/regional confidentiality laws, the ICF

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must include a valid authorization for Institution to disclose protected personal and health information created or received by Institution to Lambda or Sponsor, and a valid authorization or waiver for Lambda and Sponsor to use, process, store and disclose the protected personal and health information for purposes of the Clinical Trial.

2.8 If requested by LAMBDA or Sponsor, Investigator shall attend and participate in an investigator's meeting or other Clinical Trial initiation meeting. The Investigator is responsible for training and supervision of sub-investigators and other site Clinical Trial personnels on the procedures specified in the Protocol to ensure accurate scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.9 Investigator and Institution shall conduct the Clinical Trial in accordance with the Protocol, Ethics Committee approval, all Applicable Law and in accordance with generally accepted standards of medical care. If in the course of performing the Trial, generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects require a deviation from the Protocol, such standards will be followed. In such case, the Institution or Investigator shall immediately notify Sponsor and Lambda of the facts supporting such deviation by telephone, followed by written confirmation within twenty-four (24) hours and full documentation in such Clinical Trial Subject's CRF. For the avoidance of doubt, such a Protocol deviation shall not be deemed a per se breach of this Agreement, but only to the extent that such deviation is not performed in a manner that is negligent and does not result from intentional misconduct.

2.10 Investigator agrees that he/she has read and understands all information in the investigator's brochure provided to Investigator by LAMDBA or Sponsor, including the potential risks and side effects of the Compounds which are subject of the Clinica Trial and Investigator hereby consents to the disclosure by LAMBDA and/or Sponsor of certain personal and financial information concerning Investigator and/or any sub-Investigator.

2.11 During the term of this Agreement, Institution represents that it will not participate in any other study which, by its nature or its terms, could prevent Institution from fulfilling its obligations under this Agreement, including affecting enrollment of Clinical Trial Subjects.

2.12 Institution shall ensure that all data and other information related to the Clinical Trial is submitted to Lambda in a timely manner.

2.13 Institution and Investigator shall conduct the Clinical Trial in accordance with the Protocol and shall not make any changes thereto, nor deviate therefrom, without the prior written consent of Sponsor, except as permitted to deviate for the health and safety of the Clinical Trial Subject in Section 3.0.

2.14 Institution shall ensure that all potential Clinical Trial subjects are screened in accordance with the inclusion/exclusion criteria, as outlined in the Protocol. If Investigator fails to screen potential Clinical Trial Subjects in accordance with the inclusion/exclusion criteria within the

Add. Director of Research

screening period, as specified in the Protocol, then Sponsor through CRO has the right, at its sole discretion, to suspend or terminate this Agreement immediately by providing written notice to Institution and Investigator.

2.15 The Investigator shall communicate all relevant aspects of the Clinical Trial to the potential Clinical Trial Subjects and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.16 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of this Agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s), sub-investigator(s) and other Clinical Trial personnel, confirmation of adequate site facilities, etc.);

b) progress reporting on all aspects of the Clinical Trial (including recruitment figures) to Ethics Committee and LAMBDA on a regular basis or as otherwise requested by LAMBDA or Sponsor;

c) ensuring direct access in a timely manner by Lambda monitors, Lambda auditors, Sponsor representatives and regulatory authorities to Clinical Trial documentation including, without limitation, original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by any Regulatory Authority and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval. Institution shall, and shall ensure that Investigator, provides LAMDA and Sponsor copies of any and all information and documentation provided to or received from any Regulatory Authority related to the Clinical Trial.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of Clinical Trial closure.

g) Maintenance of accurate drug accountability records, study documents including Compound acknowledgement receipts, Clinical Trial supply receipts, payment receipts,

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EC approvals etc. e.g., Institution's and Investigator's recordkeeping obligations shall include, as applicable, without limitation, the following:
(i) maintaining written records, accounts, notes, reports and data relating to the Trial, including full case histories;
(ii) completing original, authorized informed consent forms and case report forms for each Trial Subject on a per visit basis;
(iii) maintaining adequate documentation of ICF of each Trial Subject;
(iv) preparing and submitting all safety, progress, interim, and final reports, as well as financial disclosure reports/forms (including such reports and forms required by or with respect to any sub-investigator);
(v) maintaining records of the receipt, use, and disposition of the Investigational Product and other clinical supplies;
(vi) maintaining copies of all correspondence with Sponsor, Lambda, the EC, and any regulatory authority; and
(vii) maintaining all other records indicated by the Protocol, or required by Applicable Law.

h) Handling and storage of compound according to protocol.

i) Archival of study documents including source data/patient medical records, whether in paper or electronic format in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual. Institution shall contact Sponsor at least thirty (30) days before the planned destruction of any Trial records, at which time the Sponsor may require that the Institution deliver such records to Sponsor, at Sponsor's expense. Institution shall notify Sponsor and Lambda of any accidental loss or destruction of Trial records.

2.17 All SAEs must be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death) or other Regulatory Authorities, if applicable. The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of Applicable Law. LAMBDA confirms an effective system for centralized tracking and notification to investigators and to applicable Regulatory Authorities of all findings that could adversely affect the safety of Clinical Trial Subject(s), including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial Subjects to the Ethics Committees of participating sites, and appropriate Regulatory Authorities if they deemed necessary to protect the health of Clinical Trial Subjects, provided that Sponsor is copied on such reports.
The Investigator is responsible for fully cooperating with any LAMBDA requests in development of the Clinical Trial Report.

2.18 All the biological samples in the study will handled as per instruction provide by the LAMBDA/Sponsor. No deviation is allowed until the confirmation from LAMBDA/Sponsor.

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3 CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to Applicable Lawin the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement and shall not be transferred any third parties without Sponsor's prior written consent.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining Regulatory Authority approvals for the Clinical Trial in India prior to initiation of the Clinical Trial at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the Clinical Trial-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, including the investigator's brochure or its equivalent, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. prescribing information / summary of product characteristics.). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **05 patients** within **06** months; minimum expected recruitment rate from the site is **1-2 patients per month** on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period is expected to be **06** months; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

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"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the Clinical Trial is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA in consultation with the Sponsor may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all best endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within 3 working days after completion of each visit.

4.5 The Investigator shall participate in teleconferences and meetings as requested and required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is the most stringent.

5 Payment terms

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. LAMBDA will have oversight on patient reimbursement records maintain at the site. Payment of all taxes shall be the sole responsibility of the payee hereunder.

5.2 All payments made are subject to Investigator's ultimate submission of completed case report forms for each Subject enrolled in the Clinical Trial, whether for an evaluable case or an incomplete or non-evaluable case as specified in the Protocol.

6 Period of validity of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the Site is closed, Clinical Trial and Clinical Trial Report are

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completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement.

7 Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by Applicable Laws governing the protection of personal and health information and related data.

7.2 It is expressly agreed that no Party transfers by operation of this Agreement to any of the other Parties any right in or license to any patents, copyrights, or other proprietary right owned as of the commencement date of the Agreement or arising outside of the Study conducted under this Agreement.

7.3 Institution and Investigator acknowledge and agree that the idea for the Clincial Trial was conceived and developed by Sponsor and that LAMBDA and Sponsor approached Institution and Investigator to perform the Clinical Trial. The Institution and Investigator shall promptly disclose to Sponsor and LAMBDA any discovery, modification, or invention, whether patentable or not, which are (i) conceived and/or conceived and reduced to practice during and in the course of performance of the Clinical Trial by Institution, Investigator, or Clinical Trial personnel, or (ii) which is based upon or uses Sponsor Confidential Information (collectively "Invention"). Institution and Investigator further acknowledge and agree that Sponsor or its designee shall own the exclusive rights to any and all such Inventions. Institution and Investigator do hereby assign and shall assign (and take all necessary actions to ensure that all sub-investigators and other Clinical Trial personnel are required to assign) to Sponsor all rights, title and interests each may have in any such Invention. The Institution and Investigator agree that Sponsor and LAMBDA may use the results of the Clinical Trialy performed by the Institution and Invesigator under this Agreement for any purpose it sees fit. If Sponsor, or LAMBDA on Sponsor's behalf, desires to file patent applications of such discovery or Invention, it will do so at Sponsor's own expense, and Institution and Investigator shall cause those persons participating in the discovery of the Invention, if requested by Sponsor or LAMBDA on behalf of Sponsor, to assist in the preparation of such patent applications at Sponsor's reasonable expense.

8 Publication

8.1 Clinical Trial data and results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the Sponsor.

9 Indemnity / Liability

9.1 Except for a breach of confidentiality and privacy obligations, a party's indemnification obligations hereunder or a party's gross negligence or willful misconduct, in no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute, at LAMBDA and/or Sponsor's sole

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discretion, shall repeat the Services at no additional expense to LAMBDA, or reimburse the amount paid or payable for such non-compliant work. LAMBDA has the right to terminate the services of Institution and Investigator due to any breach of this agreement.

9.3 Any (i) indemnification of Institution or Investigator by Sponsor, and (ii) compensation for Subject injury, will be set forth in a separate letter of indemnification (LOI) between Institution, Investigator and Sponsor.

9.4 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor from and against any and all claims arising out of or in connection with the performance of this Agreement, allegedly arising from: (i) Institution's, Investigator's and / or any Clinical Trial personnel's negligence or reckless or intentional misconduct, (ii) misrepresentation, breach or failure to perform its obligations and responsibilities under this Agreement including without limitation the Protocol, LAMBDA or Sponsor's written instructions relating to the use of the Compound or other materials used in the Clinical Trial, (iii) Institution's, Investigator's or Clinical Trial personnel's failure to comply with Applicable Law. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

9.5 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.6 Each party will notify other parties of any claim related to the Clinical Trial.

10 Compensation / Insurance

10.1 LAMBDA shall maintain, and shall ensure that Sponsor maintains, appropriate insurance coverage for the Clinical Trial Subjects against financial losses caused by personal injury, which are Clinical Trial and/or Compound related.

10.2 Institution and Investigator shall obtain and maintain general commercial liability insurance, professional liability insurance and workers compensation insurance (or their equivalents) in amounts sufficient to cover their obligations under this Agreement. Institution's and Investigator's provision of insurance is not intended to be a limitation of their liability under this Agreement or any specific provision within the agreement of indemnity to LAMBDA and Sponsor. Upon request, Institution and Investigator will provide written evidence of such insurance to LABMDA and/or Sponsor in the form of a certificate of insurance, and will provide LAMBDA and Sponsor with thirty (30) days prior written notice of any cancellation in any of the above coverages

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11 Confidentiality

11.1 Confidential Information. Unless otherwise agreed or required by Applicable Law, the Institution and Investigator shall treat all information provided by Sponsor or LAMBDA, regardless of format, relating to this Agreement, the Compounds and the Clinical Trial as confidential (including without limitation, the terms of this Agreement, the Protocol, investigators brochure, Compounds, any trade secret, proprietary data or technical information, procedure, method, compound or formulation) or generated in the course of the Clinical Trial (excluding patient medical records) (individually and collectively, "Confidential Information") as confidential and shall not disclose such Confidential Information to any third party or use such Confidential Information for any purpose other than the performance of the Clinical Trial without the prior express written consent of Sponsor and LAMBDA. For purposes of keeping information confidential, the Institution shall use efforts at least commensurate with those employed by the Institution and Investigator for the protection of its own confidential information, but in no case less than a reasonable degree of care. Institution and Investigator shall limit disclosure on a need-to-know basis for purposes of conducting the Clinical Trial and shall inform recipients of such Confidential Information of these obligations concerning use and disclosure and shall ensure each such recipient is bound to terms of confidentiality no less restrictive than the terms herein. The confidentiality obligations of this Agreement shall also apply to any proprietary, trade secret or other confidential information which may have been disclosed to the Institution by Sponsor or LAMBDA prior or subsequent to the execution of this Agreement.

11.2 Exceptions. Notwithstanding the obligations of confidentiality noted in Section 12.1 above, these obligations shall not apply to any information which the Institution and Investigator can prove is:

11.2.1 information that is in the public domain at the time of disclosure by Sponsor or LAMBDA, or that which subsequently enters the public domain through no breach of this Agreement;

11.2.2 information which, by clear and convincing records, can be proven to have been in the possession of the Institution or Investigator prior to disclosure hereunder;

11.2.3 information obtained by the Institution or Investigator in good faith from a third party who is not under a confidential obligation to disclose such information; or

11.2.4 information that, by clear and convincing written records, can be proven to have been independently developed by the Institution or Investigator after disclosure hereunder, without the aid, access, application or use in any way of Confidential Information received under this Agreement.

11.3 Permitted Disclosure. Notwithstanding the foregoing restrictions on disclosure of Confidential Information, Institution and Investigator may disclose Confidential Information, without violating the obligations of this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body having competent jurisdiction; *provided, that*, Institution and Investigator gives reasonable prior written notice to LAMBDA or Sponsor of such required disclosure and makes a reasonable effort to obtain, or to assist LAMBDA or Sponsor in obtaining, a protective order preventing or limiting the disclosure; and *provided, further*, that if a disclosure order is not quashed or a protective order is not obtained, such Confidential Information disclosed in response to such court or governmental order will be limited to information that is legally required to be disclosed in response to such court or governmental order. Institution's and

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Investigator's obligations of confidentiality and non-use shall continue to apply such Confidential Information for all other purposes.

11.4 The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the Parties in connection with the Study.

11.5 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12 Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to Applicable Law governing privacy and security of protected personal and health information.

12.2 Institution and Investigator shall comply, and shall require Clinical Trial personnel to comply, with all Applicable Law, governing Subject privacy and confidentiality of health information. Institution and Investigator shall take all actions necessary to comply with such Applicable Law, including agreeing to amend this Agreement as necessary for compliance. Investigator also shall obtain informed consent from Subjects as necessary to permit regulatory agencies (including Regulatory Authorities), Ethics Committees and privacy boards, Sponsor, LAMBDA, their respective affiliates, agents, and employees, other research sites that may be involved in the Clinical Trial, health care providers who may provide services to Subjects, and laboratories and other individuals and organizations that may analyze Subjects' medical information in connection with the Clinical Trial to have full access to and use of Subjects' personal and health information.

12.3 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with Regulatory Authorities and for any use by Sponsor and its affiliates and their agents.

12.4 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, Regulatory Authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.5 The Investigator and Institution will inform each Clinical Trial Subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the Regulatory Authorities and the measures being taken to ensure their privacy.

13 Independent Contractor

13.1 Investigator and Institution are independent contractors engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions

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contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14 Termination

14.1 Termination by LAMBDA. LAMBDA on behalf of Sponsor retains the right to terminate this Agreement upon thirty (30) days prior written notice to Institution or Investigator for any reason.

14.2 Termination Institution/Investigator: Investigator and Institution may terminate this Agreement upon thirty (30) days prior written notice as follows:

14.2.1 If the Investigator is unable to continue the Clinical Trial and a replacement acceptable to Sponsor and LAMBDA is not identified; or

14.2.2 Institution and Investigator determine that continuation of the Clinical Trial will compromise the safety or welfare of the Subjects; or

14.2.3 LAMBDA materially breaches the terms of this Agreement and such breach remains uncured within thirty (30) days after receipt of notice thereof;

In case of termination of the Agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall all undisputed, unpaid amounts due for services properly completed prior to the date of notice of termination. If the payments exceed the amount owed for services properly performed under the Agreement, including the Protocol, Institution and Investigator shall promptly return the excess balance to LAMBDA.

15 Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial upon request and in full accordance with Applicable Law.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all Applicable Law relating to the retention of written records, documents, accounts, notes, reports, and data of all work performed for the Clinical Trial ("Records") and shall maintain all such Records, and make them available for inspection, and shall allow prompt access by Sponsor and all applicable Regulatory Authorities for purposes of inspecting such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation of Records or transfer of archiving responsibilities.

15.3 The Site Investigator File containing Records, including the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records)

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must be archived for at least 15 (Fifteen) years or as otherwise required by Applicable Law following completion of the Clinical Trialat the Site or such other facilities as agreed between Sponsor and the Investigator.

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial Records due to any unforeseen event/s during the Clinical Trial or retention period, the Institution and/or the Investigator shall, no later than 30 days prior to the day when the Clinical Trial records are planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial Records, Institution and or Investigator may nevertheless retain a copy of Clinical Trial Records (1) as required by Applicable Law and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute intends to destroy the Site Investigator File or source data, or other Records, the Investigator/Institute should inform LAMBDA at least thirty (30) days prior to destruction to confirm it is acceptable for them to be destroyed. In no event shall Institution or Investigator destroy any Records without the prior written consent of Sponsor.

16 Representation and Warranty

16.1 The Investigator and Institution represent and warrant that (i) they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by Applicable Lawand (ii) Neither the Institution nor Investigator are sanctioned, barred or otherwise prohibited from practicing medicine and/or entering into, and performing the services required under, this Agreement.

17 Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO	:	Lambda Therapeutic Research Ltd
Address	:	Plot No. 38, Survey no 388, Near Silver Oak Club, S.G.Highway, Gota, Ahmedabad 382481, Gujarat, India.
Telephone	:	+91-79 4020 2020
Fax	:	+91-79 4020 2021
Contact Person	:	**Dr. Kiran Marthak**

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SPONSOR	:	Celerity Pharmaceuticals, LLC
Address	:	9450 W. Bryn Mawr Avenue Suite 640 Rosemont, Illinois 60018 USA
Telephone	:	+1-312 999 0130
Fax	:	+1-312 999 0130
Contact Person	:	**Dan Robins, PhD**
Investigator	:	Dr. Anand K Gudur
Telephone	:	+91-9890929412
Fax	:	+91-2164-241070
Institution	:	Krishna Institute of Medical Sciences Deemed University - Karad
Address	:	Pune - Bangalore Highway-4, Malkapur Road, Karad-415110, Taluka – Karad, Dist – Satara, Maharastra, India
Telephone	:	02164 241 555
Fax	:	+91-2164-241070
Contact Person	:	**Dr M. V Ghorpade**
SMO Name	:	**Unique Clinical Research Services**
Address	:	**Block No D-2, Sai Prakash, Prakash Housing Society , Kalewadi Phata, Thergaon, Pune 411033, Maharastra, India**
Telephone	:	020-65222284
Fax	:	020-65222284
Contact Person	:	Dr. Sunil Chaudhary

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice of receipt; b) If sent by registered letter with notification of delivery as of date it is received by the receiving party; or c) If sent by telefacsimile with transmission confirmed, on the date of receipt by the receiving party.

19 Miscellaneous

19.1 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

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19.2 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.3 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.4 All infrastructures provided by LAMBDA on behalf of sponsor for the conduct of this Clinical Trial to the Institution/Investigator will be retrieved from the Institution/Investigator upon completion of the Clinical Trial.

19.5 All the Invoices raised to LAMBDA should be GST compliant, according to the GST Invoice rules. Absence of necessary detail will result in delay /non-payment of Invoices till the time of rectification made.

19.6 Invalidity. Except as otherwise contemplated herein, in the event that any provision of this Agreement is deemed by a court of competent jurisdiction to be in violation of any Applicable Law, or is otherwise declared invalid or unenforceable by such court, the parties agree that such provision shall be of no force or effect and the remaining provisions shall remain valid and in full force and effect as though such superseded provision was not contained in this Agreement.

19.7 Survival. The parties agree that the obligations contained in **Sections 2.0** and all definitions necessary to interpret the foregoing shall survive the termination of this Agreement.

19.8 Waiver. The waiver by either party of any breach, term, provision or condition of this Agreement shall not be deemed or construed as a further or continuing waiver of any such breach, term, provision or condition or a waiver of any other or subsequent breach, term, provision or condition contained in this Agreement.

19.9 Use of Name. This Agreement does not entitle any party to the use of the name, trademarks or logos of the other Party. While Sponsor and LAMBDA are expressly permitted to quote from and/or reference any publications resulting from the Clinical Trial, the Institution and Investigator shall not use the name of Sponsor, LAMBDA or any of their respective employees or agents in any publications, public presentations, advertising promotions or other commercial materials without Sponsor's and LAMBDA'S prior express written permission. However, in order for Institution and Investigator to satisfy their reporting obligations, they may identify Sponsor as the Clinical Trial Sponsor and the amount of funding received. LAMBDA and/or Sponsor may use the name of Institution and Investigator, without their consent, in clinical trial registries and websites, regulatory submissions and communications, and in scientific papers and presentations where the names of all participating sites and/or investigators are mentioned in accordance with the relevant journal, society or other applicable publication policies or conditions.

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19.10 Counterparts. This Agreement may be executed in a number of identical counterparts, each of which shall be deemed an original for all purposes and all of which constitute, collectively, one agreement; but, in making proof of this Agreement, it shall not be necessary to produce or account for more than one such counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: Rakesh Date: 01/Oct/2018

Name : Dr. Rakesh Patel / Mr. Harshvardhan Shrivastava

Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Witness:

Sign: Date: 01/ oct/18

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd

Institute:

Sign: Date: 04/10/2018

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

Witness:

Sign: Mrs. Vaishali Date: 04/oct/18

Witness Name: Vaishali Yadav

Designation: MSW

Department/Work Unit: Medical social work dept.

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Institute Name:

Investigator:

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator:

Sign: _____ Date: 04/oct/18

Dr. Anand K Gudur

Krishna Institute of Medical Sciences Deemed University - Karad

SMO:

Sign: _____ Date: 4/10/18

Dr Sunil Chaudhary

Unique Clinical Research Services

Block No D-2, Sai Prakash, Prakash Housing Society ,

Kalewadi Phata, Thergaon, Pune 411033, Maharastra, India

Witness:

Sign: MPPatil Date: 04/oct/18

Witness Name : Madhuri Patil

Witness Address : KIMSDU, Karad

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Schedule A

Study Protocol

Protocol No: 0927-17

"A Multicentre, Open Label, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over, Study to Test for Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10 mL (2 mg/mL) and Reference product, Caelyx® [Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10 mL (2 mg/mL)] in Patients with Metastatic Breast Cancer."

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Schedule B
Budget and Payment Agreement:

(I) Budget

Sr. No.	Payment Head	Screening/ Visit 01	Visit 02/11			Visit 3/12	Visit 4/13	Visit 5/14	Visit 6/15	Visit 7/16	Visit 8/17	Visit 9/18	Visit 10	End of Study/Visit 19	Total
		Up to 14 days prior to dosing	11 hours prior to Day 0 & Day 29	Day 1 & Day 29	Day 2 & Day 30	Day 3 & Day 31	Day 4 & Day 32	Day 6 & Day 34	Day 8 & Day 36	Day 10 & Day 38	Day 12 & Day 40	Day 14 & Day 42	Day 16 & Day 44	Day 22 to 27	Day 57 ± 2 EOS	
1	Investigator Grant	6000	7000	7000	7000	7000	5000	5000	5000	5000	5000	5000	5000	5000	1000	77000
2	Co-ordinator Grant	1500	2000	2000	2000	2000	1500	1500	1500	1500	1500	1500	1500	1500	1000	22500
3	Hospitalization Charges		3800	3800	3800											11400
4	ECG (12 Lead)	400												400	400	1200
5	ECHO	1800												1800	1800	5400
6	X-Ray	500														500
7	Local Lab blood test			1500												1500
	Total	10200	12800	14300	12800	9000	6500	6500	6500	6500	6500	6500	6500	8700	6200	119500
	Institutional Overhead (25%) (If Any)	1875	2250	2250	2250	2250	1625	1625	1625	1625	1625	1625	1625	1625	1000	24875
	Total (w/ Institutional Overhead at 25%	12075	15050	16550	15050	11250	8125	8125	8125	8125	8125	8125	8125	10325	7200	144375
	Patient Compensation (actuals)	1200	2400	2400	2400	2400	1200	1200	1200	1200	1200	1200	1200	1200	1200	21600
								Total Grand/patient								165975

Note:

1. Phlebotomist for PK sample collection will be provided by Lambda. Charges are not included in this per patient grant.

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

3 Urine drug scan kits and Urine Pregnancy test Kits will be provided by Lambda and will be performed by site team as per protocol requirement

4. Pre-medications i.e. Granisetrone and Dexamethasone shall be provided by LTR. Post medications charges are also included in hospitalization charges. AE/SAE management cost will be reimbursed against the actual invoice.

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Dr. Anand K. Gudur, Karad

LAMBDA Research Accelerated

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges

(II) Payment Schedule

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

a) LAMBDA will pay a sum for every complete and evaluable patient as defined in the payment schedule.

b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately

c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

e) Central Laboratory costs will be paid by Lambda on behalf of Sponsor.

f) 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.

g) **Patient conveyance/compensation** will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **GST applicable as per union budget rules.**

h) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

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i) Payment mentioned under "Final Payment" will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

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

Payee Name	:	**Unique Clinical Research Services**
Payee Address	:	**Block No D-2, Sai Prakash, Prakash Housing Society , Kalewadi Phata, Thergaon, Pune 411033, Maharastra, India**
PAN Number	:	**AAFFU5078B**
GST Number	:	**NA**

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and e-CRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc.)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative

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- Phlebotomy expenses for safety samples
- usage of internet while filling of e-CRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc.)
- All overhead costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee

2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be made by A/C Payee Cheque to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation;
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

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8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .

9. All screen failure patients payments will be made post LPLV.

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

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भारतीय गैर न्यायिक

एक सौ रुपये **Rs. 100**

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WH 602023

LUPIN LIMITED
(Research Park)
46A/47A, Nande Village,
Tal-Mulshi, Pune-411...
Maharashtra, INDIA

06 JAN 2020

मुद्रांक विकत घेणाऱ्याची सही

Amendment – I to the Clinical Trial Agreement

This Amendment Agreement (**"Amendment – I"**) is made as of 14th February 2020 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 400055 (hereinafter "**Lupin**"); and

Gaurav Paranjpe, an Indian citizen/resident, with his address at Krishna Institute of Medical Sciences "Deemed to be University", Pune- Bangalore highway NH-4, Malkapur road, Karad-415110, Maharashtra, India (hereinafter "**Principal Investigator**"); and

Krishna Institute of Medical Sciences "Deemed to be University", with its address at Pune- Bangalore highway NH-4, Malkapur road, Karad-415110, Maharashtra, India (hereinafter "**Institution**"), and

Unique Clinical Research Services, with its address at Shree Prasad, Block No-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India (hereinafter "**SMO**").

Lupin, Principal Investigator, Institution, and SMO 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 11th July 2019 (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 January 2020 ("**Effective Date**").

2. The Parties hereby agree that with effect from the Effective Date, Clause B-2 of Attachment – B of the Agreement shall stand deleted in its entirety and shall be replaced by the following:

   "B-2 Payment Terms. Research grant payments for each Trial Subject will be made in Indian Rupees 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 submitted and 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 30 (thirty) days of such invoice issue date."

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.

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.

[SIGNATURE PAGE FOLLOWS

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

Date: 14/Feb/2020

Accepted and Agreed
by the Principal Investigator

Name: **Dr. Gaurav Paranjpe**
Assistant Professor and Principal Investigator

Date: _____

Accepted and Agreed
For Institution

By: **Dr. M.V. Ghorpade**
Its: Head of the Institute

Date: _____

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

Accepted and Agreed
For SMO

By: Dr. Sunil Chaudhary
Its: Director

Date: 04/03/2020

LUPIN LIMITED MUMBAI

LUPIN OK LEGAL

Add. Director of Research
KIMSDU, Karad

Attachment – D

RESEARCH GRANT WORKSHEET

Principal Investigator LRP/RBZ/2015/002	
Event	*Cost[1] in INR*
Screening	18000
Day 1 (Drug administration)	20000
Day 31 (Drug administration)	20000
Day 61 (Drug administration)	20000
Day 90 (End of Study)	18000
Institutional Administrative Charges (25%)	24000
Part A Total	**1,20,000**

Additional Study Related Costs (Part B)	
Patient travel reimbursement per visit (Rs.500 per visit) (Screening to End of study visit)	4500
12 Lead ECG (Only at Protocol Scheduled Time Points) (Screening, V4, V6, V8)= 350*4	1400
Hospital/ Bed Charges (Day Care) (V1, V3, V5)= 2000*3	6000
Fluorescein angiography (FA) (At screening visit)	5800
Optical coherence tomography (OCT) Rs.2500 per protocol specified visit (Screening, V4,V6,V8)= 2500*5	12500
Local Laboratory Charges (If used during the study)	On actuals
Total Additional Pass through cost (B)	**30200**
Total per patient grant (Part A + Part B) = Part C	**1,20,000+ 30200**
Total Part C	**1,50,200**
Archival charges for 15 years from the date of site close out visit	60,000

Notes:

- Screen failure charges Rs.10000/-will be paid in the ratio of 1:1 (i.e. one screen failure will be paid for one randomized patient)
- Invoiced Charges to be paid upon receipt of invoice from Principal Investigator
- Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.
- Local laboratory charges would be paid on actuals on providing supporting bills.
- Archival charges is one-time payment and will be paid post site close out visit.
- Any unscheduled visit if it happens during the study period the assessment charges and travel reimbursement will be paid on case to case basis upon receipt of supporting bills from site.

Add. Director of Research
KIMSDU, Karad

LUPIN LIMITED MUMBAI

Clinical Trial Agreement

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey No 388, Near Silver Oak Club,
S G Highway, Gota,Ahmedabad 382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
Corporate Office Building, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND:
Dr. Ananad K. Gudur
Krishna Institute of Medical Sciences
"Deemed To Be University,"
Pune-Bangalore Highway 4 Malkapur, Near Dhebewadi Phata Malkapur,
Karad, Dist. Satara-415539, Maharashtra
(Hereinafter referred to as the "Investigator")

AND:
Krishna Institute of Medical Sciences
"Deemed To Be University,"
Pune-Bangalore Highway 4 Malkapur, Near Dhebewadi Phata Malkapur,
Karad, Dist. Satara-415539, Maharashtra
(Hereinafter referred to as the "Institute")

AND:
Unique Clinical Research Services
Shree Prasad, Block No D-2,Prakash Housing Society,
Kalewadi Phata, Thergaon,
Pune 411033, Maharashtra,India.
(Hereinafter referred to as the "SMO")

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

Dr. A. Gudur, Karad

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey No 388, Near Silver Oak Club,
S G Highway, Gota,Ahmedabad 382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

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AND:
Dr. Ananad K. Gudur
Krishna Institute of Medical Sciences
"Deemed To Be University,"
Pune-Bangalore Highway 4 Malkapur,Near Dhebewadi Phata Malkapur,
Karad, Dist. Satara-415539, Maharashtra
(Hereinafter referred to as the "Investigator")

AND:
Krishna Institute of Medical Sciences
"Deemed To Be University,"
Pune-Bangalore Highway 4 Malkapur, Near Dhebewadi Phata Malkapur,
Karad, Dist. Satara-415539, Maharashtra
(Hereinafter referred to as the "Institute")

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Shree Prasad, Block No D-2,Prakash Housing Society,
Kalewadi Phata, Thergaon,
Pune 411033, Maharashtra,India.
(Hereinafter referred to as the "SMO")

Dr. A. Gudur, Karad

Director of Research

WHEREAS:

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

Intas Pharmaceuticals Limited has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled "**A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.**"("Clinical Trial") to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	Docetaxel Lipid Suspension for Injection 20/80 mg**(Test Product)**
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization
"Declarationof Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.

Dr. A. Gudur, Karad

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"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

Dr. A. Gudur, Karad

Add. Director of Research

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);

b) progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc. and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

Dr. A. Gudur, Karad

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e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure.

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

h) Handling and storage of compound according to protocol.

i) Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambdaundertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may

Add. Director of Research

be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

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3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least**1-2 patient** within **1** months; minimum expected recruitment rate from the site is **1-2 patients per month** on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be as per study design; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within **3**working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 Payment terms

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. Lambda will have oversight on patient reimbursement records maintain at the site.

6 Period of validity of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

- Archival of study documents including source data as referred to in para 2.7 (i) and Section III/k on page # 24.
- Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
- Confidentiality as per para 11

7 Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

Add. Director of Research

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

7.10 It would be the primary responsibility of the institution to maintain custody of studyrecords and all other applicable study items in purview of the study protocol and thisagreement, irrespective of the PI presence in the institution. Institution will allowregulatory authorities, sponsor and CRO to perform inspections of study data. In casethe PI has to leave the institution, the PI should handover charge of the study to anyother designee in form of document and forward all future communications received toinstitute pertaining to trial. PI is responsible to update CRO and / or sponsor for thischange and all applicable communications, henceforth. Designee will execute all PIresponsibilities, henceforth. In case of change in institution management, the institutewill inform CRO and / or sponsor

Add. Director of Research

8 Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can beperformed without the written approval by the sponsor.

9 Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

10 Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

11 Confidentiality

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the

Add. Director of Research

performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

12 Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13 Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14 Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

Add. Director of Research
KIMSDU, Karad

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.

2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.

3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.

4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.

5. The total number of patients required to be randomised is reached before the end of the recruitment period.

6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.

7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.

15 Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The

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KIMSDU, Karad

Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO	:	**Lambda Therapeutic Research Ltd**
Address:	:	Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Ahmedabad-382481, Gujarat, India.
Telephone	:	+91 79 4020 2020
Fax	:	+91 79 4020 2021
Contact Person	:	**Dr. Kiran Marthak**
Investigator	:	**Dr. Ananad K. Gudur**
Telephone:	:	+91-9890929412
Fax:	:	+91-2164-241070
Institute	:	**Krishna Institute of Medical Sciences**
Address	:	"Deemed To Be University" Pune-Bangalore Highway 4 Malkapur, Near Dhebewadi Phata Malkapur, Karad, Dist. Satara-415539, Maharashtra
Telephone	:	+91 2164 241 555
Fax	:	+91 2164 241070
Contact Person:	:	**Dr M. V. Ghorpade**
SMO	:	**Unique Clinical Research Services**
Address	:	Shree Prasad, Block No D-2, Prakash Housing Society,Kalewadi Phata, Thergaon Pune 411033, Maharashtra
Telephone	:	+91 20-65222284
Fax	:	+91 20-65222284
Contact Person:	:	**Dr. Sunil Chaudhary**

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

19.6 "All the Invoices raised to Lambda (CRO) should be GST compliant, according to the GST Invoice rules. Absence of necessary detail will result in delay /non-payment of Invoices till the time of rectification made."

Add. Director of Research
KIMSDU, Karad

Dr. A. Gudur, Karad

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ Date: 18-JAN-2019

Dr. Jogesh Mahajan/ Mr. Gautam Vaghela
Clinical Trial Management,
Lambda Therapeutics Research Ltd.

Witness:

Sign: _____ Date: 18-JAN 2019

Mr. Naresh Khemani
AGM, Finance

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

"DEEMED TO BE UNIVERSITY"

Institute: Krishna Institute of Medical Sciences, Karad

Sign: _____ Date: 22/01/2019

Witness:

Sign: _____ Date: 22/Jan/2019

Witness Name: Madhuri Patil

Designation: CRC

Department/Work Unit:

"DEEMED TO BE UNIVERSITY"

Institute Name: Krishna Institute of Medical Sciences, Karad

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

Site Management Organization: Unique Clinical Research Services

Sign: _____ Date: 22/Jan/2019

Dr. Sunil Chaudhary

Witness:

Sign: _____ Date: 22/01/2019

Witness Name : Deepak Boyde

Witness Address :Shree Prasad, Block No D-2,Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India.

Investigator:

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator:Dr. Ananad K. Gudur

Sign: _____ Date: 22/01/2019

Dr. Ananad K. Gudur

Witness:

Sign: _____ Date: 22/01/2019

Witness Name : Dr Sachin Mane

Witness Address :Krishna Institute of Medical Sciences, "Deemed To Be University," Pune-Bangalore Highway 4 Malkapur, Near Dhebewadi Phata Malkapur, Karad, Dist. Satara-415539, Maharashtra

Add. Director of Research
KIMSDU, Karad

Schedule A

Study Protocol

Protocol No: 0063-17

"A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy."

Add. Director of Research
KIMSDU, Karad

Dr. A. Gudur, Karad

Schedule BBudget and Payment Agreement:

(I) Budget:

Sr. No.	Cycle/Visit/Day/Year	Investigator Grant	Coordinator Grant	Local Lab. Test: ANC, Platelet, Creatinine, SGOT, SGPT, ALP and Total Bilirubin	Investigations Done at Site		CT Scan/MRI/Sono Scan (Chest, Abdomen & Pelvis)	Admin (Fax/Courier)	Subtotal	Institutional Overhead (25 %)	Total Grant Per Patient	Patient Conveyance	Total
					ECG	ECHO							
1	Screening/Visit 01	3500	2000		500	800	6000	100	14400	1375	14775	500	14775
2	Cycle 01/Visit 02/Day 1/Year 1	2000	1000	1000				100	4200	750	4850	500	5350
3	Visit 03/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
4	Cycle 02/Visit 04/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
5	Visit 05/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
6	Cycle 03/Visit 06/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
7	Visit 07/Day 08/Year 1	1000	500	1000	500	800		100	3900	375	4275	500	4775
8	Cycle 04/Visit 08/Day 1/Year 1	2000	1000	1000			8000	100	12100	750	12850	500	13350
9	Visit 09/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
10	Cycle 05/Visit 10/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
11	Visit 11/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
12	Cycle 06/Visit 12/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
13	Visit 13/Day 08/Year 1	1000	500	1000	500	800		100	3900	375	4275	500	4775
14	Cycle 07/Visit 14/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
15	Visit 15/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
16	Cycle 08/Visit 16/Day 1/Year 1	2000	1000	1000			8000	100	12100	750	12850	500	13350
17	Visit 17/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
18	Cycle 09/Visit 18/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
19	Visit 19/Day 08/Year 1	1000	500	1000	500	800		100	3900	375	4275	500	4775
20	Cycle 10/Visit 20/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
21	Visit 21/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
22	Cycle 11/Visit 22/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
23	Visit 23/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
24	Cycle 12/Visit 24/Day 1/Year 1	2000	1000	1000			8000	100	12100	750	12850	500	13350
25	Visit 25/Day 08/Year 1	1000	500	1000	500	800		100	3900	375	4275	500	4775
26	Cycle 13/Visit 26/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
27	Visit 27/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
28	Cycle 14/Visit 28/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
29	Visit 29/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
30	Cycle 15/Visit 30/Day 1/Year 1	2000	1000	1000				100	4100	750	4850	500	5350
31	Visit 31/Day 08/Year 1	1000	500	1000	500	800		100	3900	375	4275	500	4775
32	Cycle 16/Visit 32/Day 1/Year 1	2000	1000	1000			8000	100	12100	750	12850	500	13350
33	Visit 33/Day 08/Year 1	1000	500	1000	500			100	3100	375	3475	500	3975
34	Cycle 17/Visit 34/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
35	Visit 35/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
36	Cycle 18/Visit 36/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
37	Visit 37/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
38	Cycle 19/Visit 38/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
39	Visit 39/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
40	Cycle 20/Visit 40/Day 1/Year 2	2000	1000	1000			8000	100	12100	750	12850	500	13350
41	Visit 41/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
42	Cycle 21/Visit 42/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
43	Visit 43/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
44	Cycle 22/Visit 44/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
45	Visit 45/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
46	Cycle 23/Visit 46/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
47	Visit 47/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
48	Cycle 24/Visit 48/Day 1/Year 2	2000	1000	1000			8000	100	12100	750	12850	500	13350
49	Visit 49/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
50	Cycle 25/Visit 50/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
51	Visit 51/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
52	Cycle 26/Visit 52/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
53	Visit 53/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
54	Cycle 27/Visit 54/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
55	Visit 55/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
56	Cycle 28/Visit 56/Day 1/Year 2	2000	1000	1000			8000	100	12100	750	12850	500	13350
57	Visit 57/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
58	Cycle 29/Visit 58/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
59	Visit 59/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
60	Cycle 30/Visit 60/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
61	Visit 61/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
62	Cycle 31/Visit 62/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
63	Visit 63/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
64	Cycle 32/Visit 64/Day 1/Year 2	2000	1000	1000			8000	100	12100	750	12850	500	13350
65	Visit 65/Day 08/Year 2	1000	500	1000	500			100	3100	375	3475	500	3975
66	Cycle 33/Visit 66/Day 1/Year 2	2000	1000	1000				100	4100	750	4850	500	5350
67	Visit 67/Day 08/Year 2	1000	500	1000	500	800		100	3900	375	4275	500	4775
68	ET/Visit 68/Year 2	2000	2500		500	800	8000	100	14400	1375	14275	500	14775
	Total	128500	54000	66000	17500	10400	81000	6800	362200	33672	360075	34000	414075

Note

1. Local Lab. Test: ANC, Platelet, Serum Creatinine, SGOT, SGPT, Alkaline Phosphatase and Total Bilirubin levels will be performed before dosing in each cycle (on day 1 or previous day evening) and each Day 8 Safety Evaluation Visits.

2. LAMBDA will pay the Institute / Investigator towards archival fees INR 20,000/- for 5 yrs. on behalf of sponsor.

3. Screen Failures: All screen failure patients payments will be made post LPLV. The Screen Failure Charges will be provided bases on 10% of total number of randomization patients or for actual number of screen failure patient whichever is lesser. The amount of screen failure will be 50 % of Screening Visit amount of Investigator and Clinical Research Coordinator (means 1750 + 1000) along with actual amount of screening visit investigations (ECG, ECHO, CT-Scan) mentioned in schedule B (Budget Break-up).

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges

(II) Payment Schedule

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

a) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately

b) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

c) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

d) Any other parties designated by you (including Radiology, Local Laboratory, Cardiology, etc.) will be managed and paid by you.

e) The **Ethics Committee fees** will be paid by LAMBDA on behalf of the Sponsor, and it is separate from per patient grant as mentioned in budget.

f) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, SAE, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before randomization will be paid for screening day.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

g) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

h) Patient conveyance/compensation will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount."GST applicable as per union budget rules.

i) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

j) Payment mentioned under "Final Payment" will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

k) LAMBDA will pay the Institute / Investigator an towards archival fees **INR 20,000/- for 5 yrs.** on behalf of sponsor.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

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

Payee Name	:	**Unique Clinical Research Services**
Payee Address	:	Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra,India.
PAN / TAN Number	:	**AAFFU5078B**
GST Number	:	**NA**

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and eCRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc.)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses for safety samples
- usage of internet while filling of eCRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc.)
- All overhead costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee

2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

Dr. A. Gudur, Karad

Add. Director of Research
KIMSDU, Karad

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .

9. **Screen Failures**: All screen failure patients payments will be made post LPLV. The Screen Failure Charges will be provided bases on 10% of total number of randomization patients or for actual number of Screen Failure patient whichever is lesser. The amount of Screen failure will be 50 % of Screening Visit amount of Investigator and Clinical Research Coordinator (means 1750 + 1000) along with actual amount of screening visit investigations (ECG, ECHO, CT-Scan) mentioned in schedule B (Budget Break-up).

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

Add. Director of Research
KIMSDU, Karad

Dr. A. Gudur, Karad

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ UW 488195

Treasury Allotment Date and No. 10.05.2019 (UW 488195)	Serial No. **2801**/19 Date 27.05.2019
Nature of Document/Article No.	
Whether it is to be Registered	If Registrable Name of S.R.O.-
Property Description in brief	As per the Document
Stamp Purchaser's Name	**Abbott India Limited,** 16, Godrej BKC, Bandra (E), Mumbai 51
If through other person then Name & Address	Suhas Pawar,
Name of the Other Party	
Stamp Duty Amount	Rs.100/-
Stamp Purchaser's Signature and Date	Shri Jay R. Birwadkar, Stamp Vendor, Ls. No. 1206030 Kumbhar Chawl, Netivali, Kalyan (E) 421 306 (M) 9890732173

TREASURY OFFICE

ज्या कारणासाठी ज्याची मुद्रांक खरेदी केला त्याची त्याच कारणासाठी मुद्रांक खरेदी केल्या पासुन सहा महीन्यात वापरणे बंधनकारक आहे

10 MAY 2019

EPIDEMIOLOGICAL STUDY AGREEMENT

Abbott India Limited ("Abbott") desires to retain Krishna Institute of Medical Sciences ~~and~~ To Be Deemed University," Research Department, OPD number 21, Pune-Bangalore Highway-4, Malakapur Road, Karad. Maharashtra, INDIA ("Institution") to provide services in support of Institution's employee's Dr. Sandeep Patil (the "Investigator") conduct of a non-interventional, epidemiological study (the "Study") in relation to" **A Cross-sectional Multicenter, Epidemiological Study to Evaluate the Clinicodemographic Profile and Management Practices for Primary Prophylaxis of Overt Hepatic Encephalopathy in Patients with Cirrhosis in India"** effective as of the date this Epidemiological Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties agree as follows:

Add. Director of Research
KIMSDU, Karad

1. Conduct of Study.

   (a) Institution and Investigator will conduct the Study pursuant to the terms of this Agreement and in strict adherence to Protocol No. EPIDI067 entitled "**A Cross-sectional Multicenter, Epidemiological Study to Evaluate the Clinicodemographic Profile and Management Practices for Primary Prophylaxis of Overt Hepatic Encephalopathy in Patients with Cirrhosis in India**" (the "Protocol"), as the same may be amended from time to time in writing by Abbott, and with any other written instruction that may be provided by Abbott. The parties further agree that this Study is epidemiological and will not utilize any Abbott product(s) ("Abbott Product(s)"). Subjects may already be prescribed an Abbott Product prior to, during or after the Study however this is incidental to the conduct of the Study and any such decision to prescribe Abbott Product to any subject at any time shall be the sole decision of the relevant subject's doctor and unrelated to the Study.

   (b) Institution shall use its best efforts to complete enrollment of 30 of Institution's patients (hereinafter referred to as "subjects") within stipulated enrolment Period. Abbott may terminate this Agreement immediately if (i) IRB or IEC (defined below) approval, if required, is not obtained within 5-8 weeks of receipt of all necessary materials for IRB/IEC submission; or (ii) all essential documents have not been executed and received by Abbott within 4 weeks of Institution's receipt of IRB or IEC's written approval, if such approval is required.

   (c) Institution shall ensure that Investigator reports to Abbott and, if required, to the competent authorities: (i) all serious adverse events in relation to an Abbott Product(s) immediately, but no later than twenty-four hours (24) hours of becoming aware of such occurrence, and (ii) as required by applicable law and within timelines set forth in the Protocol all other adverse events that may occur in the course of the Study. Institution shall promptly make available to Abbott such records as may be necessary and pertinent to investigate any adverse and serious adverse events. In addition, Institution shall ensure that Investigator reports to Abbott any subject pregnancies that occur in the course of the Study within twenty-four (24) hours of becoming aware.

Contacts. Institution's contact(s) at Abbott will be be **Ms.Sneha Nair-** Head-Clinical Operations,**16th Floor, Godrej BKC,Plot C – 68, "G" Block, Bandra Kurla Complex, Near MCA Club, Bandra (East),Mumbai 400 051, India, O:+91 22-38160910, M:9970780488, Fax # 91-22 2871 7499**,, or whomever Abbott may designate in writing. Abbott's contact(s) at Investigator will be **Dr. Sandeep Patil,** Krishna Institute of Medical Sciences ~~and~~ To be Deemed University, Research Department, OPD number 21, Pune-Bangalore Highway-4, Malakapur Road, Karad. Maharashtra, INDIA or whomever Institution may designate in writing.

2. Compliance with Law.

   (a) Each of Institution and Investigator represents, warrants and covenants that it will conduct the Study and perform its obligations under this Agreement in compliance with all applicable laws, regulations and guidelines. In furtherance of the foregoing obligations and as required by law, Institution will further ensure that an Institutional Review Board ("IRB"), an Independent Ethics Committee ("IEC"), or both, as applicable, approves and oversees the conduct of the Study. Institution will comply with the directives of the IRB or IEC, or both, as applicable, respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol.

   (b) Prior to the initiation of the Study, Institution will ensure that Investigator and any subinvestigator provides Abbott with all essential regulatory documents requested by Abbott to ensure compliance with applicable regulations, including but not limited to current Curriculum Vitae and medical license, or equivalent. Institution and Investigator will comply with all applicable requirements regarding reporting and management of conflicts of interest.

   (c) Institution and Investigator agree that if services are paid for or provided without charge by Abbott, none of Institution, its agents or Investigator shall separately bill or seek reimbursement for such services from any third party including, without limitation, the subject, any private provider of insurance, or any government program or other public provider of insurance.

3. Study Supplies. Due to the epidemiological nature of this Study, Abbott will not be providing any Abbott Product(s) or reimbursement for Abbott Product(s). Abbott will provide to Institution, at no cost, sufficient quantities of the case report forms or access to an electronic data capture system ("CRFs"), as well as any other materials and information specified by the Protocol or that Abbott deems necessary to conduct the Study (together, the "Study Materials"). All Study Materials and other information provided by Abbott in connection with this Agreement will not be used for any purpose other than to conduct the Study pursuant to the Protocol and will remain the sole property of Abbott. Upon termination of the Study or at

Abbott's request, the Study Materials will be returned or destroyed pursuant to the Protocol, and Institution will document such disposition, pursuant to Abbott's direction.

4. Delivery of Progress and Post-Study Reports. Upon request, Institution will submit oral or written reports on the progress of the Study to Abbott. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with the following, unless Abbott directs otherwise in writing:

   (a) the final IRB or IEC report on the Study prepared by the Investigator for the IRB or IEC or both, as applicable;
   (b) all completed, used and unused CRFs not previously delivered to Abbott; and
   (c) all data, reports and other information generated in relation to the Study.

5. Monitoring and Audits; Record Retention.

   (a) Institution will permit Abbott and/or any Abbott designee access to Study sites during normal business hours to monitor the conduct of the Study as well as to audit records, CRFs. source documents, and other data relating to the Study. Institution may redact such records as may be legally required to protect subject confidentiality consistent with **Section 9** (Subject Confidentiality and Data Protection) of this Agreement. If Abbott requests corrective and/or preventive action as a result of its monitoring or audit activities, Institution shall comply with the timely creation and implementation of a corrective action and/or preventive action plan. Abbott's right to audit shall survive the expiration of this Agreement.

   (b) Institution will ensure that subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within five (5) business days of subject visit.

   (c) Unless prohibited by law, Institution will notify Abbott immediately upon receiving any requests by any regulatory authority to inspect or have access to documents related to the Study and will promptly provide Abbott with a copy of any such request, to include copies of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice is issued which relates to the services under this Agreement, Institution agrees to produce a summary that includes an explanation of the issues identified by the regulatory authority, any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided hereunder. Institution agrees to provide Abbott with such summary within fifteen (15) days of Institution's receipt of any regulatory citation or notice.

   (d) Institution shall retain the Study documents in accordance with applicable laws and regulations or the Protocol, whichever retention period is longer. At Abbott's request and expense, Institution shall retain the Study documents for an even longer period. Institution shall provide Abbott at least sixty (60) days' written notice before deleting any Study documents from its files.

6. Compensation.

   (a) Abbott shall pay Institution in accordance with the Study budget set forth in **Exhibit A** (the "Budget"). In addition, Institution's employees, including Investigator, may be reimbursed for reasonable and necessary expenses related to travel, consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel), and may be provided meals as may be necessary for the publication/ presentation of study results/data or at investigator meetings or other Abbott required meetings. The parties agree that the amounts set forth in the Budget represent the fair market value for the services to be rendered and have not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between or among Institution and Abbott.

   (b) The Budget is based on the full performance of services and compliance with the terms of this Agreement (including the Protocol). Abbott will not remit payments for CRFs containing incomplete or inaccurate data or data collected from subjects enrolled in violation of the Protocol ("Non-conforming CRFs"). If Abbott has paid for such Non-conforming CRFs such payment will be deducted from the next payment (or the final payment, as described in **Section 7(d)** below).

   (c) All payments shall be made in accordance with the terms of **Exhibit A** and only after all parties have signed this Agreement. If applicable, reimbursement of IRB/IEC fees is contingent upon completion of the IRB/IEC's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revisions. Abbott will not be obligated to reimburse Institution for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

(d) The final payment due to Institution under this Agreement shall be payable upon completion of all services contemplated hereunder, delivery to Abbott of all CRFs, and return to Abbott of all items described in **Section 5** (Delivery of Progress and Post-Study Reports) and will be accompanied by a financial reconciliation performed by Abbott. If the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder as revealed by the reconciliation, Abbott shall pay the outstanding amount due. If Abbott is due a refund for any unearned fees or overpayments, Institution shall remit the amount of such refund with supporting documentation to Abbott at: Clinical Operations, Abbott India Ltd,16th Floor, Godrej BKC,Plot C – 68, "G" Block Bandra Kurla Complex,Near MCA Club, Bandra (East),Mumbai 400 051, India. Any payments due from one party to the other under the reconciliation shall be made within forty-five (60) days of the notice and invoice of amount due.

(e) In the event of a payment dispute, Institution and Investigator shall not withhold Study data or information pending resolution of the dispute because such withholding may cause irreparable harm to the Study.

(f) Upon written notice, Abbott may delegate certain of its payment obligations to a contract research organization ("CRO"). In such event, Institution and Investigator agree that as to any payments delegated by Abbott to a CRO, Institution and Investigator shall first seek redress from the CRO for compensation.

(g) Investigator shall be responsible for direct compensation of Investigator, including any subinvestigators, from funds paid by Abbott to Institution under the Study Budget. Neither Investigator nor any subinvestigators shall receive any separate compensation from Abbott.

(h) In this study; Abbott has delegated its Fee payment obligations under this Agreement to **JSS Medical Research India Pvt. Ltd., Faridabad.** The Investigator will hence approach Site Management Organization (SMO) for queries or concerns in relation to compensation under this Agreement.

7. Confidentiality.

(a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees (including Investigator), agents, subcontractors and affiliates (collectively, "Receiving Party") shall not disclose Confidential Information without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Abbott, including but not limited to the Protocol, Abbott Product, Study Materials, and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which:

(i) is known to the Receiving Party prior to receipt, as evidenced by its written records;
(ii) is disclosed to the Receiving Party by a third party who has a right to make such disclosure in a non-confidential manner; or
(iii) is or becomes part of the public domain through no fault of the Receiving Party.

(b) The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.

(c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) to allow Abbott to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this **Section 8**, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on the written opinion of legal counsel.

(d) Receiving Party will not disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of such third party and Abbott.

8. Subject Confidentiality and Data Protection.

(a) The parties will comply with all applicable laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining a signed subject authorization

document for the use and disclosure of data and an Informed Consent Form, if required (collectively, "ICF") from each Study subject prior to the subject's participation in the Study. The ICF must permit Abbott and its representatives involved with or evaluating the Study to access, process, obtain copies, transfer and retain Study data. Each ICF must conform with the Protocol and be compliant with: International Conference on Harmonisation, Harmonised Tripartite Guidelines for Good Clinical Practice ("ICH"); all applicable laws and regulatory requirements; and must be approved in writing by Abbott, and if applicable by the IRB/IEC. A Study subject's participation in the Study will be contingent upon the execution of a proper ICF.

(b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others participating in or associated with the Study (the "Personal Data") it shall only do so in accordance with this Agreement, with all applicable laws and with Abbott's written instructions. Institution and Investigator shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott of any unauthorized access to or disclosure of Personal Data (the "Security Breach"), including the timing and nature of the Security Breach. Institution and Investigator shall take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.

(c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trial experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), public registration of the Study on web sites designed for this purpose such as www.clinicaltrials.gov, assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.

9. Publicity. Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution understands that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.

10. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of Abbott Product(s) or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.

11. Publications and Presentations.

(a) Publication Requirements. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication emanating from the Study, Investigator must comply with the Requirements for Scientific Publications attached hereto as **Exhibit B**.

(b) Procedures. As the Study sponsor, Abbott retains the first right to disclose the results of the Study through a Publication or any other public disclosure (collectively, a "Study Results Disclosure"). Accordingly, following the earliest of: (i) Abbott's Study Results Disclosure; or (ii) twelve (12) months after completion or termination of the Study at all Study sites, Institution and Investigator shall have the right to prepare and submit for Publication a Study Result Disclosure in appropriate scientific journals or other professional publications. If Institution or Investigator prepares a Study Results Disclosure, Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of a work for a Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator within sixty (60) days after receipt of the draft Study Results Disclosure (the "Review Period"). In addition, Institution

or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection (the "Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree that due consideration will be given to Abbott comments; and further, Abbott Confidential Information (other than the results of the Study generated hereunder) shall be deleted from any Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.

12. Representations and Warranties. Institution represents and warrants that:

(a) the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator is associated;

(b) Institution's performance of the services and acceptance of compensation, including the acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator or Institution (including its employees and agents) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such services does not present a conflict of interest with Investigator's official duties;

(c) Investigator has received any required authorization, written or otherwise, from Institution for Investigator's performance of the services and acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator hereunder;

(d) If Investigator leaves Institution's employment during the Term, then Institution will promptly notify Abbott in writing and will obtain a written acknowledgement by Investigator's new employer that Investigator is participating in the Study under the terms of this Agreement;

(e) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner;

(f) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: (i) training and expertise in relevant fields; (ii) appropriate research facilities; (iii) experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (iv) prior scientific research or clinical experience; and (v) ability to conduct the Study in accordance with applicable legal and regulatory requirements;

(g) Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. In the event that any of foregoing occurs, Investigator shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement;

(h) Institution shall ensure that Investigator does not alter in any way Investigator's normal practice for prescribing medications to patients or be influenced in any way to prescribe an Abbott product in place of any other therapy due to the conduct of this Study or payment to Institution of any compensation from Abbott for conducting this Study; and

(i) if any significant changes occur during the Term with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.

13. Term and Termination.

(a) This Agreement will be effective on the Effective Date and shall expire on the later of: (i) one (1) year from the Effective Date; (ii) the date of Study database lock if there is subject enrollment under this Agreement; or (iii) the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided below.

(b) Abbott may terminate this Agreement at any time upon written notice. Either party may terminate this Agreement upon written notice if (i) the other party has breached a material term of the Agreement, or (ii) if the Study is terminated by any governmental or regulatory authority.

(c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Institution will discontinue all then-enrolled subjects from the Study.

14. Insurance. Each party agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its respective duties and obligations under this Agreement to the extent such duties and obligations are commercially insurable. Each party further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to the other party within seven (7) business days following receipt of written request by the other party therefore.

15. Debarment and Exclusion. Institution represents and warrants that none of Institution, any Institution employees, including Investigator, agents and subcontractors performing services hereunder, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to Institution or such employees, agents or subcontractors becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual, nor are they listed on the United States Food and Drug Administrations (the "FDA") Disqualified/Restricted List for clinical investigators. Institution further covenants, represents and warrants that if, during the Term, Institution, or any of Institution's employees, including Investigator, agents or subcontractors, including any subinvestigators, performing services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual or added to FDA's Disqualified/Restricted List for clinical investigators, Institution will immediately notify Abbott, and Abbott will have the right to immediately terminate this Agreement. The provision of this paragraph regarding notice of acts occurring during the Term will survive termination or expiration of this Agreement. For purposes of this provision, the following definitions will apply:

(a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from providing services in any capacity to a person that has an approved or pending drug product application.

(b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.

(d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

16. Independent Contractor. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has authority to bind or act on behalf of Abbott.

17. Assignment. Institution may not assign this Agreement to any other party, or subcontract any of its services hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation. Further, in the event that Institution is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement in a form acceptable to Abbott obligating such subcontractor to comply with the

terms and conditions hereof, and Institution shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Institution.

18. Subinvestigators. Institution will not use any subinvestigator for the Study without Abbott's prior written consent, and only upon Institution's agreement to ensure any subinvestigators compliance with the terms and conditions of this Agreement.

19. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

If to Institution:
Dr. Sandeep Patil

Address: Krishna Institute of Medical Sciences
~~and~~ "Deemed University,
Research Department, OPD number 21,
Pune-Banglore Highway-4,
Malakapur Road, Karad.
Maharashtra, INDIA.

Phone: 8308391683/ 9146272902

If to Abbott:
Ms.Sneha Nair,
Head-Clinical Operations,
Abbott India Ltd,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct,
Mobile No : +91-9970780488

If to Investigator:
Dr. Sandeep Patil

Address: Krishna Institute of Medical Sciences
~~and~~ "Deemed University,"
Research Department, OPD number 21,
Pune-Banglore Highway-4,
Malakapur Road, Karad.
Maharashtra, INDIA.

Phone: 8308391683/ 9146272902

with a copy to:
Director – Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No. C – 68, BKC,
Near MCA Club, Bandra (E)
Mumbai – 400 051.
Phone: 91-022-2871 7488

20. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

21. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

22. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

23. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of India, excluding its conflicts of laws provisions.

24. Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Mumbai and shall be conducted in the English language. The award of the arbitrator shall

be final and binding on both parties. The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, 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. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

26. Financial Disclosure Certification. Prior to the initiation of the Study, Institution will ensure that each Investigator and any subinvestigator (a) completes and returns to Abbott the Financial Disclosure Certification. Investigator understands and will be required to certify that Investigator and all subinvestigators conducting the Study, and their immediate families may not have a direct ownership interest (e.g., intellectual property rights) in the Abbott Product, nor may they be compensated with Abbott securities in exchange for being an Investigator or subinvestigator in the Study. Investigator and any subinvestigator will promptly notify Abbott of any change in the accuracy of the Financial Disclosure Certification during the Term and for one (1) year following completion of the Study.

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

ABBOTT INDIA LIMITED

By: _____

Name: Sneha Nair

Title: Head-Clinical Operations

Date: 01/07/2019

KRISHNA INSTITUTE OF MEDICAL SCIENCES

By: _____

Name: Dr.Sandeep Patil

Title: Assistant Professor

Date: 12/JUL/2019

HEAD OF THE INSTITUTION

By: _____

Name: Dr. M.V. Ghorpade

Title: Institutional Head

Date: 16/Jul/2019

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

Exhibit A - Budget
Attachment 1 to Exhibit A
Exhibit B - Safety Reporting Obligations
Exhibit C- Requirements for Scientific Publications

EXHIBIT A
BUDGET

INVESTIGATOR	Dr. Sandeep Patil	
ADDRESS	Krishna Institute of Medical Sciences ~~and~~ To Be Deemed University, Research Department, OPD number 21, Pune-Bangalore Highway-4, Malakapur Road, Karad. Maharashtra, INDIA.	
PHONE NUMBER	8308391683/ 9146272902	
DISEASE BEING STUDIED: Hepatic Encephalopathy in patients with Cirrhosis	PROTOCOL: EPIDI067	Visits: Visit 1
Number of subjects at Institution required per Protocol/Study		
Total per subject cost (see **Attachment 1**, per subject breakdown; payments to be made per the Subject Visit Payments schedule, described below)		INR 2000 (Visit) = 2000*
Total cost for all CRFs for all subjects		INR 60,000**
Institutional Overhead Charges		25%
ADDITIONAL STUDY FEES: Payments will be made as follows, in accordance with Compensation Section of the Agreement.		
	TOTAL COMPENSATION	75000 INR

SUBJECT VISIT PAYMENT SCHEDULE: Payments will be made as follows, in accordance with the Compensation Section of the Agreement:

Subject Visit Payments: Payments for subject visits will be made according to the milestones decided in this agreement. Payments will be made after data is entered by Investigator into the CRFs and reviewed by Abbott, and will correspond to amounts listed in **Attachment 1 to Exhibit A**. Investigator understands that such payments are subject to subsequent verification by Abbott and will be adjusted per Section 7(d) (Compensation) of the Agreement if necessary. Total payment mentioned in the agreement is for a recruitment of 30 patients.
A CRO, JSS Medical Research India Private Limited has been contracted for subject recruitment, source documentation& data entry purpose. The cost of the CRC will be paid by Abbott India Ltd to JSS Medical Research India Private Limited. The site payment will be managed by JSS Medical Research India Private Limited.

A final payment shall be made following termination of the Study, delivery to Abbott of the remaining Completed CRF(s), final reconciliation of any remaining amounts due, and the return to Abbott of all items described in Section 4 (Study Supplies) of the Agreement. Abbott will not be obligated to reimburse Institution for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

CHEQUE PAYMENT INFORMATION:

Cheque shall be made payable to:	Unique Clinical Research Services
Individual's name and address to receive Payment at Institution:	Dr. Sunil Chaudhary Block No D-2, Sai Prakash, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune -411033, Maharashtra
Individual's name and e-mail address at site to receive detailed payment information:	Dr. Sunil Chaudhary email-Id - drsunilchaudhary07@gmail.com
Individual's name and address to receive Invoices at Abbott:	Dr. Prachi Bhoyer
(Information must be accurate for FDA purposes)	

Add. Director of Research
KIMSDU, Karad

Payee Name:	Unique Clinical Research Services
Bank Account No.	007305010408
IFSC Code:	ICIC0000073
Bank Name, Branch & address:	ICICI Bank Aundh Branch, Pune
GSTN, If applicable:	* ~~NA~~ 27AAFFU5078B1Z5

* Kharan. 12/07/19

Add. Director of Research
KIMSDU, Karad

ATTACHMENT 1 TO EXHIBIT A

Study Budget Breakdown

- **For participation as Principal investigator**

  1. Scope of work

  2. Table 1: Subject grant

Fee Per completed CRF per subject	On enrollment of 15 patients- 25% On enrollment of 30 patients- 25% On data entry completion of all enrolled patient- 25% On DBL- 25%
2500 (including overhead)	

Other Payment terms:

- **Cost for minimum 30 patients completing the study = 30*2000 & institutional overhead charges- 25%**
- **Total Investigator Grant = INR 75000**
- **With reference to clause 8/g towards compensation: Abbott India Ltd has delegated its payment obligation towards the investigators to a service provider (i.e. JSS Medical Research India Private Limited). Thus payment shall be made from Abbott to Investigator through (JSS Research).**
- **An invoice addressed to JSS Medical Research India Pvt Ltd will have to be provided by the investigator (on institution letterhead) to the personnel from JSS Research India Private Limited prior to release payment. A template for the same will be shared by JSS Research. Any and all invoices raised by the institution/ site under the agreement shall be paid by the Abbott within 60 days from the date of the receipt of the invoice from the institution/ site to the Abbott.**
- **Travel Expenses: Expenses towards domestic travels, hotel stay, meal and car rental for any of the study related meeting would be done by Abbott with prior written approval from Abbott.**
- **All payments under this agreement are subject to applicable taxes including service tax and the same shall be borne by Abbott. As per the Indian Tax Laws TDS would be applicable. A TDS certificate would be provided to your site before the end of the financial year.**
- **Payment will be released within 60 days of receipt of the invoice.**

Add. Director of Research
KIMSDU, Karad

EXHIBIT B

SAFETY REPORTING OBLIGATIONS

(a) Institution and Investigator shall comply with all applicable adverse event reporting and other regulatory obligations applicable for investigators and Abbott shall comply with all applicable adverse event reporting and other regulatory obligations applicable for sponsors. In addition, Institution and Investigator shall report to Abbott the following Pharmacovigilance-relevant information if spontaneously reported to Institution or Investigator and only in case relating to an Abbott product(s):

(i) adverse reactions (a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility);

(ii) product exposure (including maternal, paternal or fetal exposure) associated with a pregnancy;

(iii) trans-mammary exposure of an infant (transmission via breast milk) to a product;

(iv) overdose (i.e. administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information (Note: Clinical judgment should always be applied));

(v) abuse (i.e. persistent or sporadic, intentional non-therapeutic excessive use of a product by patient/consumer which is accompanied by harmful physical or psychological effects)

(vi) misuse (i.e. intentional and therapeutic but inappropriate use of a product by patient/consumer not in accordance with the authorized product information);

(vii) off-label use (i.e. intentional prescribed therapeutic use of a product not in accordance with the authorized product information);

(viii) occupational exposure (i.e. exposure to a product as a result of one's professional or non-professional occupation);

(ix) medication errors (i.e. unintended failure by patient/consumer or health care professional in the drug treatment process that leads to, or has the potential to lead to, harm to the patient);

(x) lack of therapeutic efficacy (i.e., "lack of effect" reports), which will be handled as a serious adverse reaction if associated with vaccine or contraceptive product or drugs used for critical conditions or for the treatment of life-threatening diseases;

(xi) suspected transmission of an infectious agent, which will be classified as a serious adverse reaction;

(xii) an unexpected therapeutic or clinical benefit from use of the product.

(b) Such information shall be reported by Institution and/or Investigator to Abbott within 24 hours of becoming aware of such occurrences. Institution and Investigator shall promptly make available to Abbott such records as may be necessary and pertinent to investigate such occurrences.

Add. Director of Research
KIMSDU, Karad

(c) All Pharmacovigilance-relevant information mentioned above relating to the Abbott Product(s) shall be reported to the following contact:

Affiliate Safety Representative (ASR)

Dr. Kirti Chavan
Manager Pharmacovigilance and Operations
Established Pharmaceuticals Division
Abbott Healthcare Private Limited
Floor 16, Godrej BKC, Plot No. C – 68,
BKC, Near MCA Club, Bandra (E)
Mumbai – 400051,
pv.india@abbott.com

(d) Abbott will acknowledge receipt of the information within 24 Hours. If investigator does not receive acknowledgement, the information will have to be re-transmitted.

Add. Director of Research
KIMSDU, Karad

Exhibit C

REQUIREMENTS FOR SCIENTIFIC PUBLICATIONS

1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit must be based on:

   (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
   (b) Drafting or revising the article for important intellectual content; and
   (c) Final approval of the version to be published.

   A person must meet all three of the above criteria to warrant authorship.

2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, must be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.

3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors will comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

4. Sponsorship. Authors must acknowledge Abbott as the funding source of a Study, and must also comply with additional sponsorship-related disclosures required by the journal or congress.

5. Access to Data. Abbott will provide all authors with the final Protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Abbott will provide a copy of the Protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication, with the understanding that the documents are confidential, the property of Abbott, and should not be disclosed to any third party without Abbott's prior written permission.

6. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not permitted. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are permitted. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is permitted. Encore presentation of data, when permitted by scientific congress policy, is permitted.

Add. Director of Research
KIMSDU, Karad

महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ AR 632989

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दस्ताचा प्रकार ...
दस्त ओळखी सादरकर्ता आहेत का ? होय/नाही.
LUPIN LIMITED
(Research Park)
46A/147A, Nande Village,
Tal-Mulshi, Pune-411042.
Maharashtra, INDIA.

वरिष्ठ कोषागार अधिकारी पुणे
27 JUN 2019
प्रथम मुद्रांक लिपीक कोषागार पुणे करिता

मुद्रांक विक्रेत्याची सही
मुद्रांक विक्रेती
परवाना क्र. 2201119
डिस्ट्रीक्ट कोर्ट कंपाउंड, शि.नगर, पुणे-
या माहितीसाठी ज्यांनी वरील खरेदी केला त्यांनी त्याच कारणासाठी
मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरला असणे आवश्यक आहे

CLINICAL TRIAL AGREEMENT
Protocol # LRP/RBZ/2015/002

This Clinical Trial Agreement ("Agreement") is made as on 11th Jul 2019 ("Effective Date") between

Lupin Limited, incorporated under the laws of India with its registered office located at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz East, Mumbai 400055 and having PAN: AAACL1069K, including its successors, assigns and Affiliates (hereinafter "**Lupin**");

and

Dr. Gaurav Paranjpe, an **Indian** citizen/resident, with his/her address at Krishna Institute of Medical Sciences "Deemed to be University", Pune- Bangalore highway NH-4, Malkapur road, Karad-415110, Maharashtra, India and having PAN: AOTPP6400L (hereinafter "**Principal Investigator**");

and

Krishna Institute of Medical Sciences "Deemed to be University", with its address at Pune- Bangalore highway NH-4, Malkapur road, Karad-415110, Maharashtra, India (hereinafter "**Institution**")

and

Unique Clinical Research Services, with its address at Shree Prasad, Block No-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India (hereinafter "**SMO**").

Lupin wishes to support a clinical trial entitled Protocol # LRP/RBZ/2015/002 "A Prospective, Randomized, Parallel Group, Double Blind, Multicenter Study to Compare the Efficacy, Safety & Immunogenicity of Lupin's Ranibizumab with Lucentis® in Patients with Neovascular Age-Related Macular Degeneration" ("**Protocol**") to be conducted at Institution and to involve Trial Subjects (collectively, "**Trial**" or "**Study**").

The parties agree as follows:

1. Definitions:

1.1 **Affiliate:** means with respect to a Person, any other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/ or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.2 **Applicable Laws** means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, licence, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.3 **Authority** means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.4 **Intellectual Property Rights**: includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or forms of protection having

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equivalent or similar effect anywhere in the world and the term 'registered' includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.5 **Invention**: shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.6 **Party:** means Lupin, Institution and Principal Investigator and "Parties" shall mean all of them.

1.7 **Person**: means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.8 **Study Site:** means the premises on which the Study will be carried out.

1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11 **Regulatory Approval**: mean any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.12 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. Investigators and Research Staff.

2.1 Principal Investigator. The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 Sub-investigators and Research Staff. Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Trial as Sub-investigators or Research Staff.

2.3 Obligations of Principal Investigator. Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standards including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any

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other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 No Substitution. Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Lupin. In the event Lupin approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Lupin does not approve a replacement principal investigator, Lupin will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 Delegation of duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Lupin promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. Protocol. The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 Amendments. The Protocol may be modified only by a written Amendment, signed by both, Lupin and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent Ethics Committee ("IEC").

3.2 Emergency Amendments. If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Lupin and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Lupin and the Principal Investigator.

3.3 No Additional Research. Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Lupin in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. Independent Ethics Committee. Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 Trial Disapproval. If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

5. Trial Conduct. Principal Investigator will conduct the Trial in accordance with the Protocol, Lupin's or its designee's written instructions and Applicable Law.

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5.1 Trial Initiation: Prior to initiation of the Trial, Lupin may organize an investigator meeting for all investigators who are taking part in the clinical trial for Lupin Drug, at such place and time as finalized by Lupin ("**Investigator Meeting**"). The purpose of the Investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Lupin Drug. The Principal Investigator agrees to attend the said Investigator Meeting along with such members of its Research Staff, as approved by Lupin ("**Attendees**"). Lupin agrees that it may arrange for the travel and boarding and lodging of the Investigator Meeting Attendees if it happens.

6. Lupin Drug. Lupin will provide the Principal Investigator with sufficient quantities of Lupin product that is being studied ("**Lupin Drug**") to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Lupin will also provide placebo or comparator drug ("**Comparator Drug**").

6.1 Custody and Dispensing. Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Lupin Drug or Comparator Drug, as well as appropriate documentation of such activities.

6.2 Control. Principal Investigator will maintain appropriate control of supplies of Lupin Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 Use. Principal Investigator will use Lupin Drug or Comparator Drug only as specified in the Protocol. Any other use of Lupin Drug or Comparator Drug constitutes a material breach of this Agreement.

6.4 Ownership of Lupin Drug. Lupin Drug is and remains the sole and exclusive property of Lupin. Lupin grants or assigns Principal Investigator no express or implied intellectual property rights in Lupin Drug or in any methods of making or using Lupin Drug.

6.5 Payment for Lupin Drug or Comparator Drug. Principal Investigator will not charge a Trial Subject or third-party payer for Lupin Drug or Comparator Drug or for any services reimbursed by Lupin under this Agreement.

7. **Representation and Warranties:**

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Lupin the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Lupin from time to time;

c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the

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applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Lupin, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set out hereunder may be relied upon in any applications to any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Laws or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Lupin in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Lupin for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Lupin in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

n. The Principal Investigator and/or the Institution shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the Agreement. Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonably required by Lupin from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Lupin hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Lupin, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Lupin, who shall claim such Intellectual Property Rights through Lupin and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Lupin, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Lupin.

8.3 Principal Investigator and the Institution hereby jointly undertake that:

a. The Principal Investigator will unequivocally transfer to Lupin the right to obtain patent on Invention.

b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Lupin. To ensure the duties set forth in this Section are carried out, Lupin may, at its own cost, request that Principal Investigator prepares and signs

appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Lupin. Lupin has the exclusive right to choose the form of protection of intellectual property.

c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Lupin in any way. Moreover, Principal Investigator agrees to inform Lupin of any known infringement of its Intellectual Property Rights, and to support Lupin, at Lupin's expense, in actions intended to protect Lupin's Intellectual Property Rights.

d. Lupin shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Lupin.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. Research Grant. Funding will be made to the Principal Investigator or the SMO on behalf of the Principal Investigator, as the case may be, by way of grant payments in accordance with Attachment-B. The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties. The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Lupin, including, but not limited to, Lupin Drug, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Lupin Drug and/or Comparator Drug administration.

Principal Investigator and the Institution hereby agree that Lupin can make payments to the SMO on their behalf and that the Principal Investigator and/or the Institution do not have any objection to the same.

It is the responsibility of the SMO, Institution and the Principal Investigator to sort out any payment related disputes amongst themselves and Lupin shall not be responsible in any manner whatsoever for the same. The SMO, Principal Investigator and the Institution hereby jointly and severally indemnify Lupin from any loss that Lupin may suffer as a result of such dispute affecting the Trial in any manner.

10. Trial Subject Enrollment. Principal Investigator has agreed to enroll Trial Subjects in the Trial in accordance with the Protocol. Lupin reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 Multi-Center Studies. Lupin may discontinue patient enrollment if the total enrollment needed for a multi-center Trial has been achieved.

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11. Informed Consent. Principal Investigator undertakes that it will obtain a written Informed Consent Form ("**ICF**") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Lupin an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Lupin or its designee to inspect signed ICFs or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Lupin for review and written approval by Lupin before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs an ICF approved by Lupin and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

12. Adverse Events. Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If a Trial Subject is physically injured by Lupin Drug or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Lupin, Lupin will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. Protected Health Information. The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting it from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 Authorization to Use and Disclose Health Information. Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Lupin and other persons and entities designated by Lupin with completed Case Report Forms ("**CRFs**"), source documents and all other information required by the Protocol. Lupin, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfill their assigned duties with respect to the Trial. Such use also will be restricted to those uses permitted in the authorization forms and neither Lupin nor any party to whom Lupin may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Lupin an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. Confidential Information. During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Lupin Affiliate.

14.1 Definition. Except as specified below, Confidential Information includes all information provided by Lupin, or developed for Lupin, Inventions (hereinafter defined), and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with Lupin, commercialization and Trial strategies, trade secrets and know-how disclosed by Lupin to Principal Investigator and/or the

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Institution directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

14.2 Exclusions. Confidential Information does not include information that is in the public domain prior to disclosure by Lupin; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

14.3 Obligations of Confidentiality. Unless Lupin provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

14.4 Disclosure Required by Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator and/or the Institution notifies Lupin or Lupin in writing as far as possible in advance of the disclosure so as to allow Lupin to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 Survival of Obligations. For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Data are described in Sections 18 (Publications) of this Agreement.

14.6 Return of Confidential Information. If requested by Lupin, Principal Investigator will return all Confidential Information, at Lupin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Trial Data, Biological Samples, and Records.

15.1 Trial Data. During the course of the Trial, Principal Investigator will collect and submit data to Lupin or its agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Lupin or its agent, such as X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. Ownership of Trial Data. Subject to Principal Investigator's right to publish, with prior written intimation to Lupin, the results of the Trial and the non-exclusive license that permits certain uses, Lupin is the exclusive owner of all Trial Data.

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b. Non-Exclusive License. Lupin grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. Medical Records. Medical records relating to Trial Subjects that are not submitted to Lupin may include some of the same information as is included in Trial Data; however, Lupin makes no claim of ownership to those documents or the information they contain.

d. Personal Information Protection. Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 Biological Samples. If so specified in the Protocol, Principal Investigator may collect and provide to Lupin or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

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

b. Sample Data. Lupin or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Lupin will not provide the results of such tests ("Sample Data") to the Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Lupin provides Sample Data to the Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

15.3 Records. Principal Investigator will ensure that Trial Subject's Trial records, which include the Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. Retention. Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Lupin authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Lupin's prior written permission to do so; provided, however, that if Lupin does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Lupin, then Principal Investigator may forward all such records to Lupin, at Lupin's expense, or continue to retain such records. Principal Investigator further agrees to permit Lupin to ensure that the records are retained for a longer period if necessary, at Lupin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

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16. Inspections and Audits.

16.1 Access. Upon reasonable request by Lupin, authorized representatives of Lupin, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy: all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe the conduct of the Trial.

16.2 Notice. Principal Investigator and/or the Institution will inform Lupin within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Lupin with a copy of any communications sent by such persons; and will provide Lupin or Lupin the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 Cooperation. Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Lupin copies of any inspection findings that Principal Investigator receives from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Lupin with an opportunity to prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Lupin. Principal Investigator will assign all interest in any such Invention to Lupin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Lupin in filing and prosecuting any patent applications relating to Invention, at Lupin's expense.

18. Publications. Principal Investigator acknowledges that Lupin has the right to use the Study Results in any manner deemed appropriate to Lupin's business interests, both during, and following termination/expiry of, this Agreement. Lupin shall have the sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Lupin shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Lupin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial, Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. Publicity. Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Lupin reserves the right to identify the Principal Investigator in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

20. Indemnification.

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20.1 Lupin agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, 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 arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Lupin Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Lupin further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees 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. Principal Investigator further agrees to promptly notify Lupin in writing of any such medical injury.

a. Exclusions. Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Lupin (b) failure of an Indemnified Party to comply with any Applicable Law and governmental regulations, or (c) fraud, negligence or willful misconduct by an Indemnified Party.

b. Notice and Cooperation. Principal Investigator agrees to provide Lupin with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Lupin, Principal Investigator agrees to authorize Lupin to carry out the sole management of defense of an indemnified claim.

c. Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on Lupin without Lupin's prior written consent. Lupin will not unreasonably withhold such consent of a settlement or compromise. Neither party will admit fault on behalf of the other party without the written approval of that party.

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Lupin including its directors, employees, representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Lupin;
b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Lupin to redo the Study;
c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;
d. any negligent act or omission or willful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential or special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Lupin shall, in addition

to any other right that Lupin may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Lupin the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Lupin may incur for repeating the Study. Further without prejudice to any other rights that Lupin may have under law or equity, Lupin may, at its discretion, forthwith terminate this Agreement.

21. Term and Termination.

21.1 This Agreement will be effective from the Effective Date and shall be valid in full force and effect till the completion of the Study at the Study Site. The Study shall be deemed completed at the Study Site once Lupin prepares Study close-out report and informs the EC about the completion of the Study at the Study Site.

21.2 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. Disapproval by IEC. If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. Trial Completion. For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subjects; receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

c. Early Termination of Trial. If the Trial is terminated early as described below, the Agreement will terminate after receipt by Lupin of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either party.

(1) Termination of Trial Upon Notice. Lupin reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) Immediate Termination of Trial by Lupin. Lupin further reserves the right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Lupin notifying Principal Investigator of such breach; (ii) failure to enroll Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Lupin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Lupin Drug or Comparator Drug.

(3) Immediate Termination of Trial by Principal Investigator. Principal Investigator reserves the right to terminate the Trial immediately upon notification to Lupin or Lupin if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.3 Payment upon Termination. If the Trial is terminated early in accordance with this Agreement, Lupin will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with Attachment-B, less payments already made. The termination payment will include any non-cancelable expenses, other

LUPIN LIMITED MUMBAI

than future personnel costs, so long as they were properly incurred and prospectively approved by Lupin, and, only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IEC, Lupin will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Lupin.

21.4 Return of Materials. Unless Lupin instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Lupin, at Lupin's expense, for Trial conduct, and any Lupin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Lupin, at Lupin's expense, unless otherwise specified by Lupin, any unused Lupin Drug or Comparator Drug.

22. Insurance. The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

23. Debarment, Exclusion, Licensure and Response. Principal Investigator and the Institution jointly and severally 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. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution 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 the Institution will notify Lupin 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 Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Lupin regarding any responsive action necessary.

24. Assignment and Delegation. Lupin may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Lupin or substitute Lupin with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Lupin, and the express agreement of Principal Investigator and/or the Institution, Lupin, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Lupin, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Lupin.

25. Equipment. Lupin may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

26. Survival of Obligations. Obligations relating to Research Grant, Confidential Information, Inventions, Records, Publications, Publicity, Debarment and Exclusion, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. Entire Agreement. This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific

LUPIN LIMITED MUMBAI

Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. Conflict with Attachments. To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

29. Relationship of the Parties. The relationship of Principal Investigator and/or the Institution to Lupin is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. Force Majeure. Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. Governing Law. Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Mumbai.

32. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO LUPIN:
Attn. To: Dr. Dhananjay Bakhle
Executive Vice President, Lupin Limited (Research Park)
Survey No.46A/47A, Village Nande,
Taluka Mulshi, Pune, 412115, Maharashtra, India

TO PRINCIPAL INVESTIGATOR:
Dr. Gaurav Paranjpe
Krishna Institute of Medical Sciences, "Deemed to be University",
Pune- Bangalore highway NH-4,
Malkapur road, Karad-415110,
Maharashtra, India

LUPIN LIMITED MUMBAI

TO INSTITUTION:
Dr. M V Ghorpade
Krishna Institute of Medical Sciences, "Deemed to be University",
Pune- Bangalore highway NH-4,
Malkapur road, Karad-415110,
Maharashtra, India.

TO SMO:
Dr. Sunil Chaudhary
Unique Clinical Research Services
Shree Prasad,
Block No. D-2,
Prakash Housing Society,
Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India

In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence a binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

LUPIN LIMITED MUMBAI

Add. Director of Research
KIMSDU, Karad

ACCEPTED AND AGREED BY:

PRINCIPAL INVESTIGATOR

By:
Signature

Dr. Gaurav Paranjpe
Printed Name

Assistant Professor and Principal Investigator
Title

18/ Jul/ 2019
Date

ACCEPTED AND AGREED BY:

LUPIN LIMITED

By:
Signature

Dr. Dhananjay Bakhle
Printed Name

EVP- Medical Research
Title

15/ Jul/ 2019
Date

ACCEPTED AND AGREED BY:

INSTITUTION

By:
Signature

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

Dr. M V Ghorpade
Printed Name

Head of the Institute
Title

18/ Jul/ 2019
Date

ACCEPTED AND AGREED BY:

SMO

By:
Signature

Dr. Sunil Chaudhary
Printed Name

Director
Title

22/ Jul/ 2019
Date

LUPIN LIMITED MUMBAI

LUPIN OK LEGAL

Add. Director of Research
KIMSDU, Karad

Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 02 Aug 2018 and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol # LRP/RBZ/2015/002 "A Prospective, Randomized, Parallel Group, Double Blind, Multicenter Study to Compare the Efficacy, Safety & Immunogenicity of Lupin's Ranibizumab with Lucentis® in Patients with Neovascular Age-Related Macular Degeneration"

LUPIN LIMITED MUMBAI

Add. Director of Research
KIMSDU, Karad

Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. General Terms. Principal Investigator or the SMO (on behalf of the Principal Investigator), as the case may be, ("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 submitted and 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

Add. Director of Research
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responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

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. 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-9. Payee. The research grant payments will be made to the following payee and address:

Payee Name: Unique Clinical Research Services
Payee Address: Shree Prasad, Block No. D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India
Payee PAN No.: AAFFU5078B
Payee GST Number: 27AAFFU5078B1Z5
Payee Bank Account Details:
Bank Name: ICICI Bank
Bank Address: ICICI Bank, Aundh Branch, Pune
Bank Account Number: 007305010408
Account type: Current
IBAN Number: DE92501108006231605970
SWIFT Code: ICICINBBCTS
IFSC Code: ICIC0000073
Email address for remittance information: drsunilchaudhary07@gmail.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-10. 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 to: Dr. Chirag Shah

Each invoice must contain: (1) Lupin name, (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

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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.

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Add. Director of Research
KIMSDU, Karad

Attachment C

EQUIPMENT USE, OWNERSHIP & DISPOSITION

1. Use. During the term of this Agreement, Principal Investigator may use Equipment only for purposes of this Trial.

2. Ownership. Until the termination of this Agreement, this Equipment remains the property of the respective vendors that have provided the equipment to Lupin and must be returned either within a reasonable period of time upon request by Lupin, not to exceed five (5) calendar days, or immediately upon termination of this Agreement. Principal Investigator agrees to return the Equipment in the manner directed by Lupin in substantially the same condition as when received by Principal Investigator. Principal Investigator agrees to be financially responsible for obtaining insurance to cover any loss or destruction to Equipment while in Principal Investigator's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Trial. Principal Investigator further agrees that unless otherwise authorized in writing by Lupin of this Trial, Principal Investigator will not alter the Equipment in any way. Principal Investigator must not install any components or software, if applicable, without express approval of Lupin. Any software provided to Principal Investigator may not be duplicated. Principal Investigator is not permitted to use the Equipment for any other purpose than for the performance of this Trial in accordance with the Protocol. Lupin shall not have any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the negligence or willful misconduct of Lupin, as applicable, and except to the extent that a personal injury constitutes a compensable Trial Subject injury to be paid by Lupin as described in this Agreement.

3. Return to Lupin. After completion of Trial conduct or at an earlier time specified by Lupin, Principal Investigator will arrange for return of Equipment and Lupin materials, at Lupin's expense, to Lupin or a location designated by Lupin.

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Add. Director of Research
KIMSDU, Karad

Attachment D

RESEARCH GRANT WORKSHEET

Principal Investigator LRP/RBZ/2015/002	
Event	***Cost[1] in INR***
Screening	12000
Day 1 (Drug administration)	15000
Day 31 (Drug administration)	15000
Day 61 (Drug administration)	15000
Day 90 (End of Study)	11500
Institutional Administrative Charges (25%)	17,125
Investigator Grant Per Patient (A)	**85,625**

Additional Study Related Costs	***Cost***
Patient travel reimbursement per visit	4500
12 Lead ECG (Only at Protocol Scheduled Time Points) Per ECG (350*4)	1400
Hospital/ Bed Charges (Day Care) (2000*3)	6000
Fluorescein angiography (FA) (5800*1)	5800
Optical coherence tomography (OCT)(2500*5)	12500
Local Laboratory Charges (If used during the study)	On actuals
(Additional pass through cost) B	**30,200**
Per Patient Budget(A+B)	**1,15,825**
Archival Charges for 15 years from the date of site close out visit	**60,000**

Notes:

- Total Costs are inclusive of indirect cost.
- Screen failure will be paid for screening visit in the ratio of 1:1 (i.e. one screen failure will be paid for one randomized patient at INR 10,000)
- Invoiced Charges to be paid upon receipt of invoice from Principal Investigator
- Institutional Overheads would be calculated per total investigator grant payment and would be paid as a part of each quarterly payment.
- Local laboratory charges would be paid on actuals on providing supporting bills.
- Assessments performed for any unscheduled visits will be paid as per the unit cost mentioned in table B.
- Archival charges is one-time payment and will be paid post site close out visit.

Add. Director of Research
KIMSDU, Karad

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Receipts of Clinical Trials

Add. Director of Research
KIMSDU, Karad

TNBC hospital bills
Dr. Anand Gudu

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No -(02164) 242170

KIMSU /KH / ACC/ 525 /2019

Date :-08-April-2019

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub : Bills of Clinical Trial Patients.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.

The Details are as under :-

Sr No	Name of Workers	Bill Date	Echo	ECG	Lab Test	C.T SCAN	X-Ray	Total	Remark
1	JADHAV USHA PARSHURAM	12.03.19	1200	200		5200	150	6750	OPD Bill
		25.03.19			960			960	
		01.04.19		200	960			1160	
2	DESAI NAINA	14.03.19			120			120	OPD Bill
		15.03.19				5200		5200	
		Total	1200	400	2040	10400	150		
							Total	14190	

Please Arrenge to Make the payment at the earliest

Thanking You,

Your Sincerely,

Accountant,
K.I.M.S.D.U Karad.

avs

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED TO BE UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No -(02164) 242170

KIMSU /KH / ACC/2219 /2019

Date :-17-05-2019

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub : Bills of Clinical Trial Patients.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.
The Details are as under :-

Sr No.	Name of Workers	Bill Date	Echo	ECG	Lab Test	C T SCAN	X-Ray	Ambulance	Total	Remark
1	Ladi Lharti	06.04.19	1200	200	120	0	150		1670	OPD Bill
		08.04.19				5200			5200	
		17.04.19			580				580	
		25.04.19		200	580				780	
		06.05.19			580				580	
		17.05.19		200	580				780	
		22.05.19			920				920	
		30.05.19			660				660	
2	Jagtap Jaymala	09.04.19	1200	200	120	5200	150		6870	OPD Bill
		06.05.19		200	580				780	
		07.05.19						2800	2800	OPD Bill
		Total	2400	1000	4720	10400	300	2800		
							Grand Total		21620	

Please Arrenge to Make the payment at the earliest

Thanking You,

Your Sincerely,
Accountant,
K.I.M.S.D.U Karad.

ava

Add. Director of Research
KIMSDU, Karad

kotak

Nagras Tower, Nagras Road, Aundh.
Pune - 411007
Maharashtra India
IFSC : KKBK0000726

Valid for three months from date of issue

दिनांक Date 0 7 0 1 2 0 2 0
D D M M Y Y Y Y

Pay Krishna Institute of medical Sciences Deemed to be University or Bearer

रुपये Rupees Thirty Six thousand Nine Hundred and fourty Six only. अदा करें ₹ 369461-

For Unique Clinical Research Services

खाता सं A/c No 3912801512

KOTAK EDGE CURRENT ACCOUNT
CBS

Authorized signatory

Please sign above

15-05-2019
Payable At-par at all branch locations of Kotak Mahindra Bank Ltd.

⑈000133⑈ 411485005⑆ 001406⑈ 29

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES UNIVERSITY

KRISHNA HOSPITAL KARAD.

P.B.ROAD MALKAPUR
KARAD. Pin- 415539
Phone No. 02164-241555/56/57/58

CASH RECEIPT

Name : Unique Clinical Research Service

Receipt No : 1573
Date : 23/01/2020
Time : 02:49PM

SrNo	HeadName	Rate	Quantity	Amount
1	OPD A/C	35,094.00	1	35,094.00

Total Amount : 35,094.00
Net Amount : 35,094.00
Received Amount : 35,094.00

Amount in words : Rs. Thirty Five Thousand Ninety Four Only

Remark : Being Cheque Received As OPD Patients As Per Letter no KIMSU/KH/ACC/528-849-/2019

Cash /Cheque/Card/ECS Details

Type	Bank Name	Branch Name	Chq/ECS./Card No	Date	Amount
Cheque	Kotak Mahindra Bank	Pune	000133	23/1/2020	35,094.00

Cashier

Krishna hospital Karad.

User : Rohit Kakaso Patil

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES UNIVERSITY

KRISHNA HOSPITAL KARAD.

P.B.ROAD MALKAPUR
KARAD. Pin- 415539
Phone No. 02164-241555/56/57/58

CASH RECEIPT

Name : Unique Clinical Research Service

Receipt No : 1574
Date : 23/01/2020
Time : 02:56PM

SrNo	HeadName	Rate	Quantity		Amount
1	IPD A/C	1,852.00	1		1,852.00
		Total Amount		:	1,852.00
		Net Amount		:	1,852.00
		Received Amount		:	1,852.00

Amount in words : Rs. One Thousand Eight Hundred Fifty Two Only
Remark : Being Cheque Received As IPD Patients As Per Letter no KIMSU/KH/ACC/527/2019

Cash /Cheque/Card/ECS Details

Type	Bank Name	Branch Name	Chq/ECS./Card No	Date	Amount
Cheque	Kotak Mahindra Bank	Pune	000133	23/1/2020	1,852.00

Cashier

User : Rohit Kakaso Patil

Krishna hospital Karad.

Add. Director of Research
KIMSDU, Karad

AMD

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No. (02164) 242170

KIMSU /KH / ACC/ 592 /2020 Date :-24.06.2020

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub :- Bills of Clinical Trial Patient.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.
The Details are as under :-

Sr No.	Name of Workers	Bills no.	Date	Bill Amts	Remark
1	NAIKWADI SADASHIV ABA	36547	13.03.20	5160.00	IPD Bill
2	GHADAGE DHONDIRAM BALU	36540	13.03.20	5270.00	IPD Bill
3	PATIL VISHWANATH BANDU	37225	20.03.20	5074.00	IPD Bill
4	SHELAR LAXMAN RAMCHANDRA	36544	13.03.20	5200.00	IPD Bill
5	PATIL MASHNU DADAPPA	33833	14.02.20	7399.00	IPD Bill
			Total	**28103.00**	

Please Arrenge to Make the payment at the earliest

Thanking You,

Add. Director of Research
KIMSDU, Karad

Your Sincerely,

Accountant,
K.I.M.S.D.U Kar

MVS

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No -(02164) 242170

KIMSU /KH / ACC/293 /2020

Date :-07.02.2020

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub :- Bills of Clinical Trial Patient.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.

The Details are as under :-

Sr No	Name of Workers	Bills no.	Date	Bill Amts	Remark
1	GAWADE ADHIKRAO DAJI	16608	07.09.19	5312.00	IPD Bill
2	HOWAL RAMESH MAHADEV	16609	07.09.19	5312.00	IPD Bill
3	HOWAL RAMESH MAHADEV	19901	04.10.19	6640.00	IPD Bill
4	GAWADE ADHIKRAO DAJI	19902	04.10.19	7002.00	IPD Bill
5	HOWAL RAMESH MAHADEV	23483	09.11.19	4397.00	IPD Bill
6	GAWADE ADHIKRAO DAJI	23484	09.11.19	4520.00	IPD Bill
7	MUJAWAR BANUBI RAJJAK	25316	22.11.19	6107.00	IPD Bill
8	PATIL MASHNU DADAPPA	27678	13.12.19	5484.00	IPD Bill
9	MUJAWAR BANUBI RAJJAK	28463	20.12.19	5809.00	IPD Bill
10	SHELAR LAXMAN RAMCHANDRA	28963	27.12.19	5850.00	IPD Bi
11	PATIL MANSHU DADAPA	30419	10.01.20	6809.00	IPD B
12	BORGE JALINDAR KHASHABA	31821	24.01.20	5506.00	IPD E
13	MALI SONABAI LAXMAN	31818	24.01.20	5506.00	IPD

Add. Director of Research
KIMSDU, Karad

14	MUJAWAR BANUBI RAJJAK	31814	24.01.20	5630.00	IPD Bill
15	SHELAR LAXMAN RAMCHANDRA	31815	24.01.20	5647.00	IPD Bill
			Total	**85531.00**	

Please Arrenge to Make the payment at the earliest

Thanking You,

Your Sincerely,

Accountant,
K.I.M.S.D.U Karad

NVS

Add. Director of Research
KIMSDU, Karad

KRISHNA HOSPITAL KARAD.

P.B.ROAD MALKAPUR

KARAD. Pin- 415539

Phone No. 02164-241555/56/57/58

CASH RECEIPT

Receipt No : 363

Date : 08/09/2020

Time : 01:17PM

Sr. No	HeadName	Rate	Quantity	Amount
1	IPD A/C	111,930.00	1	111,930.00

Total Amount : 111,930.00

Net Amount : 111,930.00

Received Amount : 111,930.00

Amount in words : Rs. One Lac Eleven Thousand Nine Hundred Thirty Only

Remark : Being NEFT Received As IPD Patients As Per Letter no KIMSU/KH/ACC/592 & 243/2020

Cash /Cheque/Card/ECS Details				
Type	Bank Name	Branch Name	Chq/ECS./Card No	Date	Amount
			KKBK0021268200	08/9/2020	111,930.00

Cashier

Krishna Hospital Karad.

Add. Director of Research
KIMSDU, Karad

MBC study
Hospital bills
Dr. Anand Gudur

UNIQUE
Clinical Research Services

Date- 07-Jun-2019

To,
The Account Officer
Institutional Ethics Committee of Krishna Institute of Medical Sciences
Krishna Institute of Medical Sciences Deemed University Karad
Pune-Bangalore Highway 4 Malkapur,
Karad Dist.Satara 415110

RE: multicentre, open label, Randomized, Two treatment, Two period, Two-sequence, Single dose, Cross-Over, Study to Test for Bioequivalence between Celeritys Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20mg/10mL(2mg/mL) and the Reference product, Caelyx®[Doxorubicin Hydrochloride(pegylated liposomal)Injection 20mg/10mL(2mg/mL)] in Patients with Metastatic Breast Cancer.

Subject: Payment made for hospital IPD bills and laboratory investigation bills for above referenced protocol

Dear Sir,

Please find enclosed cheque towards Payment for hospital bills of MBC patients
Cheque details are mentioned below:

Sr. No.	Payment	Cheque Number	Amount Rs.	Tax Deducted Rs.	Net Amount Rs.	Date
01	Hospital and lab payment	000162	37505	750	36755	03-Jun-2019

Please provide the acknowledge copy of this letter.
Please feel free to contact us should you require any clarification from us.

Thanks & Regards,

Mr. Damodhar Bagde
Site Executive
(UCRS)

Unique Clinical Research Services

Acknowledgement of Receipt		
Arvind D. Salunkhe		7/6/19
Name	**Signature**	**Date**

ACCOUNTANT
KRISHNA INSTITUTE OF MEDICAL SCIENCES
UNIVERSITY
KARAD

Add. Director of Research
KIMSDU, Karad

kotak

Nagras Tower, Nagras Road, Aundh,
Pune - 411007
Maharashtra India
IFSC : KKBK0000726

Valid for three months from date of issue

दिनांक Date 0 3 0 6 2 0 1 9
D D M M Y Y Y Y

या धारक को Or Bearer

Krishna Institute of Medical Sciences

रुपये Rupees Thirty Six Thousand Seven Hundred and fifty five

अदा करें ₹ 36,755/-

For Unique Clinical Research Services

खाता सं. A/c No. 3912801512

KOTAK EDGE CURRENT ACCOUNT
CBS

Authorized signatory

Please sign above

15-05-2019
Payable At-par at all branch locations of Kotak Mahindra Bank Ltd.

⑈000662⑈ 411485005⑆ 001406⑈ 29

D Agarwal

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES UNIVERSITY

KRISHNA HOSPITAL KARAD.

P.B.ROAD MALKAPUR
KARAD. Pin 415539
Phone No. 02164 241555/56/57/58

CASH RECEIPT

Name : UNIQUE CLINICAL RESEARCH SERVICE

Receipt No : 164
Date : 08/09/2020
Time : 01:23PM

Sr.No.	HeadName	Rate	Quantity	Amount
1	OPD A/C	14,164.00	1	14,164.00

Total Amount : 14,164.00
Net Amount : 14,164.00
Received Amount : 14,164.00

Amount in words : Rs. Fourteen Thousand One Hundred Sixty Four Only.
Remark : Being NEFT Received As OPD Patients As Per Letter no KIMSU/KH/ACC/244 & 563/2020

Cash /Cheque/Card/ECS Details				
Type	Bank Name	Branch Name	Chq/ECS./Card No	Date	Amount
NEFT	SBI	0	KKBK1202326001	19/8/2020	14,164.00

Cashier

Krishna Hospital Karad.

User : Rohit R Kulkarni

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED TO BE UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No -(02164) 242170

KIMSU /KH / ACC/ 593 /2020 Date :-24.05.2020

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub : Bills of Clinical Trial Patients.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.

The Details are as under :-

Sr No.	Name of Workers	Bill Date	Lab Test	E C G	Echo	X-Ray	Total	Remark
1	NAIKWADI SADASHIV ABA	02.03.20	550	200			750	OPD Bill
	GHADAGE DHONDIRAM BALU	09.03.20			1200	150	1350	OPD Bill
		06.03.20	550	200			750	OPD Bill
2	PATIL VISHWANATH BANDU	12.03.20	550	200			750	OPD Bill
		15.06.20		200			200	OPD Bill
		Total	1650	800	1200	150		
					Grand Total		3800	

Please Arrenge to Make the payment at the earliest

Thanking You,

Your Sincerely,

NVS

Accountant,
K.I.M.S.D.U Karad.

Add. Director of Research
KIMSDU, Karad

KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED TO BE UNIVERSITY
KRISHNA HOSPITAL, KARAD.

Phone No.(02164)241555,241556,241557,241558
Fax No (02164) 242170

KIMSU /KH / ACC/ 24/4 /2020 **Date :-07.02.2020**

To,
Unique Clinical Research Service,
Block No.D/2 Prakash Housing Society,
Kalewadi Phata,
Thergaon, Pune - 411 033

Sub : Bills of Clinical Trial Patients.

Sir,

Please Find enclosed herewith Medical Treatment bills of your Patients.

The Details are as under :-

Sr No.	Name of Workers	Bill Date	Lab Test	E C G	Echo	U S G	Total	Remark
1	LADI BHARATI	17.07.19	660	0	1200	0	1860	OPD Bill
		25.07.19	700	200	0	0	900	OPD Bill
		14.08.19	0	0	0	300	300	OPD Bill
2	HOWAL RAMESH MAHADEV	28.08.19	0	200	0	0	200	OPD Bill
		04.10.19		200	0	0	200	OPD Bill
		06.12.19		200	0	0	200	OPD Bill
3	GAWADE ADHIKRAO	30.08.19	0	200	0	0	200	OPD Bill
		04.10.19	0	200	0	0	200	OPD Bill
		06.12.19	0	200	0	0	200	OPD Bill
4	BHINGARDIVE KASHINATH	22.10.19	550	200	0	0	750	OPD Bill
5	MUJAWAR BANUBI	23.01.20	0	200	0	0	200	OPD Bill
		12.11.19	300	200	0	0	500	OPD Bill
6	SHELAR LAXMAN	24.01.20	0	200	0	0	200	OPD Bill
		17.12.19	550	200	0	0	750	OPD Bill
7	BARGE JALINDAR KHASHABA	18.01.20	550	200	0	0	750	OPD Bill
8	MALI SONABAI LAXMAN	17.01.20	60	0	0	0	60	OPD Bill
		11.01.20	550	200	0	0	750	OPD Bill
9	PATIL MANISHA T	06.12.19	1360	0	0	0	1360	OPD Bill
10	MULIK KERU S	12.11.19	300	200	0	0	500	OPD Bill
11	PATIL MANISHA TANNAPA	03.12.19	300	200	0	0	500	OPD Bill

Add. Director of Research

		Total	5880	3200	1200	300		
					Grand Total		10580	

Please Arrengr to Make the payment at the earliest

Thanking You,

Your Sincerely,

Accountant,
K.I.M.S.D.U Karad.

Add. Director of Research
KIMSDU, Karad

ICICI Bank

Covid-19 study (CROM)
Dr. Sujata Patil
RTPCR bills (hospital bill)

Receipt

Date : 28-Jul-2020, 01:30pm

Reference ID : 372185123
From Account : 639005500711
From Account Name : CROM CLINICAL RESEARCH AND MEDICAL TOURISM PRIVATE LIMITED
To Account : 11406275566
To Account Name : KIMSKARADSITE
Amount : 752000
Date : 28-Jul-2020, 01:30pm
Remarks : RTPCR PAYMENT

500000/- Advance

Add. Director of Research
KIMSDU, Karad

To,

Date: 22/Dec/2020

Director of Research,

Krishna Institute of medical sciences Deemed To Be University,

Pune-Banglore highway-4, Malkapur road karad- 415110

Subject: Payment (PI grant) made for below mentioned studies

Respected Sir,

Please find the enclosed payment receipt (PI grant) for below mentioned studies

Sr.no	Study Name	Protocol no.	PI grant	total amount	
1	TNBC	0063-17	31500/2	15750	PI (2)
2	Onco tissue collection	MBT/TB-70	112200/2	56100	PI (3)
3	HE study	EPDI	75000/2	37500	PI (4)
4	AMD study (EC fees)	LRP/RBZ/2015-002		40000	EC
				149350/-	

Total payable amount to KIMSDU: 149350/-

TDS 7.5% : 11201/-

Net payable amount: 138149 /-

Please provide the acknowledge copy of this letter

Please feel free to contact us for any clarification from us

Thanks and Regards

Madhuri Patil (CRC)

UCRS, Pune

Acknowledgement of Receipt		
Name & Designation	Signature	Date

Add. Director of Research
KIMSDU, Karad

UNIQUE
Clinical Research Services

Date: - 29-12-2020

To,

Dr. A. R. Risbud
Director, Research
Krishna Institute of Medical sciences,
'Deemed to be University',
Malkapur, Karad- 415539

Dear Dr Risbud,

This is to provide you update as of December 29,2020, about the clinical trials that we conducted together after the date (June 20, 2018) of signing of MOU between two of us (KIMSDU &UCRS).

As you are aware, we have conducted five clinical trials during the period.

A summary data of these trials is enclosed herewith for your perusal. The data also includes the total funds received from each sponsor and its sharing between the two parties as agreed in the MOU.

Thanks & regards.

Sincerely,

Amit Agrawal.
Account Head
UCRS, Pune

Unique Clinical Research Services
PUNE

Add. Director of Research
KIMSDU, Karad

Details of the Clinical trials undertaken at KIMSDU along with the UCRS.

Sr. No	Name of Study	Sponsor	Principal Investigator	Number of patients	Receivable amount From Sponsor	Amount Received by UCRS	Amount Received by KIMSDU	Duration	Period	Remarks
1)	**Metastatic Breast Cancer: Protocol No:0927-17** multicentre, open label, Randomized, Two treatment, Two period, Two-sequence, Single dose, Cross-Over, Study to Test for Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20mg/10mL(2mg/mL) and the Reference product, Caelyx®[Doxorubicin Hydrochloride(pegylated liposomal)Injection 20mg/10mL(2mg/mL)] in Patients with	Celerity Pharma. LLC	Dr. Anand Gudur	06 Randomized: 03 Screen fail: 03	PI grant: 231000 Hospital charges:36755 Institutional overheads: 57750 **Total: 325505**	PI grant: 115500 Hospital charges: 0 Institutional overheads: 57750 **Total: 173250**	PI grant: 115500 Hospital charges: 36755 Institutional overheads: 0 **Total: 152255**	1 year 5 months	2018-2020	complete d

Add. Director of Research,
KIMSDU, Karad

Unique Clinical Research Services

Unique Clinical Research Services PUNE

Dr. D. Y. Patil Hospital, Dr. D. Y. Patil Road, Ravet, Pune 412 101.

	Metastatic Breast Cancer.									
2)	Triple Negative Breast Cancer: Protocol: 0063-17_A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.	Intas Pharma.Inc	Dr. Anand Gudur	03 Randomized: 03 Screen fail: 00	PI grant: 31500 Hospital charges: 36946 Institutional : overheads: 7875 **Total: 76321**	PI grant: 15750 Hospital charges: Nil Institutional : overheads: 7875 **Total: 23625**	PI grant: 15750 Hospital charges: 36946 Institutional : overheads: Nil **Total: 52696**	07 months	ongoing	Stopped by EC
3)	**Surplus fresh onco tissue collection : Protocol Number: MBT-TB-057-** Prospective analysis of surplus fresh tumor tissue to understand the changes in tumor immune cells on exposure to immunomodulators	CRO-Innovate Research	Dr. Anand Gudur	111 Randomized: 102 Screen fail :09	PI grant: 112200 Hospital charges: Nil Institutional overheads: Nil	PI grant: 56100 Hospital charges: Nil Institutional overheads: Nil	PI grant: 56100 Hospital charges: Nil Institutional overheads: Nil	11 months	2019-2019	Completed-31-Dec-2019

Site Address : Clinical Research Department, Dist Maharashtra Hospital, Dr. D. Y. Patil Road, Kasba Peth, Pune 411 101.

Unique Clinical Research Services PUNE

Add. Director of Research
KIMSDU, Karad

UNIQUE Clinical Research Services

	using CANscript				**Total: 112200**	Total: **56100**	**Total: 56100**			
4	**A Cross-sectional Multicenter, Epidemiological Study to Evaluate the Clinicodemographic Profile and Management Practices for Primary Prophylaxis of Overt Hepatic Encephalopathy in Patients with Cirrhosis in India**	**Abott**	**Dr. Sandeep Patil**	28	PI grant: 75000/- Hospital charges: Nil Institutional overheads: Nil **Total: 75000**	PI grant: 37500/- Hospital charges: Nil Institutional overheads: Nil **Total: 37500/-**	PI grant: 37500/- Hospital charges: Nil Institutional overheads: Nil **Total: 37500/-**	02 months	2019-2019	**Completed 2020**
5	A Prospective, Randomized, Parallel Group, Double Blind, Multicenter Study to Compare the Efficacy, Safety & Immunogenicity of Ranibizumab of Lupin Ltd with Lucentis® in Patients of Neovascular Age Related Macular Degeneration	Lupin	Dr. Gaurav Paranjpe	11 Randomized: 10 Screen fail :01	PI grant: 404000/- Hospital charges: 126084 Institutional overheads: 101000 **Total: 631084**	PI grant: 202000 Hospital charges: Nil Institutional overheads: 101000 **Total: 303000**	PI grant: 202000(pending) Hospital charges: 126084 Institutional overheads: Nil **Total:328084**	ongoing	2019-2021	**Ongoing**

Unique Clinical Research Services PUNE

Add. Director of Research
KIMSDU, Karad

UNIQUE Clinical Research Services

Note:

KIMSDU engaged a Pune based Unique Clinical research (UCRS) a Site monitoring Organisation (SMO) for implementing clinical trials at the campus. An MOU was signed between UCRS and KIMSDU for conduct of clinical trials. As per the fund sharing terms in the MOU, Principle Investigator's grant was to be equally divided between the two parties, the hospital expenditure (hospital stay, investigations, treatment) was to be totally reimbursed to the Krishna hospital and the institutional overheads to be received by the UCRS. It was also agreed that UCRS will be a payee and will receive all receivables from the sponsor of the trial and will pay to KIMSDU its share.

Unique Clinical Research Services PUNE

Add. Director of Research
KIMSDU, Karad

UNIQUE
Clinical Research Services

To,

Date: 22/Dec/2020

Director of Research,

Krishna Institute of medical sciences Deemed To Be University,

Pune-Banglore highway-4, Malkapur road karad- 415110

Subject: Payment (PI grant) made for below mentioned studies.

Respected Sir,

Please find the enclosed payment receipt (PI grant) for below mentioned studies

Sr.no	Study Name	Protocol no.	PI grant	total amount
1	TNBC	0063-17	31500/2	15750
2	Onco tissue collection	MBT/TB-70	112200/2	56100
3	HE study	EPDI	75000/2	37500
4	AMD study (EC fees)	LRP/RBZ/2015-002		40000
				149350/-

Total payable amount to KIMSDU: 149350/-

TDS 7.5% : 11201/-

Net payable amount: 138149 /-

Please provide the acknowledge copy of this letter

Please feel free to contact us for any clarification from us

Thanks and Regards

MPatil

Madhuri Patil (CRC)

UCRS, Pune

Acknowledgement of Receipt		
Name & Designation	Signature	Date

Add. Director of Research
KIMSDU Karad

12:40 LTE

Payment Successful

Payment Successful

Send Fund Transfer Receipt to the Beneficiary

Transfer Details

Reference No. (UTR No.)/IMPS
KKBKH20357770962

Date & Time
22 Dec 2020 - 12:40 PM

Transfer Amount
₹138149.00

Beneficiary Name
Krishna Institute Of Medical Sciences Deemed Unive

Bank Name
STATE BANK OF INDIA

Account Number
11406275566

IFSC
SBIN0004648

Remarks
Krishna institute PI grant payment

Add. Director of Research
KIMSDU, Karad

Add Beneficiary to favourites

Back to Home | Send Money Again

rBCG (COVID-19) study

Title: A Multicentre, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Duration of Acute Respiratory Symptoms Among Exposed (High-Risk) Subjects During the COVID-19 Pandemic by Enhanced Trained Immune Response Through VPM1002

Ptotocol: SII-RBCGCOVID-19/IN-01

PI name :

Dr. Sujata Patil (Associate professor, community medicine)

Funds: 33 lakhs

Date of Initiation: 05-May-2020

Date of completion: Ongoing

Add. Director of Research
KIMSDU, Karad

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँचसौ रुपये सत्यमेव जयते Rs. 500

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2020 ◑ AY 043239

21 AUG 2020

500/-

11634 वि. मु.ड्यु.रक्कम

वस्ताचा प्रकार Agreement

दस्त नोंदणी करणार आहेत का ? होय/नाही.

मिळकतीचा प्रकार

मुद्रांक विकत घेणाऱ्याचे नांव For Serum Institute of India Pvt. Ltd.

पक्ष

सुरात्या पक्षकाराचे नांव

हस्ते व्यक्तीचे नांव व पत्ता

विक्रेता देवराज स्टाम्प वेंडर

परवाना क्र.

मुद्रांक विकत घेणाऱ्याची सही

ज्या कारणासाठी खरेदी करावयाचा, त्याची स्वाक्षरी

खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

This stamp paper forms an integral part vide section 24.4 of the Clinical Trial Agreement by and amongst Serum Institute of India Private Limited, Diagnosearch Life Sciences Private Limited, Dr. Sujata Patil and Krishna Institute of Medical Sciences and CROM Clinical Research and Medical Tourism Pvt. Ltd. dated 14th May, 2020.

Serum Institute of India Pvt. Ltd. Pune

CI DL CRO Pharma PI Institution CMO

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KIMSDU, Karad

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of _____ day of _____2020 (hereinafter "Effective Date") by and between:

Serum Institute of India Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter "Sponsor");

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter "CRO"), acting on behalf of **Serum Institute of India Pvt. Ltd. / the Sponsor;**

Dr. Sujata Patil, Krishna Institute of Medical Sciences Deemed to be University, Pune,-Bangalore, NH4 Highway, Karad, Dist. Satara.Maharashtra - 415539; hereinafter referred to as Investigator;

AND

Krishna Institute of Medical Sciences an Deemed University operating, owned and run under Krishna Institute of Medical Sciences, having office at Near Dhabewadi Road, Pune,-Bangalore, NH4 Highway, Karad-, Dist. Satara Maharashtra – 415110 hereinafter; referred to as Institution;

AND

CROM Clinical Research & Medical Tourism Pvt. Ltd., a Company incorporated under Companies Act, 1956 having its registered office at Caculo Enclave, c/o Vintage Hospital, St. Inez Panaji North Goa GA 403001; hereinafter referred to as SMO.

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled:

A Multicenter, Phase III, Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subject under Protocol no. – SII-rBCG/COVID-19/IN-01, Version 3.0 Dated: 11 April 2020 ("the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **SII-rBCG/COVID-**

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19/IN-01, Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution, Investigator have each reviewed sufficient information regarding Sponsor's vaccine viz. SII-rBCG VPM1002 (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

WHERE AS, SMO is in the business of providing site management services and Institution and Investigator has approached Sponsor/CRO that it intends to appoint SMO to provide them certain site management services for this Protocol/Study which shall be including ensuring overall day-to-day support for the site management and administration activities by providing the team of Clinical Research personnel including coordinators to the Institution, and performing all the protocol related and operational activities in compliance with Regulatory Requirements as may be delegated.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator , Institution & SMO agree as follows.

The Sponsor, CRO, Investigator, Institution & SMO are sometimes hereinafter individually referred to as a Party and collectively as Parties.

Article 1 – The Study

1.1 The Institution, Investigator and SMO undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) (f) Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (g) such other guidelines as may be issued by Indian Council of Medical Research and Ministry of Health and Family Welfare and (h) data privacy laws as may be applicable and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time (hereinafter "Regulatory Requirements"). It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the

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development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution, Investigator and hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.3 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein to any third party. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease and decision on the continuation of subjects already recruited in the Study will be taken jointly by CRO & Sponsor on a case to case basis. However, it is agreed between the Parties that, the outgoing Investigator shall be liable and responsible for all his acts, deeds, actions, omissions, and liabilities arising there from, during the period he / she acts as a Principle Investigator.

1.4 The Institution, Investigator and SMO undertake to conduct the Study in an efficient and professional manner under the provisions of this Agreement and will use their best efforts to complete the Study within the time period agreed between the Parties.

1.5 Parties agree to coordinate the day-to-day management of the Study with each other and to comply with and perform their respective responsibilities and activities as set forth in this agreement.

1.6 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the Study.

1.7 Before commencing the Study, within seven (7) business days the Investigator will seek approval to conduct the Study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. Sponsor may terminate this Agreement under Article 9 (**Term and Termination; Effect of Termination**) upon the failure of the Investigator to seek the aforementioned approval from IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the party being referred to. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock

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of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

1.8 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.9 The Investigator, Institution & SMO hereby warrants that they:

(a) shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions in writing or over an email and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

(b) shall not charge any Study subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

(c) received a copy of the Investigator Brochure and has read and understood its contents.

(d) shall prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(e) shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure and safe delivery of the shipment);

(f) shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of 'Adverse Events' and 'Serious Adverse Events' and the reporting procedure are included in the Protocol, which shall be followed for such reporting.

(g) agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

1.10 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such

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notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.11 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

1.12 Institution, Investigator and SMO shall keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor) in accordance with Regulatory Requirements.

1.13 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.14 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution and Investigator may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.15 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.16 Institution/Investigator/SMO agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the subjects in accordance with the requirement set out in the Protocol.

1.17 Upon reasonable notice and at reasonable times, Institution/ Investigator/SMO shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and

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whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements. CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

1.18 Institution and Investigator Agree that they shall be jointly and severally responsible for securing all performance and any or all the breaches, acts, actions, non actions, inactions taken by and/or non performance by SMO during the course of this Agreement for the tasks delegated by Institution/Investigator to SMO time to time. Institution/Investigator agree that they shall notify Sponsor/CRO immediately upon discontinuation of the services of SMO under this Agreement if any. Institution/Investigator agree further that such discontinuation of the service by SMO if any under this Agreement, shall not have any impact on the Study to be conducted by Institution and Investigator.

Article 2 – Compensation

2.1 All payments will be made by CRO/Sponsor as per payment schedule provided in schedule B hereto and assumptions provided thereunder.

2.2 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator / Institution directly or through the SMO. Invoices shall be addressed to CRO and be sent at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.
702, Dosti Pinnacle, Wagle Estate
Thane – 400 604, India

2.3 All amounts payable to the Investigator / Institution/SMO will be subject to Tax Deduction at source as required by the relevant tax provisions

2.4 It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - **"Supply to SEZ Unit or SEZ Developer for Authorised Operations under Bond or Legal Undertaking without payment of Integrated Tax (LUT)"** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit and ARN no for LUT.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - **"Supply to SEZ Unit or SEZ Developer for Authorised Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and**

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Sponsor will not reimburse GST paid." Further these invoices should also mention GSTIN No 27AABCS4225M2Z6 of our SEZ unit.

(iii) However, the Sponsor shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.5 The payment shall be made only by electronic transfer to the beneficiary account details given below in Schedule B of the Agreement

2.6 Payments of invoice amount by CRO to SMO as prescribed under clause 2.5 against the invoice raised by Institution/Investigator shall be valid discharge of the payments obligations by Sponsor/CRO under this Agreement. Neither Institution nor Investigator, shall raise any dispute to Sponsor/CRO about the non or inappropriate receipt of the amount from SMO as contemplated under this Agreement. Also the non receipt of the amount from SMO shall not a ground for Institution and/or Investigator to discontinue the performance or termination of this Agreement.

2.7 Institution / Investigator agree that it shall be their exclusive responsibility to settle service charges to SMO for the services performed during the course of this Agreement for the tasks delegated by the Institution / Investigator to SMO, without recourse to the Sponsor/CRO.

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator, sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator/SMO shall deal with all issues relating to the employment or engagement of the Institution/Investigator/SMO staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

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3.3 The Investigator and the Institution will take appropriate steps to inform each physician, Study staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement. "**Study Staff**" mean the individuals providing services under the supervision of the Investigator with respect to the conduct of the clinical study, including without limitation sub-investigators, study coordinators, and other trial Site employees, agents, any support staff etc.

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB/IEC.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data including Study Data generated under this Agreement shall be the property and Confidential Information of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution and the Investigator shall provide such expense statements/reports to Sponsor as CRO/Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one year thereafter, Investigator and each sub-investigator shall update such forms promptly and provide the same to the Sponsor/CRO as may be requested by Sponsor and whenever any material changes occur in the information disclosed by the previous forms.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of fifteen (15) years from conclusion of the Study. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 The Investigator/SMO agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party,

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without the Sponsor's prior written consent.

4.8 All Study Data and reports and any other information that generated, provided to and created by Investigator or Institution or SMO, in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times. The Parties hereby agree that, subject to the applicable laws and requirements and each Party's rights and obligations under this Agreement, Sponsor shall be the sole owner of all the information mentioned above and shall have the unrestricted right during and after the term of this Agreement, to use the same for any purpose; "Study Data" shall mean all records and reports, (other than Study Subject's medical records), generated, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g. CRFs, data summaries, interim reports and the final report) etc.

Article 5 – Inventions

5.1 The Institution, Investigator and SMO hereby acknowledge and agree that Sponsor shall own all right, title and interest in and to the Protocol, all intellectual property rights arising from the Study including but not limited to reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Institution, Investigator, SMO , Sub investigator and Study Staff in the performance of the Study or relating to the Study Vaccine or which incorporate Sponsor's confidential Information (collectively, the "Inventions"), and the Institution, Investigator and SMO hereby expressly and irrevocably assign, and will cause Sub-investigators and Study Staff to assign, to the Sponsor, all right, title and interests that they may have in any such Inventions without payment of additional consideration.

5.2 The Investigator shall promptly disclose to the CRO/Sponsor in writing any and all Inventions generated pursuant to this Agreement and undertake not to use such Inventions than for the purposes of this Agreement without the prior written consent of the Sponsor.

5.3 If CRO/Sponsor requests, Institution, Investigator and SMO shall execute, and will cause the Sub investigators and Study Staff to execute, any instruments or testify as Sponsor deems necessary for Sponsor and/or Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor 's interest in the Inventions . CRO/Sponsor will reasonably compensate Institution and/or Investigator (as applicable) for the time devoted to such activities and will reimburse Institution and or Investigator (as applicable) for reasonable and necessary expenses incurred. The Institution, Investigator and SMO hereby grant to Sponsor an exclusive, worldwide, irrevocable, non-restrictive and full royalty free license under such Inventions to exploit the same for any purpose whatsoever.

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5.4 The obligations of this Section shall survive termination of this Agreement.

Article 6 – Publication; Publicity

Except as otherwise expressly agreed between the Parties, Institution, Investigator and SMO agree that they will not issue nor allow their employees, sub-investigators or representatives to issue or disseminate any press release or statement, nor any communication of information regarding the Study, written or oral, to the communications media or any third party without the prior written consent of Sponsor. Additionally, all announcements or publicity concerning the Study, or this Agreement by Institution or Investigator or SMO may be approved by the Sponsor, at its sole discretion.

The Institution, Investigator and SMO agree not to publish any Study related material, including the Results, other than in accordance with this Section 6.

Article 7 - Confidential Information

7.1 In connection with the performance of Study services, CRO and/or Sponsor may provide, or have provided, certain Confidential Information (hereinafter defined) to Institution and Investigator solely for the purpose of enabling the Institution and Investigator to conduct the Study. Institution, Investigator and SMO agree not to use, or permit the use of Confidential Information except for the performance of this Agreement and not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution, Investigator and SMO shall safeguard Sponsor / CRO Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event less than reasonable care.

7.2 In this Agreement "Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans, processes, procedures) of Sponsor / CRO or their Affiliates that are: (1) provided to Institution, Investigator and SMO in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, SMO, Sub-investigators or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

7.3 The obligations of confidentiality and limited use under this Section shall not extend to:

i) any information that is or becomes publicly available, except through breach of this Agreement;

ii) any information that Institution/ Investigator/ SMO can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

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iii) any information that Institution/ Investigator/ SMO receives from a third party (other than Sponsor or its Affiliates) which is not legally prohibited from disclosing such information;

iv) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

7.4 Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

7.5 If Institution, Investigator SMO jointly or severally are required by law to disclose certain confidential information to statutory authorities then it shall do so based on legal advice from its legal advisors and only to the extent required. It shall also intimate the CRO and Sponsor immediately on receipt of such disclosure request / notice / order so that CRO / Sponsor can take necessary steps if they wish to in order to limit the dissemination of the Confidential information.

Article 8 – Independent Contractor

The relationship of Sponsor, CRO, Institution, Investigator and SMO under the Agreement is that of independent contractors. The Parties do not intend to create a partnership or joint venture employer-employee relationship between themselves. Institution and/or Investigator are not an agent of CRO / Sponsor and have no right or authority to bind CRO and/or Sponsor in any manner to any agreement or obligation whatsoever.

Each Party shall act solely as an independent contractor and shall have no right to act for or to sign the name of or bind the other Party in any way or to make quotations or to write letters under the name of the other Party or to represent that such other Party is in any way responsible for any acts or omissions of such Party. This Agreement does not in any way create a master and servant relationship between Parties. Under no circumstances, the Employees of the Institution, Investigator and SMO shall be considered as employees of Sponsor /CRO nor shall such relationship be considered to exist.

Article 9 – Term and Termination; Effect of Termination

9.1 This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study.

9.2 This Agreement may be terminated by the Sponsor or by the CRO acting solely on the instructions received from the Sponsor in this behalf, at any time, with or without cause, immediately upon notice to Investigator to this effect; a notice by CRO and/or Sponsor that the Study is terminated shall also constitute effective notice of termination of this Agreement.

9.3 Upon termination or expiry of this Agreement:

(a) Institution, Investigator and SMO will not enroll additional Study Subjects, and will cooperate with CRO and Sponsor in the orderly discontinuation of the Study;

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(b) the Parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study;

(c) Institution, Investigator and SMO shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study;

(d) Investigator, Institution and SMO shall be entitled to receive payment by CRO of any amounts accrued as of the date of termination for Study- related work actually performed and expenses actually and reasonably incurred; in the event CRO has pre-paid Investigator and/or Institution for Study services not yet performed as of the date of termination, Investigator shall promptly refund to CRO all such pre-payments; It is further agreed by the Parties that Payment made to SMO shall relieve the Sponsor and the CRO from all of their payment obligations towards the Institution and the Investigator as stated above in Clause 2.6.

(e) Investigator, Institution and SMO shall deliver to CRO/Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in their possession or under their control; and

(f) Investigator, Institution and SMO shall either return to CRO / Sponsor or destroy, in accordance with CRO / Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Vaccine in their possession or under their control.

(g) All Confidential Information of Sponsor (except for such records that the Institution and Investigator are required by law or regulation to retain) which in the Institution's and/or Investigator's and/or SMO's possession shall be promptly delivered to Sponsor, or at Sponsor's discretion destroyed with destruction certified in writing.

(h) Institution represents that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

(i) No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date. Articles 4, 5, 6, 7, 10, and 11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 10 – Indemnification

10.1 Sponsor shall defend, indemnify, save and hold harmless the Institution, its directors, officers, employees, agents, assigns and the Investigator (each, an "Institution Indemnitee") from any and all liabilities, claims, actions or suits by third parties for bodily injury or death, that arise out of Institution's administration of the Study Vaccine or procedures provided for by the

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Protocol ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

a) failure by Institution Indemnitees and/or SMO to conduct the Study in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by CRO/Sponsor concerning conduct and administration of the Study, (iii) all applicable government laws, rules and regulations and (iv) the manner required of a reasonable and prudent clinical investigator or physician; and

b) the negligence or willful malfeasance of any Institution Indemnitee and/or SMO, or any other person on the Institution's property or under its control, exclusive of CRO / Sponsor employees.

10.2 Sponsor's obligations under this Section with respect to an Institution Claim are conditioned on:

a) Prompt written notification to Sponsor of the Institution Claim so that Sponsor's ability to defend or settle the Institution Claim is not prejudiced; and

b) Institution Indemnitees' and SMO agree that CRO/Sponsor has full control over the defense or settlement of the Institution Claim and to fully cooperate with CRO/Sponsor in the defense or settlement of the Institution Claim; provided, that CRO/Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee and/or SMO to undertake a future course of action without that Indemnitee's written consent to such components.

10.3 Additionally, Sponsor also agrees to compensate as required by the current compensation guidelines under the new Drugs and Clinical Trials Rules, 2019), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3, Sponsor shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

(i) A failure to adhere to the terms of this Agreement, Sponsor's written instructions relating to the Study (including the Study Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Sponsor and CRO.

(ii) Institute shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless or willful malfeasance by Investigator, Institution, and SMO or the Study Staff.

10.4 The Investigator, Institution and SMO, jointly and severally will indemnify and hold the

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CRO, the Sponsor and their affiliated corporations, successors, directors, trustees, officers, employees and agents harmless from any and all liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from;

(a) negligence or intentional or gross fault on the part of the Institution, Investigator and SMO or any other Study staff, personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Vaccine in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Investigator's failure to obtain IRB review and approval;

(d) the Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any applicable laws by the Institution, Investigator and SMO, or any other Study personnel involved in the performance of the Study.

In the event a claim or action is or may be asserted, an Institution Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Institution Indemnitee exercises such right, all costs and expenses incurred by such Institution Indemnitee for such separate counsel shall be fully borne by the Institution Indemnitee; provided, that without CRO/Sponsor prior written consent, the Institution Indemnitee 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.

The obligations of this section shall survive termination of this Agreement.

Article 11 – Limitation of Liability

Except for as provided in 10.1 and 10.3, whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor/CRO's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by CRO to Investigator and/or Institution for Services under this Agreement.

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 SUBJECT 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.

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Article 12- Insurance

12.1 Sponsor Insurance: Sponsor shall at all times during the term of this Agreement obtain and maintain at its own cost and expense, clinical trial insurance policy, with respect to its activities hereunder as required by the laws of India or laws as per the country where the clinical trial shall be conducted. Such insurance shall be placed at commercially appropriate levels of insurance.

12.2 Institution Insurance: Institution shall maintain medical professional liability insurance with limits in accordance with the laws of India or laws of the country where the clinical trial shall be conducted, for each medical professional involved in the Study or require that each medical professional maintain such insurance.

12.3 Evidence of Insurance: Upon request, Sponsor and Institution respectively, will provide to each other a certificate of insurance evidencing such coverage.

Article 13 - Human Rights

Institution and SMO represents that, with respect to employment and conducting the Study under this Agreement, Institution and SMO will comply with all applicable human rights/employment laws /labour laws, including but not limited to compliance with rules and regulations governing child labor, forced labor, safe and healthy work place, minimum wages, employee non-discrimination etc.

Article 14 - Anti-Bribery and Anti-Corruption

The Institution, Investigator and SMO represent and warrant that they shall not, directly or indirectly, take any action which would cause them, or their employees and sub-investigators to be in violation of any anticorruption or anti-bribery law or regulations applicable to the Investigator ("Anticorruption Laws").

Article 15 – Equipment

15.1 With respect to any equipment ("Loaned Equipment") provided to Institution and/or SMO and/or Investigator by CRO or Sponsor exclusively to perform the Services pursuant to this Agreement Institution, Investigator and SMO agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by CRO/Sponsor, that the Loaned Equipment will not be transferred by Institution, Investigator and SMO to the possession of any third party without the written consent of CRO/Sponsor, and that, at the completion of the Study or at CRO's/Sponsor's request, Institution, Investigator and SMO will return the Loaned Equipment and all related training materials and documentation to CRO /Sponsor.

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15.2 Investigator/Investigator/ SMO and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution/Investigator/ SMO will be responsible for arranging and paying for any required electricity supply, backup power supply, internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. Institution, Investigator and SMO shall also be responsible for maintenance cost and annual calibration cost which is required to keep the loaned equipment in a working condition. If the Institution, Investigator and SMO fails to return the Loaned Equipment within the timeframe specified by CRO/Sponsor, the Institution, Investigator and SMO will be responsible for reimbursing CRO/Sponsor for any penalties, late fees, and/or replacement costs.

15.3 Institution, Investigator and SMO acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution , Investigator and SMO will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights,
(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or
(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

Article 16 – Force Majeure and Delays

In the event either Party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the Party provides notice of the existence of and reason for such nonperformance or delay in specific detail. In the event of a delay for a consecutive of 90 days, the non-affected Party will have right to terminate this Agreement by serving written notice to the other Party.

Article 17 – Applicable Law

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of India and dispute under this Agreement and shall be subjected to the exclusive jurisdiction of courts of the City of Pune without regard to its conflict of laws provisions.

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Article 18 - Recordkeeping and Regulatory Inspection:

18.1 Throughout the term of this Agreement, Institution/ Investigator shall maintain and Investigator shall require SMO, Study Staff to maintain the complete and accurate books and records (including scientific, clinical and financial records) pertaining to all work performed and expenses incurred hereunder in connection with the Study and preserve them as per the directions of Sponsor/CRO for a minimum of fifteen (15) years from the date of completion of the Study or termination of this Agreement, whichever is earlier, or such longer period as required by the Protocol and the a pplicable laws and requirements. Archival of these records will be with Institution. Sponsor and its representatives shall have access to these records during the period of 15 years stated above. If required, Institution and SMO shall provide the copies of these records to Sponsor.

18.1.1 Sponsor or its designee shall have the right upon prior written notice to have their representatives review and copy all books and records of Investigator, Institution and SMO the t rial Site and the Study Staff relating to the Study, including without limitation books and records relating to any funds expended hereunder in connection with the Study. In each case access to such books and records shall occur during regular business hours (or such other agreed time) following reasonable notice to Institution whose records are sought for review.

18.1.2 Sponsor or its designee upon reasonable advance notice, and during regular business hours (or such other agreed time), shall have the right to access the t rial s ite to carry out Sponsor's rights and obligations hereunder and to inspect such trial site's facilities used in the conduct of the Study. The Parties agree to maintain the confidentiality of any subject-identifiable medical records should such information be made accessible under this Article 18.1.2.

18.2 The Investigator/Institution/SMO shall notify the Sponsor/CRO immediately by telephone or facsimile in case they receive any communication from Food and drug Administration or any other governmental or regulatory body with regard to Inspection/Audit of the Institution's facility relating to the Study during the term of this Agreement and shall allow CRO/Sponsor to be present at the inspection or participate in any response to the action, and provide to Sponsor/CRO copies of all materials correspondence, statements forms and records which the site receives, obtains or generate pursuant to any such Inspection. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

Article 19 – Electronic Record and Electronic Signature

Investigator/ Institution/SMO acknowledges that Electronic Records (defined hereinafter), Electronic Signatures (defined hereinafter), and handwritten signatures executed to Electronic Records, utilized for capturing study related data and for performing services under this Agreement, will be trustworthy, reliable, and are equivalent to paper records and handwritten signatures executed on paper.

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As defined in 21 CFR Part 11 "Electronic record" shall mean any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. "Electronic signature" shall mean a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Investigator/ Institution/SMO shall remain accountable and responsible for actions initiated under its Electronic Signature.

Article 20 – Representations and warranties

The Parties each represent and warrant that the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which it is a party and no Party will enter into any, agreements, assignments or encumbrances binding on it or its respective Affiliates inconsistent with the provisions of this Agreement.

Article 21 - Assignment:

No Party may assign this Agreement or any interest hereunder without the prior written consent of other Party; provided, however, that Sponsor may assign this Agreement to any corporation with which it may merge or consolidate or to which it may sell all or substantially all of its assets, without obtaining the prior written consent of Institution. In the event of any assignment by any Party permitted under this Agreement, such assignment will be effective only if (i) the assignee has the requisite power, authority and capability to fulfill all obligations of the assignor Party under this Agreement and (ii) such assignee agrees in writing to other Party, in a form reasonably acceptable to the other Party, to fulfill all obligations and liabilities of the assignor Party under this Agreement. Each Party will promptly notify other Party of any such assignment. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

Article 22 – Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected. In the event that the terms and conditions of this Agreement are materially altered as a result of this Article 20, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities, adhering as closely as possible to the original intent of the Parties.

Article 23 – Waiver / Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by a Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by a Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

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Article 24 – Miscellaneous

24.1 Institution/SMO will obtain written consent from staff involved in the Study that allows Sponsor, Sponsor affiliates, and third party suppliers working for Sponsor or its affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the SPONSOR group of companies, and for compliance with applicable procedures, laws, and regulations. Investigator consents to the use, storage and processing of his/her personal data as set out above.

24.2 This Agreement, including the annexed Schedules and Appendices , sets forth the entire understanding between the Parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof and supersedes all other prior agreements, discussions whether oral or in writing. This Agreement may not be changed or supplemented, except by a writing executed by all Parties.

24.3 All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

If to the Institution, to:

Krishna Institute of Medical Sciences
Deemed to be University, Pune- Bangalore,
NH4 Highway, Karad, Dist. Satara,
Maharashtra – 415539
Name: Dr. Shivaji T. Mohite
Designation: Dean
Phone No.: 02164-241555-58
Email: contact@kimsuniversity.in

If to the Investigator, to:

Name: Dr Sujata Patil
Designation: Principal Investigator
Krishna Institute of Medical Sciences
Deemed to be University
NH4 Highway, Karad, Dist. Satara
Maharashtra – 415539
Phone No.: +91-9518723884
Email: kimsmedcollege@gmail.com

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If to the CRO, to:

Name: Mr. Mandar Vaidya, Director - Operations
DiagnoSearch Life Sciences Pvt. Ltd
702, Dosti Pinnacle, Plot No. E-7, Road No. 22,
Wagle Industrial Estate, Thane- 400604,
Maharashtra, India
Name: Mr. Mandar Vaidya
Phone No.: 022 6777 6314
Email: mandar.vaidya@diagnosearch.com

If to the Sponsor, to: Dr. Hitt Sharma
Additional Medical Director
Serum Institute of India Private Limited 212/2 Hadapsar, Pune 411 028, India
Phone: 91-20-26602451
Facsimile: 91-20-26993921
Email: drhjs@seruminstitute.com

With a copy to:
Name: Makarand Karkare, General Counsel
Serum Institute of India Private Limited,
Sarosh Bhavan, 16/B-1, Dr. Ambedkar Road
Pune 411001
Phone: 91-20-26100341
Email: mac@seruminstitute.com

If to the CMO, to:

Name: Dr. Dhananjay Lad
Designation: Director CROM Clinical Research & Medical Tourism Pvt. Ltd.
Address: CROM Premises Main Administrative building, Oppo.7 Sea View hotel , Inside Car parking , Arambol Beach, Goa, 403524;
Phone: 9158592177
Email: clinicalresearchgoa@gmail.com, cromgoa@gmail.com

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

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24.4 The Parties hereby agree that, considering the current scenario of Novel COVID-19 pandemic and non availability of stamp papers, the Agreement shall be executed on the plain paper and subsequently upon availability the stamp paper signed / initialed by all the Parties shall be appended to the Agreement which shall form an integral part of the Agreement

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives

FOR Principal Investigator:

By: Patil Date 14/05/2020

Name: Dr Sujata Patil
Title: Principal Investigator

FOR AND ON BEHALF OF:
Krishna Institute of Medical Sciences, Deemed to be University, KARAD.

By: Date 14/05/2020

Name: Dr M V Ghorpade
Title: Registrar

Krishna Institute of Medical Sciences "Deemed To Be University" Karad

FOR AND ON BEHALF OF:
DiagnoSearch Life Sciences Pvt. Ltd.

By: Sharma Date May 14, 2020

Name: Mr Gajendra Sharma
Title: Controller Finance and Accounts

FOR AND ON BEHALF OF:
Serum Institute of India Pvt. Ltd.

By: Date 14th May, 2020

Name: Dr Hitt Sharma
Title: Additional Medical Director

FOR AND ON BEHALF OF:
CROM Clinical Research & Medical Tourism Pvt. Ltd.

By: Date 14 may 2020

Name: Dr Dhananjay La
Title: Director

CROM Clinical Research & Medical Tourism Pvt. Ltd. Reg No. U73100GA 2012PTC 006951

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SCHEDULE A
PROTOCOL NUMBER: SII-rBCG/COVID-19/IN-01
CLINICAL TRIAL PROTOCOL SYNOPSIS

STUDY TITLE	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects
SPONSOR	Serum Institute of India Pvt. Ltd.
CLINICAL RESEARCH ORGANIZATION (CRO)	DiagnoSearch Life Sciences Pvt. Ltd.
PROTOCOL ID	SII-rBCG/COVID-19/IN-01
CLINICAL DEVELOPMENT PHASE	Phase III
INDICATION	Protection of high-risk population from SARS-CoV-2/COVID-19 through immune boost/activation by rBCG (VPM1002) vaccination
NUMBER OF SITES	Approximately 40 sites will be initiated to enroll the required population
STUDY POPULATION	A total of 5946 male and female adults ≥18 years of age who are at a high risk of SARS-CoV-2/COVID-19 infection
DURATION OF PARTICIPATION	The maximum duration of study participation for a subject will be 194 days

STUDY RATIONALE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is accelerating globally leading to an increase in morbidity and mortality. Although individuals of any age can acquire SARS-CoV-2/COVID-19, certain individuals are at a higher risk of infection with SARS-CoV-2/ COVID-19. The high-risk group includes the health care workers (HCW) (physicians and paramedical staff) working amid SARS-CoV-2/COVID-19 infected patients and all other people including household contacts of SARS-CoV-2/ COVID-19 confirmed patients or people currently residing or working in SARS-CoV-2/ COVID-19 hotspots/outbreak areas where there is a high risk of transmission of COVID-19 infection. Though SARS-CoV-2/ COVID-19 infection may cause mild symptoms in many, nearly 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (ICU). In severe cases, COVID-19 can be complicated by the acute respiratory distress syndrome, sepsis, septic shock and multiorgan failure with an estimated case fatality of 3.5% in China.

The COVID-19 pandemic is rapidly worsening in all parts of the world, overwhelming health systems. There is a

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serious threat to HCW capacity in a thickly populated country like India. Also, reports from all over the world demonstrate that the disease takes a severe course in the elderly people and people with co-morbid conditions leading to higher mortality rates. Thus, there is an urgent need to ensure the safety and health of existing HCWs and all other people living in SARS-CoV-2/COVID-19 infected areas where there is a high risk of disease transmission and find strategies to reduce the incidence, duration and intensity of SARS-CoV-2/COVID-19 infection among such population. Evidence from experimental studies suggest that Bacille Calmette Guérin (BCG) vaccine has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases other than tuberculosis. BCG vaccine can potentiate immune responses to other vaccines through induction of trained innate immunity and heterologous adaptive immunity. Based on this evidence it is hypothesized that BCG vaccination may induce protection against susceptibility to SARS-CoV-2/COVID-19 infection. VPM1002, a genetically modified BCG vaccine, is being developed with an aim to replace BCG by a vaccine that has a better safety profile and superior efficacy. Evidence from pre-clinical and clinical studies demonstrate that VPM1002 is safer and more immunogenic. It is therefore anticipated that VPM1002 will perform well and may improve the clinical course of SARS CoV-2/COVID-19 infection. Even though vaccine manufacturers across the globe have embarked on rapid development, SARS-CoV-2 vaccines are many months away from widespread availability to the masses. VPM1002 rBCG may act to ameliorate disease severity and mitigate transmission. Even moderate individual efficacy can have dramatic impact at population level directly by reducing severe disease burden on health systems and possibly indirectly by reducing the disease transmission and spread thereby sustaining health systems through this crisis, using a safe, affordable and available vaccine. The manufacture of VPM1002 using state-of-the-art production methods will help hasten the production of millions of doses in a very short time and thus would be beneficial in the current situation. Investment in large scale manufacturing will depend on strong evidence of efficacy from randomized evaluation. Thus, the current study will evaluate the efficacy of VPM1002 in reducing infection incidence and disease severity of SARS-CoV-2/COVID-19 infection including hospital admissions and clinical consequences of SARS-CoV-2 infection in the high-risk subjects.	
INVESTIGATIONAL VACCINE	**VPM1002** The active ingredient of the recombinant BCG vaccine, VPM1002 is Mycobacterium bovis rBCG ΔureC::hly, freeze-dried and standardized to number of viable colony forming units (CFU) of mycobacteria per application available as lyophilized cake. After reconstitution with water for injection, 1 dose (0.1 ml) contains VPM1002, live, 2-8 x 10e5 CFU. A single dose of 0.1 ml of the reconstituted vaccine is to be administered as

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	an intradermal injection in the arm, over the distal insertion of the deltoid muscle onto the humerus (approximately one third down the upper arm) OR lateral to posterior aspect of forearm.
COMPARATOR	**Placebo,** 0.1ml 0.9% sodium chloride, will be used as the comparator
PRIMARY OBJECTIVE	1. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among health care workers (HCW) 2. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among other high-risk subjects
PRIMARY ENDPOINT	1. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among HCWs 2. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among other high-risk subjects 3. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among HCWs 4. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among other high-risk subjects
SECONDARY OBJECTIVE	1. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in other high-risk subjects 3. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in HCWs 4. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in other high-risk subjects 5. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in elderly subjects (≥ 60 years of age) 6. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in subjects with co-morbidities 7. To assess the safety of VPM1002 when administered as a single dose in

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	subjects at a high-risk of disease exposure during the SARS-CoV-2 outbreak
SECONDARY ENDPOINT	1. Duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. Duration of SARS-CoV-2/COVID-19 symptoms in other high-risk subjects 3. Severe Disease Outcomes in HCWs: • Cumulative incidence of hospital admission among HCWs due to documented SARS-CoV-2 infection • Cumulative incidence of ICU admission among HCWs due to documented SARS-CoV-2 infection • Cumulative incidence of requirement of mechanical ventilation among HCWs due to documented SARS-CoV-2 infection • Cumulative incidence of deaths among HCWs due to documented SARS-CoV-2 infection 4. Severe Disease Outcomes in other high-risk subjects • Cumulative incidence of hospital admission among other high-risk subjects due to documented SARS-CoV-2 infection • Cumulative incidence of ICU admission among other high-risk subjects due to documented SARS-CoV-2 infection • Cumulative incidence of requirement of mechanical ventilation among other high-risk subjects due to documented SARS-CoV-2 infection • Cumulative incidence of deaths among other high-risk subjects due to documented SARS-CoV-2 infection 5. Severe Disease Outcomes among in elderly subjects (≥ 60 years) • Cumulative incidence of hospital admission among elderly subjects due to documented SARS-CoV-2 infection • Cumulative ICU admission among elderly subjects due to documented SARS-CoV-2 infection • Cumulative incidence of requirement of mechanical ventilation among elderly subjects due to documented SARS-CoV-2 infection • Cumulative incidence of deaths among elderly subjects due to

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	documented SARS-CoV-2 infection 6. Severe Disease Outcomes among subjects with Co-morbidities (including hypertension, diabetes mellitus, COPD, asthma, any other cardiac conditions) • Cumulative incidence of hospital admission among subjects with co-morbidities due to documented SARS-CoV-2 infection • Cumulative incidence of ICU admission among subjects with co-morbidities due to documented SARS-CoV-2 infection • Cumulative incidence of requirement of mechanical ventilation among subjects with co-morbidities due to documented SARS-CoV-2 infection • Cumulative incidence of deaths among subjects with co-morbidities due to documented SARS-CoV-2 infection 7. Incidence of Adverse Events (AE) and Serious Adverse Events (SAE)
EXPLORATORY OBJECTIVE	Immunogenicity analysis will be performed in a subset of approximately 500 subjects who provide consent for the same. Blood samples will be collected at baseline prior to vaccine administration and at 3 months post vaccine administration

STUDY DESIGN

This is a placebo controlled, randomized, double blind, adaptive study to evaluate the reduction in infection incidence and severity of SARS-CoV-2/ COVID-19 infection among high-risk subjects by enhanced trained immune response through VPM1002 vaccine.

A total of 5946 subjects who fulfil the criteria for high-risk will be enrolled across various hospitals treating COVID-19 patients in India. The Investigator/site staff at each site will inform the Health care workers (HCWs) about the clinical trial while other high-risk subjects (household contacts or people living or working in SARS-CoV-2/ COVID-19 infected areas) will be recruited through contact tracing of confirmed SARS-CoV-2/ COVID-19 cases and through posters/advertisements.

All interested subjects will be requested to download a mobile application/portal designed for the study on their smart phone/tablet/laptops and to register themselves. The study has a screening period of up to 14 days during which subjects who provide informed consent will be assessed for eligibility criteria which includes RT-PCR testing to rule out SARS-CoV-2/ COVID-19 infection. Among the household contacts, the laboratory sampling to rule out SARS-CoV-2/ COVID-19 infection will be done 14 days after the last contact with the confirmed SARS-CoV-2/ COVID-19 patient while in other high risk subjects, the laboratory sampling will be performed on the day of screening. The subjects who fulfill all the eligibility criteria will be randomized in a 2:1 ratio to receive a single

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dose (0.1 ml) of either VPM1002 or placebo, administered as an intradermal injection. The preparation and administration of the study vaccine will be done by designated unblinded personnel who will not participate in any of the clinical study evaluations. Considering that India is currently in a lockdown situation, the vaccine administration may happen at the study clinic or at the place of isolation of the subject. All the study personnel working with the subjects will wear personal protective equipment with adequate gloves as recommended by Indian Council of Medical Research (ICMR) and Ministry of Health and Family Welfare (MoHFW). The study vaccine should be administered within 48 hours of randomization.

Post vaccination the subjects will be observed for 20 minutes for any hypersensitivity/anaphylactic reactions.

While the monthly follow-up visits are telephonic for all subjects, in case of HCWs, these may be clinic visits depending on the circumstances (e.g., if they are reporting for their routine duty at the study site). Subjects can consult/visit the study site or request for home visit anytime during the study for emergencies or any safety concerns.

Follow-up information must be entered by the subjects regularly. In case the follow-up information is not completed within 7 days, subjects will receive reminders via the mobile application/portal and further telephonic reminders, if required. In case the subjects do not answer the telephone, information on subject's well-being and symptoms may be obtained from alternate contacts. Additionally, follow-up information regarding hospital admission, ICU admission or death will also be retrieved from the hospital.

The duration of follow-up will be based on the results of interim analysis however the maximum follow-up period will be up to 180 days.

Immunogenicity analysis is planned in a subset of approximately 500 subjects. Immunogenicity samples will be collected, from approximately 500 subjects who provide consent for the same, at two time-points, at baseline prior to vaccine administration and at the end of at 3 months (± 14 days) post vaccination. Based on the circumstances, if necessary, the immunogenicity sampling may be done at subject's place of isolation.

During the follow-up, if any subject experiences fever AND cough and/or shortness of breath, all attempts should be made to obtain a throat (nasopharyngeal and/or oropharyngeal) swab or any appropriate sample as directed by the treating physician. Subjects can consult/visit the study site anytime during the study for emergencies or any safety concerns. The sample will be collected by trained health care professionals who shall wear appropriate PPE with adequate gloves (as recommended by ICMR) while collecting the sample from the subject and maintain proper infection control when collecting specimens.

All treatment protocols for HCW and household contacts as recommended by ICMR and MoHFW will be permitted throughout the duration of the study.

Subjects will receive a notification on the mobile application/portal whenever the study ends and will be requested to fill in an end-of- study questionnaire. A subject is considered to have completed the study if he/she completes the end-of-study questionnaire. The end of the study is defined as the last subject's completion of end of study questionnaire in the mobile application/portal.

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Interim analyses are planned at 2-monthly intervals during the study to assess the efficacy and futility based on which the study will be stopped.

An independent Data and Safety Monitoring Board (DSMB) will be appointed to review the safety and primary endpoint data for efficacy/futility. Safety data pertaining to incidences of SARS-CoV-2/COVID-19 infections, hospitalizations, ICU admissions and deaths and interim analysis data will be provided to the DSMB, at 2-monthly intervals. The DSMB will provide their observations to the sponsor with recommendations as to whether there are safety concerns and whether the study should continue without change, be modified, or terminated. The DSMB recommendations will be carefully considered by the sponsor. The final decision rests with the sponsor.

STUDY ELIGIBILITY CRITERIA

INCLUSION CRITERIA	Subjects are eligible to be included in the study only if all of the following criteria apply 1. Male or Female subjects ≥ 18 years of age at high-risk of SARS-CoV-2/COVID-19 infection Subjects with high-risk of infection to COVID-19 cases defined as: • Health care workers (physicians, nurses, ward boys, paramedical staff) working in direct contact with COVID-19 patients • Other high-risk subjects: o House-hold contacts* defined as a resident in the same dwelling as a confirmed case of COVID-19 o People currently residing or working in COVID-19 hotspots/outbreak areas with a history of contact* with suspected or confirmed case of SARS-CoV-2/COVID-19 infection * Definition of contact • Face-to-face contact with a suspected/confirmed case (as applicable) within 1 meter and for more than 15 minutes • Direct physical contact with a suspected/confirmed case (as applicable) • Direct care for a patient with a confirmed COVID-19 disease without using proper personal protective equipment, OR • Other situations as indicated by local risk assessments Adapted from WHO Definition [**Error! Reference source not found.**] 2. Test negative for SARS-CoV-2 infection (RT-PCR test) at screening • For House-hold contacts, the sampling should be performed 14 days after the last contact with the confirmed SARS-CoV-2 patient and the result should be negative.

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	• For HCWs and other high- risk subjects, the sampling can be done on the day of screening 3. Capable of giving informed consent
EXCLUSION CRITERIA	Subjects are excluded from the study if any of the following criteria apply 1. Previous history of Tuberculosis or known active Mycobacterium tuberculosis infection 2. Received BCG vaccine within one year prior to screening 3. Fever (≥ 38 °C/100.4°F) or any other respiratory symptoms/illnesses within the past 14 days 4. Pregnant or lactating women 5. Women of child-bearing potential not agreeing to use adequate contraception 6. Current active viral or bacterial infection 7. Expected vaccination during the study period, independently of the type of vaccination 8. Severely immunocompromised subjects. This exclusion category comprises a) subjects with known infection by the HIV; b) subjects with solid organ transplantation; c) subjects with bone marrow transplantation; d) subjects under chemotherapy/radiotherapy; e) subjects with primary immunodeficiency; g) treatment with any anticytokine therapies. h) treatment with oral or intravenous steroids defined as daily doses of 10mg prednisolone or equivalent for longer than 3 months from the time of screening, or probable use of oral or intravenous steroids in the following four weeks 9. Active solid or non-solid malignancy or lymphoma within the prior two years 10. Individuals known to be hypersensitive to any component of the vaccine 11. Eczema or other significant skin lesion or infection at the site/s of injection. 12. Any other medical condition which in the opinion of the investigator may affect the subject's safety or study participation and conduct
SAFETY ASSESSMENTS	Subjects will be observed for 20-minutes post vaccination for any

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	hypersensitivity/ anaphylactic reactions. After this, data regarding documented SARS-CoV-2/COVID-19 infections, hospitalizations, any other AEs will be obtained via various short questionnaires configured in the mobile application/portal. The investigators will review the safety data and if required, may call the subject to obtain more details or may ask the subject to visit the site for further evaluation. All AEs and SAEs will be collected from the time of informed consent until the end of study. The investigator/designee will report all SAEs, irrespective of causality or expectedness to the sponsor, DCG(I) and ethics committee (IEC) within 24 hours of occurrence of the SAE.
SAMPLE SIZE	This is adaptive design based on Bayesian approach. Since sufficient data is not available for COVID-19 disease if assumptions change then sample size re-estimation can be done. For initial sample size calculation, we used Fisher's exact test for testing two independent proportion in terms of Relative Risk (RR) [Hazard ratio (HR) for cox proportional hazard model], considering following assumptions: RR under H_1 = 0.7 (30% reduction in incidence of laboratory confirmed SARS-CoV-2/COVID-19 infection observed in Other High-Risk Subjects / HCWs. Same assumption is used for two primary endpoints defined for each strata), Power = ~ 90% α = 0.0125 (one-sided, adjusted for two primary endpoints analyzed for strata: Other High-Risk Subjects) Allocation Ratio: VPM1002 group: Placebo group = 2:1 The study is separately powered in "Other High-Risk Subjects" and "HCWs" treating them as strata. • Other High-Risk Subjects: Assumption - Percentage of "Other High Risk" Subjects in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 20% (same assumption is used for two primary endpoints) Thus, for stratum "Other High-Risk Subjects", the total sample size calculated is 2228 evaluable subjects, 1485 in VPM1002 group and 743 in Placebo group. Considering approximately 10% drop out rate we need to randomize 2478 subjects, 1652 in VPM1002 group and 826 in Placebo

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	group. • HCWs Assumption - Percentage of HCWs in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 15% (same assumption is used for two primary endpoints) Similarly, for stratum "HCWs" for the total sample size calculated is 3119 evaluable subjects, 2079 in VPM1002 group and 1040 in Placebo group. Considering approximately 10% drop out rate we need to randomize 3468 subjects, 2312 in VPM1002 group and 1156 in Placebo group. Thus, we require 5946 randomized subjects in two strata distributed in 2:1 ratio in two groups VPM1002 and Placebo.
STATISTICAL ANALYSIS	Data will be reported quantitatively. Efficacy analyses will be performed on FAS population using the intention-to-treat principle. Two primary endpoints for each strata are "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection" and "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator". These endpoints are treated as Time-to-event data. The endpoints represent incidence of first laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator. The events will be considered till time point when study is stopped due to decision rule of interim analysis or patient is discontinued due to any reason or followed up to maximum follow-up of 180 days (6 months follow-up). To analyze this endpoint hazard ratio (HR) is calculated and compared between VPM1002 vaccine group and Placebo group. Cox proportional hazards model will be used treating treatment groups as fixed effects and hospital, age, comorbidities, severity, time to recovery will be evaluated as covariates for including them in the model. Secondary endpoints related to severe disease outcomes in HCWs, Other high risk subjects, Elderly subjects (≥ 60 years) and subjects with co-morbidities measured in terms of incidence such as cumulative incidence of hospital admission due to documented SARS-CoV-2 infection, Cumulative incidence of ICU Admission due to documented SARS-CoV-2 infection, Cumulative incidence of death due to documented SARS-CoV-2 infection, Cumulative incidence of requirement of mechanical ventilation due to documented SARS-CoV-2 infection will be analyzed using cox

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	proportional Hazard model. Secondary endpoints related to duration such as Duration of SARS-CoV-2/COVID-19 symptoms in HCWs and Other high-risk subjects will be analyzed by analysis of covariance using mixed model analysis. Continuous baseline characteristics will be reported as mean and standard deviation or median and inter-quartile range, as appropriate. Categorical baseline characteristics will be reported as count and percentage. No statistical testing for baseline characteristics will be performed. Safety data related to AE, SAE will be analyzed as frequency and % by System organ Class (SOC) and Preferred term (PT) Coded using MedDRA. The frequency and % will be provided for overall AEs, AEs by severity and relatedness.
INTERIM ANALYSIS	An interim analysis will be performed by the study statistician of the trial, once every 2 months. The results if available for futility or efficacy (with group level unblinding) will also be provided to the DSMB, once every 2 months along with safety data. In case of suggested futility or efficacy, the DSMB statistician may independently replicate the full data analysis before drawing conclusions. The Bayesian model used for primary endpoint yields a posterior distribution of the relative risk RR (hazard ratio (HR) of incidence rates). The posterior probability of the superiority hypothesis (RR < 1) will be calculated as well as the posterior probability of futility hypothesis (RR > 0.7). If during any of the interim analyses, the posterior probability of superiority is > 0.995 or the posterior probability of futility is > 0.99, a conclusion is reached, and the trial will be stopped. These posterior probability breakpoints have been chosen such that the type-1 error rate is <0.025 (similar to a two-sided alpha of 0.05) and the power of detecting superiority is > 90% if the true RR is 0.7.

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SCHEDULE B
STUDY BUDGET AND PAYMENT SCHEDULE

No.	Budget Head	Unit	No. of Subjects	Unit Fees / Cost	Total
1	Investigator & Site Team Fees (Screening visit + vaccination)	Screening visit + vaccination	175	INR 5,000.00	INR 8,75,000.00
2	Investigator & Site Team Fees (Post screening visit data completion)	Post screening visit data completion	175	INR 4,000.00	INR 7,00,000.00
3	Investigator & Site Team Fees (End of study visit data completion)	End of study visit data completion	175	INR 2,000.00	INR 3,50,000.00
4	Transportation expenses for home visits (assumed average one per subject for High Risk Subject) *	Subject	100	INR 1,000.00	INR 1,00,000.00
5	Subject compensation (transportation expenses for site visits, if required) **	Subject			
	For Health care workers	04 visits (Per visit Rs. 500)	75	INR 2,000.00	INR 1,50,000.00
	For High Risk subjects	02 visits (per visit Rs. 500)	100	INR 1,000.00	INR 1,00,000.00
6	Advertisements, recruitment Related, Referrals expenses CRC marketing strategies, miscellaneous charges	Site	175	INR 30,000.00	INR 525000.00
7	Payment for screen failures ***	Screen failed subject**	18	INR 4,000.00	INR 72,000.00
8	Institutional overheads (applicable on Investigator & Site Team Fees and Payment for screen failures)	Percentage	20% on Sr. No.1,2,3		INR 385000.00
9	Archival expenses	Site	1	INR 50,000.00	INR 50,000.00
	Total				**INR 33,07,000.00**

*	Transportation cost will be applicable for visits outside site i.e. for home visit of high risk subjects or in rare case Health Care workers as well
**	Average number of subjects estimated per site. Since recruitment will be competitive, the actual number per site may vary and even the proportion of Health Care worker and other High risk subjects may also vary accordingly subject compensation visits will also vary
***	Payment for screen failures refers to payment for the Investigator's and site team members' time towards activities conducted for screen-failed subjects. For each 10 eligible subjects, payment will be made for one screen failed-subject.
****	Cost of RT-PCR COVID test will be reimbursed.
*****	Expenses for medical care for related AEs and expenses related to treatment or compensation in case of related SAEs has not been included herein. These will be paid at actuals.
******	Personal Protective Equipment cost will be provided to the site.

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In connection with the Study, Sponsor will pay in accordance with the terms set forth in the Budget (schedule B):

1. Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. The Investigator /Institution/SMO shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

3. In full and complete consideration of Investigator's, Institution's and SMO's participation in the Study and of their covenants and obligations hereunder, within the date agreed in the Agreement or any alternative that may be granted by the CRO/Sponsor (including submissions of technical report and financial statements that may be required under the Agreement), and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

4. Institution, Investigator, SMO agrees to apply all funds received from CRO, including all interest accrued on such funds, if any, toward the performance of the Study. Within the Study Budget as provided in Schedule B, Institution may adjust budget line item amounts as reasonably necessary for performance of this Agreement; provided, however, that such adjustments shall not exceed ten percent (10%) of any line item without the prior written approval of Sponsor. Without the prior written approval of Sponsor/CRO, the total payments to Institution shall not exceed the amounts set forth in the Study Budget.

5. If a subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

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6. There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

7. All payment obligations are conditioned upon Institution's and Investigator's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator/SMO will repay to CRO any payments for Study visits, procedures, or other work associated with a Study subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the subject was not conducted by Investigator, sub investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

8. Investigator, Institution and SMO are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution/SMO under this agreement.

9. The payments represent all Study costs, and no other money will be payable by CRO.

10. Payments (Investigator Grant, Institutional overheads and Patient Compensation) will be made on monthly basis for the amount proportional to the no. of subject visits completed in the preceding month. Site should submit the invoice for the completed subject visit at the end of each month. Sponsor/ designee will arrange to remit the funds to site within 45 days of receipt of correct invoice from the site. If for any reason, site is unable to randomize even one patient in the study, the advance payment(if applicable) will be returned to the Sponsor/ designee within a reasonable period (not exceeding 30 calendar days) on receipt of written communication from Sponsor/ designee to refund this amount.

11. Monthly invoices will be cleared by the Sponsor/ designee within 45 days of submission irrespective of the data being source verified by the monitors. However, site needs to ensure that source data is updated real time and electronic Case Report Form is filled within 05 working days of subject visit. While clearing the invoices at Sponsor/ designee end, in-house monitors will remotely review the compliance to the data entered vs. actual patient visit in the period of invoicing

12. Payment will be pro-rata based on the actual no. of visits completed by the subject.

13. Screen failures would be paid at 4000 INR per subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 10% of randomized subjects at site.

14. Reimbursement for any investigation performed for safety evaluation will be on actuals on submission of bills.

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Other Terms and conditions:

1. Investigator acknowledges that the Study is a multicenter study and the recruitment for this Study will be through competitive enrolment, and investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. CRO / Sponsor retain the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. Payment for drop outs or early terminated subjects would be pro-rated depending on the number of completed study visits. Invoice for completed visit will be raised at the end of each month.

3. If the payment towards the Institutional grant and subject compensation is paid to the investigator/institute directly by DiagnoSearch then it will be sole responsibility of the investigator/institute to pay the same to the concerned parties / individual (as applicable)

PAYMENT INSTRUCTIONS

All payments except subject compensation will be released after deduction of applicable taxes.

Payments will be made through cheque / bank transfer as per the payee details provided below

To SMO	
Payee Name:	CROM Clinical Research & Medical Tourism Pvt. Ltd.
Bank Name:	ICICI Bank
Bank Address	2139, B Ward, Kolekar 2139, B Ward, Kolekar Tikti, Mangalwar Peth, Kolhapur.
Beneficiary Account No.	639005500711
TAX ID NUMBER (PAN)	AAFCC4022N
IFSC Code	ICIC0006390

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