Sri Devaraj Urs Academy of Higher Education & Research
Comprising Sri Devaraj Urs Medical College
A DEEMED TO BE UNIVERSITY
Research and Development Cell
Declared under Section 3 of UGC Act, 1956, MHRD GOI No.F.9-36/2006-U.3 (A) Dt. 25th May 2007
POST BOX NO.62, TAMAKA, KOLAR-563 101, KARNATAKA, INDIA
Ph.: 08152-243003, 210604, 210605, Fax: 08152-243008, E-mail: co.rd@sduaher.ac.in website: www.sduaher.ac.in

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Prof. Dr. Kalyani . R.
MD(Path), Ph.D, FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

MAMTA HIMC
BRIDGE TO HEALTH & BEYOND

Mamta Health Institute for Mother and Chi
B-5, Greater Kailash Enclave-II, New Delhi 110 048
t: +91 11 41069597 / 41720210 I 43535440
e: mamta@mamtahimc.in / mamta@yrshr.in I w: www.mamtahimc.in

Date: 1st March, 2025

Dr. Kowshick R
Sri Devaraj Urs Medical College,
Karnataka

With reference to your proposal Student ID: 2024-25/MD/002, titled, "Are our Rural Adolescent boys safe from Porn Addiction? A Mixed method study", you are awarded **INR 1,00,000** for study. In addition, article publication fees up to **INR 50,000** will be granted on acceptance of publication in peer-reviewed journal. The process of disbursement of stipend amount will be done as per the following guidelines:

Instalments	On Submission of	Timeline	Amount to be released
First Installment	Final Study Proposal along with following documents: – Study Tools – Institutional Ethical Certificate – One Pager of the study (Background, Objective, Methodology, Expected Outcome) – Updated PPT	April, 2025	Rs. 10,000
Second Installment	1) Data collection report 2) Analysis Tables (Dummy)	July, 2025	Rs. 10,000
Third Installment	1) First draft of study report 2) Publication Plan which will include: – Title of the proposed papers – Identified journals for publication – Proposed timeline for publication	October,2025	Rs. 40,000
Fourth Installment	1) Final study Report 2) One Pager (Background, Objective, Methodology, Results) 3) Your contribution in adolescent health in one page 4) Any paper from the proposed research communicated for publication	January,2026	Rs. 40,000

Guidelines and conditions for MAMTA AHA Research Scholarship Excellence Awards in Adolescent Health:

1. All the deliverables should be accompanied by progress reports and documents. Please note that scholarship will not be disbursed until you submit the required quarter wise progress reports. All the quarter-wise progress report should be approved and forwarded by your guide/ supervisor.
2. You will be requested to devote at least 3 days in a month to the study.
3. It is your responsibility to immediately report any change in your study application status to MAMTA Health Institute for Mother and Child. Changes in status include (but are not limited to): deferring admissions after receiving an award, or plans to withdraw from the university, another study, an academic appointment, change of the Guide and supervisor, extension of time limits and a training grant.
4. Financial support, Journal Publication Fees up to **INR 50,000** (After submission of fees receipt) will be valid till March 2031, which will be granted on acceptance of publication in peer-reviewed journal. Manuscripts/ paper communicated for publication should be sent to MAMTA Health Institute of Mother and Child. If the MAMTA research team contributes extensively to reviewing the manuscript, they will be considered for authorship.

MAMTA Health Institute for Mother and Child
New Delhi

5. Throughout the process of drafting the paper and leading up to its submission to journals, it is essential to involve members of the MAMTA Research Team in discussions and reviews.
6. It is your responsibility to keep MAMTA Health Institute of Mother and Child informed about your submission /acceptance/publication of any study paper arising out of the study work done during the tenure of the Study.
7. You must acknowledge the support of MAMTA Health Institute of Mother and Child in all the publication(s). **"This Study has been funded by Mamta Health Institute for Mother and Child as part of MAMTA Scholarship Excellence Award"**. Copy of the research paper(s) published must be sent to MAMTA Health Institute of Mother and Child at each stage of publication including preprint, final proof-reading document and published article manuscript/reprint.
8. Mamta follows the Government of India guidelines/policy for the Prevention of Sexual Harassment (PoSH) at the workplace.
9. Mamta HIMC has a policy of erasing all confidential information, ideas/concepts submitted in proposals/applications after the selection process is completed. "Confidentiality of Applicants" Mamta shall not be liable to share the list of shortlisted applicants with any party outside the organization. The organization takes all necessary measures to protect the confidentiality of applicants, and shall not disclose any personal information, process and data related to the application, except as required by law.
10. If a student is found to have obtained a scholarship by false statements, his/her scholarship will be cancelled forthwith and the amount of the scholarship paid will be recovered, at the discretion of the organization. The student concerned will be blacklisted and debarred for scholarship in any scheme forever.
11. A scholarship awarded may be cancelled if the scholar changes the subject of the course of study for which the scholarship was originally awarded or changes the Institution of study, without prior approval of the organization. The amount already paid may also be recovered at the discretion of the organization.

Congratulations and best wishes for a great academic year!

Best Wishes,

Mrs. Neelima Sehgal
Deputy Director (Finance)

Accepted

Dr. Kowshick R

सत्यमेव जयते

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Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL60598413899458W
Certificate Issued Date	:	24-Sep-2024 01:19 PM
Account Reference	:	IMPACC (IV)/ dl1050803/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL1050803719473327195O4W
Purchased by	:	Insignia Clinical Services Private Ltd
Description of Document	:	Article 5 General Agreement
Property Description	:	Quadripartite Clinical Trial Agreement
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Insignia Clinical Services Private Ltd
Second Party	:	R L Jalappa Hospital and Research Centre and Adichunchanagiri University and Dr Lokanatha Dasappa
Stamp Duty Paid By	:	Insignia Clinical Services Private Ltd
Stamp Duty Amount(Rs.)	:	500 (Five Hundred only)

Please write or type below this line

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INSIGNIA CLINICAL SERVICES DELHI

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Dept. of Pathology, SDUMC

CENTRAL TRIAL MONITORING ORGANIZATION
Adichunchanagiri University, B G Nagara 571448

Dr. D Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

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Unique Doc. Reference	:	SUBIN-DLDL1050803719486313147 72W
Purchased by	:	Insignia Clinical Services Private Ltd
Description of Document	:	Article 5 General Agreement
Property Description	:	Quadripartite Clinical Trial Agreement
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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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Statutory Alert:
The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding.
Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
The onus of checking the legitimacy is on the users of the certificate.
In case of any discrepancy please inform the Competent Authority.

Clinical Trial Agreement by/and between

Insignia Clinical Services Pvt. Ltd.,
(CRO)

AND

R.L Jalappa Hospital and Research Centre,
attached to Sri Devaraj Urs Medical College
(Trial Site)

AND

Adichunchanagiri University,(CTMO)
AND

Dr. Lokanatha Dasappa
(Principal Investigator)

as of 26-Sep-2024
(effective date)

CRO **Trial Site** **CTMO** **Principal Investigator**

Prof. Dr. Kalyani . R.
(Path., Mumbai), FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Adichunchanagiri University, B G Nagara

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Clinical Trial Agreement

This Clinical Trial Agreement herein after known as "CTA/Agreement" has been executed on 26-Sep-2024 by and between:

Insignia Clinical Services Private Ltd. (ICS), a company incorporated under the laws of India as registered under the Indian Companies Act, 1956 having its business address at Unit No. 512, 5th Floor, Best Sky Tower, Netaji Subhash Place, Pitampura, New Delhi-110034 (hereinafter referred to as "**CRO**") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through **Mr. Kartik Sahni,** who has been authorized by M/s CuratTeQ Biologics Private Limited (hereinafter referred to as **"Sponsor"**) to execute this CTA on behalf of CRO and Sponsor.

AND

R.L. Jalappa Hospital and Research Centre is a teaching Hospital attached to Sri Devaraj Urs Medical College, Sri Devaraj Urs Academy of Higher Education and Research (A deemed to be University),located at Tamaka, Kolar, Karnataka 563103, India (hereinafter referred to as "Trial Site") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through **Dr. Kalyani R** ,who has been authorized to execute this CTA on behalf of Trial Site.

AND

Adichunchanagiri University with business address at Adichunchanagiri Hospital, Adichunchanagiri University at B.G Nagara, Mandya, Karnataka – 571 448, (hereinafter referred to as "Central Trial Monitoring Organization" or "CTMO") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through its authorized representative **Dr. Rajesh Venkataraman.**

AND

Dr. Lokanatha Dasappa (hereinafter referred to as the "Principal Investigator" or "PI"), an independent consultant / employee of the Trial Site has been appointed as Principal Investigator for the purpose of conducting clinical trial at Trial Site.

(hereinafter each referred to as a "Party", and collectively as "Parties").

WHEREAS:

A. **ICS** is a Delhi-based Contract Research Organization (CRO) providing services primarily in India, directly or through its affiliates, associates, agents and subsidiaries. The major activities conducted by ICS include design, setup and management of clinical studies with

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human beings for the owners and / or manufacturers of pharmaceutical products, medical devices and food supplements / nutraceuticals.

B. **M/s Curateq Biologics Private Limited (Sponsor) is a pharmaceutical manufacturing company** engaged in manufacturing and distribution of pharmaceutical product and desires to carry out a Phase- III Clinical Study involving study drug **BP01 (Bevacizumab) and Avastin along with XELOX chemotherapy** in metastatic colorectal cancer patients according the protocol titled "**A prospective, Randomized, Double Blind, Multicentric, Parallel Group Phase-III Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of BP01 (Bevacizumab) Versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients.**" Protocol No: ICS/CUR/2023-006, Version 1.0; Date: 19 OCT 2023 (herein after referred to as '**Study**') incorporated herein by reference as **Exhibit- A** and all subsequent amendments thereto;

C. Sponsor has appointed CRO to manage the Study and assist Sponsor with site selection & management services for conduct of clinical trials at Trial Site. (For all information/documentation provided by Trial Site/PI to CRO under the Agreement, the CRO shall then provide the same to Sponsor);

D. The **PI** is a qualified medical practitioner and has been engaged by the Trial Site to participate in the study as an investigator and being responsible to conduct the study, statement issued by Trial Site attached hereto as **Exhibit –C** working with the **Trial Site** and has agreed to conduct the Study at the Trial Site only after the prior written approval of **Institutional Review Board / Independent Ethics Committee** (IRB/IEC) at the Trial Site.

E. The **Trial Site** is a Teaching Hospital qualified and equipped with adequate resources to undertake the study and the Trial Site and PI have agreed to perform the study on the terms and conditions hereinafter setforth.

F. **Adichunchanagiri University** and **Sri Devaraj Urs Academy of Higher Education and Research** has a Bilateral MOU dated 05 Feb 2024, wherein both the Universities has agreed to develop and perform collaborative activities in research and academic areas of mutual interest, Hence (Adichunchanagiri University) Central Trial Monitoring Organization will be overseeing and managing the Clinical research activities performed at the Trial Site.

CRO **Trial Site** **CTMO** **Principal Investigator**

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Adichunchanagiri University, B G Nagara

Dr. Ramanatha
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NOW, THEREFORE in consideration of the premises and the mutual promises and covenants express herein the Parties agree herein:

1. PERFORMANCE OF THE STUDY:

1.1 Compliance with the Agreement: The purpose of this agreement is to conduct the study at the Trial Site. The protocol has been sponsored by the sponsor and is approved by / or is subject to the approval of the Drug Controller general of India (DCGI) under the Drugs & Cosmetics Act, 1940 including any amendments thereof (hereinafter referred as Drugs & Cosmetics Act. 1940) and / or any other law or rules for the time being in force in India as well as approved by the Ethics Committee (EC). In the event the protocol is amended, such change shall be notified and if required under the law, prior approval of DCGI and/or EC shall be obtained. The Trial Site and the PI agree to perform the study in strict compliance with the protocol and terms and conditions of this agreement including any amendments thereto. The PI shall perform the study at the study site of the institution. The Trial Site and PI further represent, warrant and covenant that the PI is and at all times, during the term of this agreement, shall be (a) in good professional standing, (b) in possession of all requisite professional licenses, approval and permissions, (c) full qualified to conduct the study and to act as PI under this agreement , (d) fully experienced and knowledgeable with respect to all matters pertaining to the study and (e) responsible for supervision of all persons who may assist the PI or otherwise be engaged in the Study. In the event that the Trial Site and/or the PI use the services of sub-investigator, investigational staff, or other to conduct the study pursuant to this agreement, the PI and Trial Site shall be responsible that all are appropriately licensed and credentialed and shall conduct the study in compliance with the terms and conditions of this agreement. The Trial Site and PI shall be liable for any breach of such agreement by such individuals.

1.2 Replacement of Principal Investigator: In the event the PI is unable to continue, either on account of his death or early termination of engagement from Trial Site or becoming incapacitated. , in such circumstances, the Trial Site shall provide a written notice to CRO within three (3) calendar days of becoming aware of PI's inability to continue. The Sponsor/ CRO shall then appoint the Co-Investigator as a party to this agreement by way of amendment to this agreement. In case the Sponsor /CRO terminate this agreement, the Trial Site shall take all necessary steps to accommodate the decision.

1.3 Delegation of duties: The PI will personally supervise the study and may not delegate this duty to any other individual without Sponsor/ CRO's prior written approval. He /She may delegate other duties as necessary to their investigators and qualified personal in accordance with regulatory requirement and upon notice to sponsor /CRO. The Trial Site may not replace the PI without Sponsor's/CRO's prior written approval. If the PI is to be temporarily absent from the Trial Site, the Trial Site shall designate an Investigator qualified and trained to assume such

responsibilities to temporarily supervise the study on behalf of PI. All such designation of responsibility will be reported to Sponsor/ CRO in writing and DCGI and/or EC prior to its commencement.

1.4 Investigator and Staff Training: The Trial Site and PI Shall insure that other investigator and designated staff attend all study related training conducted by Sponsor/CRO.

1.5 Use of Study drug: CRO shall provide the study drug and all related document and any material wherever require for conduct of study. Neither the PI not Trial Site shall make use of study drug, study related documents and materials , for purposes other than performance of the study in accordance of the protocol and this study. The PI and Trial Site shall account for and return to CRO or otherwise dispose of in accordance with CRO's Instruction any unused study drug, materials and equipments and confidential information provided for the purposes of the study. In case of destruction of study drug at Trial Site, the Trial Site shall promptly provide certificate of such destruction. This provision does not apply to the documents that should be maintained and retained in secure manner by the PI at the Trial Site as per study protocol, the agreement and /or applicable guidelines laws and regulations.

1.6 Adverse Event Reporting: Principal Investigator and Trial Site also agrees to report to Licensing Authority as defined in New Drugs and Clinical Trials Rules, 2019 including any amendments thereof, Ethics Committee and CRO immediately, but not later than 24 hours or within such mandatory timelines as amended from time to time and specifically mentioned hereabove, After learning of any adverse event and all other important medical events, including but not limited to adverse reactions, as identified in the protocol, affecting any Study Subject. Principal Investigator and Institution further agree to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements.

1.7 Additional research: Trial Site and PI shall not conduct any additional research nor facilitate any third party to conduct any such research on study subject during the study OR biological samples collected from study subjects during the study, data derived from the study without prior written concern of Sponsor and CRO.

2. TRIAL DRUG; MATERIALS TRANSFER; RECORDS RETENTION; INSPECTION:

2.1 Trial Site and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor/CRO and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Trial Site or Investigator for the Trial, shall be construed to grant to either Trial Site or Principal Investigator any rights in or to the Compound.

CRO **Trial Site** **CTMO** **Principal Investigator**

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Tamaka, Kolar-563103.

2.2 Except as otherwise agreed by the Parties, CRO will provide the Compound and any control/placebo material to be administered to Trial subjects as part of the Trial (collectively, the "Trial Drug") free of charge to Trial Site for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

2.3 Trial Site and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Trial Site and Principal Investigator shall handle, store, ship and dispose of the Trial drug as directed by Sponsor/CRO or its designee and in compliance with all applicable laws, rules and regulations.

2.4 Trial Site and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to CRO in accordance with the Protocol.

2.5 Neither support of the Trial, nor Trials Site's participation in the Trial, impose any obligation, express or implied, on Trial Site or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's/ CRO's products.

2.6 Unless required by the Protocol, Trial Site will not modify the Trial Drug or its container. If the Trial Site policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor/CRO. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Trial Site for use in a future study to be approved by Ethics Committee (EC).

3. RECORDS MAINTENANCE AND RETENTION:

3.1 The Trial Site and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Ethics Committee (EC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Trial Site or Principal Investigator shall cooperate with the Sponsor/CRO in making records, reports and Data developed under this Agreement.

Trial Site or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor/CRO requires

the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor/CRO's written approval shall be obtained.

4. PAYMENTS:

4.1 Budget And Compensation: The compensation and fees to be paid by the Sponsor/CRO for this study is contained in the budget described in **Exhibit- B** attached hereto and incorporated by reference in this agreement. Payment shall be due and payable in accordance with the schedule set forth in **Exhibit- B.**

4.2 Fair Market Value: The party's acknowledge and agree that the compensation and support provided by the Sponsor/CRO to the CTMO/Trial Site provision to this agreement represents the fair market value for the research service conducted by Trial Site and the Principal Investigator has been negotiated in an arm's length transaction, and has been determined in a manner that takes into account the volume or value of any reference or other business otherwise generated between the Sponsor/CRO and the situation are the principal investigator.

4.3 Third Party Pay or billing: Neither the CTMO nor the Trial Site nor the Principal Investigator shall bill any third party for the Study Drug or any other item or services furnished by the Sponsor/CRO in connection with the Study, or any services provided to subjects in connection with the Study for which payment is made as part of the study except as may be specifically authorised by compensation standard set forth in **Exhibit- B**.

4.4 No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging of the referral of business or the ordering of item of services; nor are the payments intended to include illegal referrals of business Nothing contained in this agreement shall be construed connected in any manner as an obligation or inducement for the Trial Site or Principal Investigator to recommend that any person or entity purchase Sponsor's/CRO's product or those of any entity affiliate with the Sponsor/CRO

5. TERM & TERMINATION:

5.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement. The Date of execution of this Agreement shall be the effective Date.

5.2 This Agreement will become effective after it is fully executed and signed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

CRO **Trial Site** **CTMO** **Principal Investigator**

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5.3 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 6 months after completion of Study at Trial Site (hereinafter known as "**Expiration Date**").

6. TERMINATION BY SPONSOR/CRO:

6.1 The Agreement may be terminated by the Sponsor/CRO at any time in the exercise of its sole discretion upon thirty (30) calendar days prior written notice to the Trial Site. reasons for termination may include but not limited to;

- Breach of Contract, including failure to comply with protocol and applicable laws and regulations,
- Receipt of safety information that makes it prudent to do so.
- No subject recruited within 6 months at study site following initiation of study at site.
- Notwithstanding the above Sponsor/CRO may immediately terminate the study within its sole judgment, if such termination is necessary based on patient safety, OR breach of compliance with applicable laws and regulations or evidence suggesting lack of sufficient efficacy of study drug herein without sponsor /CRO having any financial or other liability of any nature resulting in any such termination.

6.2 Upon notice of termination of this Agreement by either Trial Site or Sponsor/CRO or Principal Investigator, Trial Site shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

6.3 Upon any early termination for any reason other than breach of this agreement by the Trial Site /CTMO or PI, the Sponsor/CRO shall reimburse the Trial Site / CTMO fornon-cancellable commitments made or incurred in accordance with this agreement prior to Trial Site receipt of Notice of Termination (reduced by all applicable prior payments made by Sponsor/CRO under this agreement). No cancellation penalty shall apply. Upon notice of such receipt of notice of termination, the Trial Site, the CTMO and PI shall use all reasonable efforts to avoid any additional cost and expenses. In the event the prepaid any portion of payment for work pursuant to this agreement that is not actually performed as a result of termination of this agreement, the Trial Site and PI shall return such payment for such unperformed services or unexpended or cancelled fees.

6.4 If, upon the Effective Date of Termination, Sponsor/CRO has advanced funds which remain unutilized or surplus, Trial Site/CTMO shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Trial Site/CTMO fails to repay such funds in a timely manner, Sponsor/CRO may deduct an equivalent amount from any payment then or later

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due from Sponsor/CRO to Trial Site or CTMO under this or any other arrangement between the parties.

6.5 Upon termination of this Agreement, all unused Materials and all Sponsor's/CRO's Confidential Information (except for such records that Trial Site is required by law or regulation to retain) in Trial Site's possession shall be promptly delivered to Sponsor/CRO at Sponsor/CRO's expense, or, at Sponsor/CRO's option, destroyed with the destruction certified in writing.

7. OWNERSHIP:

7.1 All reports, data, technical information,(including without limitation, written, printed, graphic video and audio material, any computed data base and computer data readable data form), original works of authorship and all other information generated(the "**Data**") by the Trial Site, the PI , any other designated personnel in the course of conducting the study shall be the sole and exclusive property of Sponsor or its designee i.e. CRO, which may utilise the Data in any way it deems appropriate, subject to and in accordance with applicable laws and regulations of India and the terms of this agreement .

8. CONFIDENTIALITY:

8.1 Both parties agree to treat any confidential information obtained from the other party, or generated by the party or its Representatives as a sole and direct result of performing the services under this Agreement including, without limitation, confidential commercial, business, scientific, medical and technical information, the study drug, Protocol, Investigator Brochure, Case Report Forms, safety information, and any other data or information generated or resulting from the study recorded and available in any form or on any media (paper, disc, photos, computer systems) (hereinafter "the Confidential Information")

8.2 Both parties agree not to divulge the Confidential Information to any third party or parties, unless necessary as it relates to the performance of duties outlined in the scope of services or use said Confidential Information for any purposes other than understanding and evaluating the performance of those services. Parties further agrees to limit disclosure only to those of its officers, employees, agents, affiliates and consultants as are necessary to carry out the services in this Agreement. Parties shall take all reasonable steps to prevent the disclosure of the Confidential Information as provided herein.

8.3 Parties will ensure that it will incorporate similar confidentiality language (no less restrictive than this Agreement) in its written contracts with all representatives, agents, affiliates and consultants to protect Confidential Information. Any Confidential Information or IP produced

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for performing services under this agreement can only be used by the Sponsor/CRO for the specific study.

8.4 The above provisions of confidentiality shall not apply to that part of the Information which any party is able to demonstrate by documentary evidence:

a. was fully in their possession prior to receipt from the other party; or
b. was in the public domain at the time of receipt; or
c. becomes part of the public domain through no fault of the party; or
d. is lawfully received by it from a third party having a right of further disclosure; or
e. is developed by it independent of the Information; or
f. is required by law or upon a court injunction to be disclosed.

Parties agree that upon termination or expiration of this Agreement, at the other party's request, it shall return to the other party all Confidential Information, retaining copies of any such Confidential Information as is reasonably necessary for regulatory and insurance purposes or as it deems necessary to demonstrate the satisfaction of its obligations hereunder, all subject to the ongoing obligation to maintain the confidentiality of such Confidential Information.

9. DISCLOSURES:

9.1 The confidentiality obligation shall not, however, be applied to Confidential Information, which:

a. Was, as evidenced, in the possession of the receiving party prior to receipt of the confidential information from the other party,
b. The party has received from a third party without any obligation of confidentiality and which has a right to deliver such information to the other party, or
c. On ground of law has to be delivered.

Any party invoking and exception set forth above has the burden of proof with respect to the existence of such an exception.

9.2 Each party shall promptly return to the other party and Confidential Information no longer needed for the purposes of this agreement or if so requested by the other party.

9.3 Should any third party, e.g. Regulatory Authority demand access to Confidential Information on grounds of law, the party shall without any delay and prior to making such a disclosure notify the other party of such a demand in writing and take prior written consent before making such disclosure. The party may then deliver only the specified Confidential Information, which the request concerns.

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10. PUBLICATION:

10.1 The Parties also understand and recognize that this Study is part of a multi-site study and that data from all sites will be pooled and analyzed, and agree that premature disclosures of data from a single site may be misleading. Sponsor /CRO, shall have the right to coordinate one or more publications of the aggregate multi-site Study results.

10.2 The Trial Site/PI will report the findings of the Study to Sponsor/CRO in the form of Study reports, to be submitted to Sponsor/CRO at such stages or intervals in such forms and containing such information as set out in the Protocol (including for instance the progress and the number of included patients) and/or as further agreed between the Parties.

10.3 The Parties acknowledge that Sponsor/CRO shall have the exclusive right to publish and present the results of the Study. Sponsor/CRO shall take into account that these results represent a joint effort among Sponsor, CRO, Trial Site and PI. Sponsor/CRO shall mention the PI of the Site in a footnote in the manuscript as one of the participating Principal Investigators of the Study.

10.4 The PI/Trial Site shall have no right to publish and present the results of the Study unless the prior written consent of Sponsor/CRO has been obtained. Sponsor/CRO recognizes the wishes of Site/PI to publish details of academic research in scientific journals. Sponsor/CRO shall however have the full right to withhold such consent.

10.5 Sponsor/CRO shall retain ownership of all original and completed CRFs, data, analyses and reports that result or are derived from the Study.

11. INVENTIONS& PATENTS:

11.1 Any invention, discovery, or improvement related to Sponsor/CRO's products or technology which is conceived or reduced to practice as a consequence of Trial Site's performance of the services hereunder (the "Inventions") shall be the sole and exclusive property of Sponsor/CRO and shall be used by Sponsor/CRO as Sponsor/CRO deems appropriate. Trial Site agrees to execute and have executed, at Sponsor/CRO's cost, assignments of the Inventions to Sponsor / CRO (including ensuring contracts between Trial Site and its Representatives include appropriate assignment language to require its Representatives to comply with the terms of this assignment provision and this Agreement), along with other documents that may be necessary or helpful to Sponsor / CRO in filing patent applications, or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of, and

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without expense to, Trial Site/PI or its Representatives. Trial Site/PI acknowledges that Sponsor / CRO has the exclusive right to file patent applications in connection with the Inventions. Trial Site /PI warrants that it will not, and will ensure (including incorporating similar language in its contracts with study sites and investigators) that its Representatives will not prevent Sponsor / CRO from filing patent applications for, or from applying the results of research carried out for Sponsor / CRO hereunder.

11.2 All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor / CRO, or created specifically for Sponsor / CRO as a deliverable under this Agreement ("Work Product"), shall be the sole and exclusive property of Sponsor.

11.3 Notwithstanding the foregoing, Sponsor / CRO acknowledges that Trial Site /PI possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by Trial Site /PI and which relate to its business or operations (collectively "Trial Site Property"). Sponsor / CRO and Trial Site /PI agree that any Trial Site Property or improvements thereto which are used, improved, modified or developed by Sponsor / CRO under or during the term of this Agreement are the sole and exclusive property of Trial Site /PI and Sponsor / CRO shall be liable for any misuse or unauthorized use/ dissemination of the same. In no event shall Trial Site /PI be precluded from use of this Property and its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing services under this Agreement.

12. INSURANCE AND INDEMNIFICATION:

12.1 Trial Site shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

12.2 The sponsor/CRO shall indemnify and hold harmless the Trial Site from any and all liability of trial subjects, loss, or damage it may suffer as a result of the sponsor's negligence or breach of contract or caused by the investigational medicines, compliance with the protocol written by the sponsor, or use of the Results. Sponsor/CRO will ensure that appropriate medical insurance cover is obtained to cover the financial cost of any liabilities arising out of loss / damages occurring to trial subjects as a result of participation in Clinical Trial under the conditions specified as per the terms of this agreement.

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12.3 The Trial Site and PI agrees to indemnify and hold harmless the sponsor/CRO from any and all liability of trial subjects, loss, or damage it may suffer as a result of the Trial Site's negligence or breach of contract.

12.4 The obligation of the Sponsor hereunder shall apply only if the Indemnities provides prompt notification upon receipt of notice of any claim or suit, permits the Sponsor and its attorneys and personnel to handle and control the defense of such claims or suits including pretrial , trial or settlement and the indemnitees further agrees that it will not settle or compromise any such claim or suit without the prior written consent of the Sponsor/CRO.

13. USE OF OTHER PARTIES' NAMES:

13.1 The Principal Investigator and Trial Site shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO.

14. NO JOINT VENTURE ETC.:

14.1 This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

15. MONITORING; AUDIT; REGULATORY INSPECTIONS:

15.1 The Principal Investigator and Trial Site shall, permit authorized personnel of the Sponsor/ CRO and any Regulatory Authority including EC to inspect the facilities of the Study Site before, during and after the Study.

15.2 The Principal Investigator and Trial Site shall notify to the Sponsor/CRO immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Trial Site's facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Trial Site receives, obtains, or generates pursuant to any such study.

15.3 The Principal Investigator and Trial Site will permit the Sponsor/CRO to;

(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

(b) Inspect and copy all Data, documents and records related to such work and the Study.

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16. FORCE MAJEURE:

16.1 Any event occurring after signing the agreement, which a party could not reasonably have taken into account at the time of the conclusion of the agreement and which prevents or delays the affected party from fulfilling of its obligations under the agreement or makes the fulfillment thereof unreasonably difficult and which cannot be overcome without unreasonable loss of time or cost, shall constitute an event of force majeure. An event of force majeure shall include: strike, war, revolt, import or export prohibition, acts of God, interruption of public traffic or distribution of energy, legal labour dispute, fire or any other reason having as severe and unusual effects beyond the control of the party.

16.2 If a party would wish to invoke existence of an event of force majeure as a cause for the non-compliance with any of its obligations under the agreement or delay or exemption from liability, it shall without delay inform the other party of the delay or termination of its contractual obligation in writing

17. GOVERNING LAW:

17.1 The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable within the NCT of Delhi.

18. JURISDICTION:

18.1 The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Delhi, notwithstanding any other provision to the contrary in any law in this regard.

19. ARBITRATION:

19.1 All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this Agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed mutually by the Parties within a period of thirty (30) days of the receipt of a written request by the aggrieved. The Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings. The award of the arbitrator shall be final and binding on all the parties thereto.

20. AMENDMENT:

20.1 This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements

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and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in quadripartite, by their officers, thereunto duly authorized to sign on behalf of their party.

1. **Insignia Clinical Services Pvt. Ltd.:**

INSIGNIA CLINICAL SERVICES PVT. LTD. DELHI

2. **R.L. Jalappa Hospital and Research Centre,**

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3. **Adichunchanagiri University,**

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4. **Principal Investigator:**

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PROTOCOL SYNOPSIS

TITLE:	A Prospective, Randomized, Double Blind, Multicentric, Parallel Group Phase-III Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of BP01 (Bevacizumab) Versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients.
PROTOCOL NUMBER:	ICS/CUR/2023-006
VERSION & DATE:	1.0; 19 OCT 2023

NUMBER OF SUBJECTS TO BE ENROLLED AND RANDOMIZED:

Appropriate number of subjects will be screened and total of 168 subjects who meet the required eligibility criteria will be randomized in 2:1 ratio in Test Vs. Reference groups to achieve minimum number of 153 completed / evaluable subjects (102:51 in Test: Reference) which is a statistically powered sample size. An attempt will be made to have the number of subjects equally distributed amongst sites.

CLINICAL PHASE:	Phase-III Clinical Trial.
INDICATION:	Metastatic Colorectal Cancer.

STUDY OBJECTIVES:

Primary Objective

- To evaluate and compare the efficacy of BP01(Bevacizumab) versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients.

Secondary Objective(s)

- To evaluate and compare the immunogenicity of BP01(Bevacizumab) versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients.
- To evaluate and compare the safety of BP01(Bevacizumab) versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients.

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STUDY DURATION:

Subject participation will last for a total of 22 weeks, which includes up to 4 weeks of screening, 15 weeks of Study Medication administration, and up to 3 weeks of End of Study follow-up assessments.

STUDY DESIGN AND METHODOLOGY:

This is a Prospective Phase III, Multicentric, Comparative, Randomized, Double-blind, Active Controlled, Parallel group clinical study to evaluate and compare the efficacy, immunogenicity and safety of BP01(Bevacizumab) mfg. by CuraTeQ Biologics Private Limited with reference medicinal product EU approved Avastin® (Bevacizumab of Roche) along with chemotherapy XELOX in metastatic colorectal cancer patients.

Male and female subjects, age 18 years and above with histopathologically confirmed metastatic colorectal cancer diagnosis that is not amenable to curative surgery and/or radiation and who have not received any treatment for metastatic colorectal cancer [i.e., only 1st line mCRC patients] will be screened for participation in the study. Subjects at the time of screening should have a measurable disease on radiological assessment according to RECIST 1.1 criteria, Eastern Cooperative Oncology Group (ECOG) PS 0 or 1 at the time of screening and before first infusion with life expectancy of at least 4 months as per the investigator.

All subjects who meet the above criteria will be screened for participation as per the inclusion/exclusion criteria specified in Section 4.2 and 4.3 of the protocol.

Subjects will visit the study center for screening procedures to determine eligibility within 28 days before randomization. All the eligible subjects will be screened and included in the study after verifying the inclusion and exclusion criteria. All subjects who are eligible for the study will be randomized into a 2:1 (Test: Reference) allocation ratio in either of the two treatment groups using central IWRS-based randomization.

Study medications (Test or Reference) shall be administered intravenously at a dose of 7.5mg/kg b.w. along with chemotherapy XELOX (Oxaliplatin + Capecitabine) every 3 weeks for 6 cycles. Oxaliplatin will be administered at a dose of 130 mg/m^2 as an IV infusion in 500 mL of 5% dextrose over 2h on Day 1 of each cycle after the completion of BP01(Bevacizumab)/Avastin®

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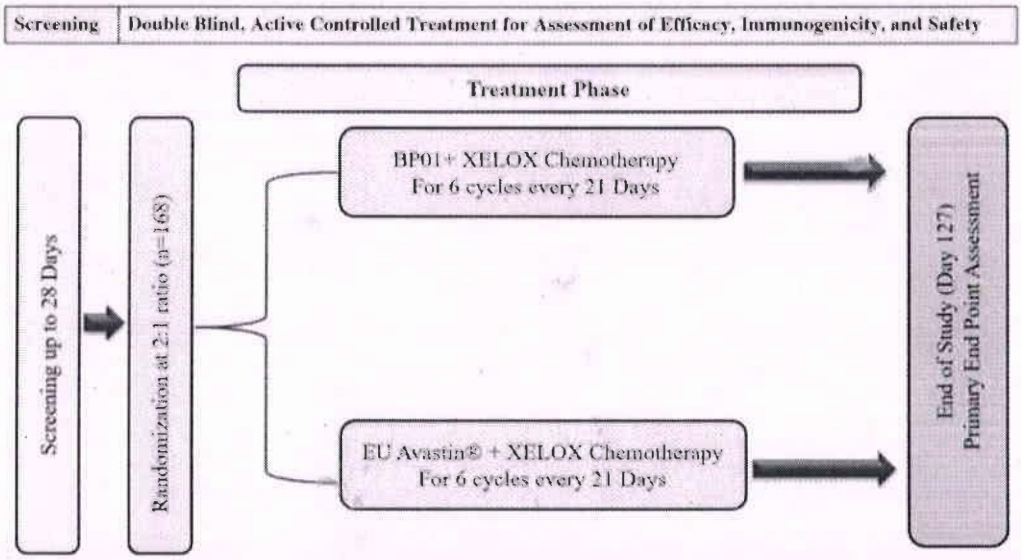
Study Flow-Chart:



In addition to the efficacy and safety investigations, samples will also be collected for Immunogenicity assessment(s). Immunogenicity (anti-bevacizumab antibodies) samples will be collected from all subjects at baseline (pre-dose before cycle 1), at Cycle 3 (Day 43 ± 3 Days) after completion of chemotherapy cycle and End of Study Visit (Day 127 ± 5 Days) or at withdrawal visit.

A DSMB will be constituted to monitor the safety of the investigational products. First fifteen (15) patients randomly assigned to the study shall undergo evaluation of drug related toxicities after first dose. Further recruitment would take place once the DSMB has reviewed the safety data of these patients.

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TARGET POPULATION AND KEY INCLUSION / EXCLUSION CRITERIA:

Inclusion Criteria:

1. Male and female patients 18 years and above.
2. Histopathologically confirmed colorectal cancer.
3. Diagnosis of metastatic colorectal cancer which is not amenable to curative surgery and/or radiation.
4. Patients who have not received any treatment for metastatic colorectal cancer [i.e., only 1st line mCRC patients].
5. Measurable disease on radiological assessment according to RECIST 1.1 criteria.
6. Subjects with Eastern Cooperative Oncology Group (ECOG) PS 0 or 1 at the time of screening and before the first infusion.
7. Have a life expectancy of at least 4 months as per the investigator.
8. The Patient is able to understand and is willing to give informed consent and is able to comply with the requirements of the study protocol.
9. A woman of childbearing potential must have a negative highly sensitive serum (β-human chorionic gonadotropin [β-hCG]) at screening and urine β-hCG test at randomization.
10. Women of childbearing potential and men must be using two acceptable methods of contraception, (e.g., intra-uterine device plus condom, spermicidal gel plus condom, diaphragm plus condom, etc.) for the entire duration of the study from the time of screening and 4 months following the completion of therapy.

Exclusion Criteria:

1. Received prior chemotherapy for metastatic disease [chemotherapy for primary disease is acceptable].
2. Prior treatment with bevacizumab.
3. History of haemoptysis, thrombotic or haemorrhagic event in the past 6 months.
4. Therapeutic anticoagulation; regular use of aspirin (325 mg/day), NSAIDs, or agents known to inhibit platelet function.
5. Radiation therapy for metastatic disease or surgery within 1 month of randomization.
6. Serious non-healing wound or bone fracture.
7. Known hypersensitivity to bevacizumab, capecitabine, or oxaliplatin.
8. Urine protein on dipstick analysis ≥ 2+ [If urine protein is ≥2+, further assessments should show urine protein: creatinine ratio 0.5 grams protein per gram creatinine by urinalysis OR

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total urinary protein 1,000 mg by 24-hour urine collection for inclusion.

9. Patients with known dihydropyrimidine dehydrogenase (DPD) deficiency.
10. High levels of SGOT 3 x ULN and 5 x ULN in patients with liver metastasis. Serum bilirubin 1.5 X ULN.
11. Patients with known or suspected brain metastases. Patients with a history of CNS metastases are eligible if they have been successfully treated and are off steroids for at least 4 weeks before randomization.
12. Patients with a history of prior malignancy other than colorectal cancer.
13. Other invasive malignancies within the past 5 years except for nonmelanoma skin cancer and successfully treated cervical carcinoma in situ.
14. Patients with severe renal impairment (estimated creatinine clearance below 30 mL/min) study.
15. Patients with a current history of drug/alcohol abuse.
16. Patient in the opinion of the investigator is not capable of complying with the study.
17. The patient is unable or unwilling to give written informed consent.
18. The patient has participated in an investigational drug study within the last one month.
19. Receipt of IV antibiotics for infection within 14 days of randomization.
20. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (e.g., compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments.
21. History of hepatitis B surface antigen (HBsAg) or hepatitis C antibody (anti-HCV) positive, or other clinically active liver disease, or tests positive for HBsAg or anti-HCV at Screening.
22. History of human immunodeficiency virus (HIV) antibody positive, or tests positive for HIV.
23. Received an investigational intervention (including investigational live vaccines) or used an invasive investigational medical device within 30 days or 5 half-lives before the Baseline, whichever is longer, before signing the consent.

INVESTIGATIONAL PRODUCT(s):

Test product (T):
BP01 (Bevacizumab 400mg) concentrate for solution for intravenous infusion.
Dosage Form & Strength: Concentrate for solution for intravenous infusion containing Bevacizumab 400mg/16 ml.

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Reference Product (R):
EU approved Avastin® (Bevacizumab 400mg) concentrate for solution for intravenous infusion. Dosage Form & Strength: Concentrate for solution for intravenous infusion containing Bevacizumab 400mg/16 ml.

PERMITTED CONCOMITANT MEDICATIONS

In addition to the study medication, BP01(Bevacizumab) or EU approved Avastin®, all subjects shall receive XELOX Chemotherapy containing Oxaliplatin administered at a dose 130 mg/m^2 as an IV infusion in 500 mL of 5% dextrose over 2h on Day 1 of each cycle after the completion of BP01-/Avastin infusion and Oral capecitabine 1000 mg/m^2 administered twice daily on Day 1 through Day 15 (28 doses) of a 21-day cycle. The first dose of capecitabine will be started on the evening of Day 1 and the last dose on the morning of Day 15, for each cycle.

Patients will be instructed to take capecitabine tablets within 30 min after the end of a meal with a glass of water (breakfast and dinner). It is planned that this dose of XELOX chemotherapy will remain stable for the entire duration of the study. Chemotherapy dose modifications are permitted during the study in case of drug-related toxicities or any safety events to study subjects.

Pre-medication is to be used to reduce the risk of occurrence of Infusion-related reactions (IRRs). Prophylactic anti-emetic therapy (Dexamethasone 4 to 12mg plus NK-1 & 5-HT$_3$ antagonists) within 30 to 60 minutes before the start of chemotherapy is recommended (as per PI discretion) for all subjects before receiving chemotherapy. Pharmacotherapy is allowed for the management of emesis, diarrhea, fever, and other post chemotherapy complications.

Patients will be allowed to continue other concomitant medications as directed by the physician. Any new medications prescribed by other providers or non-prescription medications obtained by the patient shall be reported to the Principal Investigator and noted in the patient's medical record.

- Low-dose aspirin < 325 mg/d) may be continued in subjects at higher risk for arterial thromboembolic disease. Subjects developing signs of arterial ischemia.
- Palliative and supportive care for disease-related symptoms will be offered as needed to all patients in this study.
- Colony-stimulating factors (i.e., G- or GM-CSF) may be used at the discretion of the Investigator.
- Patients taking therapeutic dose-levels of coumarin-derivate anticoagulants concomitantly

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with capecitabine should be switched to low molecular weight heparin. Low-dose coumadin (e.g., 1 mg po per day) in patients with in-dwelling venous access devices is allowed but frequent INR monitoring is recommended.

- Increased phenytoin plasma concentrations have been reported during concomitant use of capecitabine with phenytoin, suggesting a potential interaction. Patients taking phenytoin concomitantly with capecitabine should be regularly monitored (e.g., weekly phenytoin and albumin levels) for increased phenytoin plasma concentrations and associated clinical symptoms.

Rescue Medications:

The rescue medication will only be administered at the discretion of the Investigator. Details of rescue medication and any hospitalization will be documented in CRF in line with the primary and secondary objective assessment requirements.

DOSE AND MODE OF ADMINISTRATION:

- BP01 (Proposed Bevacizumab biosimilar) and reference biologic EU approved Avastin® are the investigational medicinal products administered intravenously to the patients in the study.

BP01/ Avastin® Dose Preparation and Handling:

BP01/ Avastin® will be provided as single use vials containing 400 mg/16 mL concentrate for solution for infusion with the final protein concentration of 25 mg/mL Bevacizumab. Bevacizumab will be a sterile, preservative-free, and clear to slightly opalescent, colorless to pale brown liquid for IV infusion in single use vials. Bevacizumab BP01/ Avastin® vials should be stored unopened at 2° to 8°C. Vials should be protected from light in the outer carton and should not be frozen or shaken.

The drug product is diluted in 0.9 % sodium chloride solution before administration. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 25±2°C.

BP01/ Avastin® should be prepared by a healthcare professional using an aseptic technique to ensure the sterility of the prepared solution. A sterile needle and syringe should be used to

prepare BP01/Avastin®. The necessary amount of bevacizumab should be withdrawn and diluted to the required administration volume with sodium chloride 9 mg/ml (0.9%) solution for injection. The concentration of the final bevacizumab solution should be kept within the range of 1.4 mg/ml to 16.5 mg/ml. The necessary amount of BP01/Avastin® should be diluted with 0.9 % sodium chloride solution for injection to a total volume of 100 mL. Final reconstituted medicinal products should be inspected visually for particulate matter and discolouration prior to administration. No incompatibilities between Bevacizumab BP01/Avastin® and polyvinyl chloride or polyolefine bags or infusion sets have been observed. Any unused medicinal product or waste material will be returned to Sponsor/CRO/clinical supply vendor.

Dose Administration:

BP01/ Avastin® will be administered at a dose of 7.5 mg/kg b.w. The initial dose will be delivered over 90±15 minutes. If the first infusion is tolerated without infusion-associated adverse events (fever and/or chills), the second infusion may be delivered over 60±10 minutes. If the 60-minute infusion is well tolerated, all subsequent infusions may be delivered over 30±10 minutes.

If a subject experiences an infusion–associated adverse event, he or she may be premedicated for the next study drug infusion; however, the infusion time may not be decreased for the subsequent infusion. If the next infusion is well tolerated with premedication, the subsequent infusion time may then be decreased by 30±10 minutes as long as the subject continues to be premedicated. If a subject experiences an infusion-associated adverse event with the 60-minute infusion, all subsequent doses should be given over 90±15 minutes. Similarly, if a subject experiences an infusion-associated adverse event with the 30-minute infusion, all subsequent doses should be given over 60±10 minutes.

Bevacizumab infusions should not be administered or mixed with glucose solutions.

Patients should be observed for at least six hours after the start of the first infusion and for two hours after the start of the subsequent infusions for symptoms like fever and chills or other infusion-related symptoms. Interruption or slowing the rate of the infusion may help control such symptoms. The infusion may be resumed when symptoms abate.

- XELOX Chemotherapy containing IV Oxaliplatin and Oral Capecitabine will be administered to all subjects along with BP01/ Avastin®:

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Oxaliplatin Dosing:
Oxaliplatin will be administered at a dose of 130 mg/m^2 as an IV infusion in 500 mL of 5% dextrose over 2h on Day 1 of each cycle after the completion of BP01/ Avastin® infusion.

Capecitabine Dosing:
Oral capecitabine 1000 mg/m^2 will be administered twice daily on Day 1 through Day 15 (28 doses) of a 21-day cycle. The first dose of capecitabine should be started in the evening of Day 1 and the last dose should be taken on the morning of Day 15, for each cycle. Patients will be instructed to take capecitabine tablets within 30 min after the end of a meal with a glass of water (breakfast and dinner).

DOSE MODIFICATIONS AND/OR ADJUSTMENTS DUE TO TOXICITY:

Toxicity will be graded according to the NCI CTCAE, Version 5.0 except for neurosensory and skin toxicity. Neurosensory toxicity will be graded according to the Neurologic Toxicity Scale for Oxaliplatin Dose Adjustments (see **Table 6**). For any CTCAE toxicity thought to be at least possibly related to therapy, further treatment will be guided by the dose adjustment **Tables 4, 5, and 7**.

For any event that is apparent at baseline, the dose modification will apply according to the corresponding shift in toxicity grade if the investigator feels this is appropriate, (e.g., if a patient has grade 1 asthenia at baseline which increases to grade 2 during treatment, this will be considered as a shift of 1 grade and treated as a grade 1 toxicity for dose modification purposes). Neurosensory toxicity does not result in dose reduction for capecitabine or bevacizumab. If creatinine clearance declines to <50 ml/min during the study, no capecitabine dose reduction is required unless there are concomitant AEs requiring reduction.
In patients with known Gilbert's syndrome, direct bilirubin will be used to assess organ function instead of total bilirubin.

Capecitabine treatment interruptions are regarded as lost treatment days and missed doses should not be replaced; the planned treatment schedule should be maintained. Once a dose of capecitabine or oxaliplatin has been reduced, it should not be increased at a later time. Reasons for dose modifications or delays, the supportive measures taken, and the outcome will be documented in progress notes. Radiographic tumor evaluation should be performed every 3 cycles.

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A new cycle of chemotherapy with capecitabine, oxaliplatin, and bevacizumab will be delayed until:

- Absolute neutrophil count ≥ 1000/mm^3 and platelet count ≥ 75,000/mm^3
- Recovery from any treatment-related non-hematological toxicity (except alopecia, and oxaliplatin-related neurosensory toxicity) to baseline or ≤ grade 1. At the treating physician's discretion, a new cycle may be started with a grade 2 toxicity, if the toxicity is not felt to be clinically meaningful and is in the best interest of the patient.

If toxicity requires a dosing delay for more than two consecutive cycles of Bevacizumab from the planned cycle time, study treatment will be discontinued. If capecitabine or bevacizumab must be discontinued permanently due to toxicity, the subject will be discontinued from the study. If oxaliplatin must be discontinued permanently due to either neurological toxicity or hypersensitivity reaction, then treatment with capecitabine and bevacizumab may continue on the protocol. In addition, oxaliplatin may be discontinued permanently for recurrent thrombocytopenia (Grade 3 or Grade 2 thrombocytopenia that is not recovered to grade ≤1 by Day 28) despite two oxaliplatin dose reductions and for persistent fatigue in patients who have been on treatment for over six months.

Persistent fatigue is defined as grade 2 or more fatigue on two sequential cycles in a patient who has been on study for greater than six months from the first dose of the study drug. If the reason for oxaliplatin discontinuation is due to any other toxicity then study treatment will be discontinued. Two dose reductions are allowed for capecitabine and oxaliplatin (see **Table 7**). If a third reduction is required then that patient will be removed from the study. If the treating physician feels that the given toxicity requiring dose adjustment is only due to one study drug, oxaliplatin or capecitabine, then dose adjustment for only that one study drug may be done. There are no dose adjustments for bevacizumab. For management of adverse events due to bevacizumab see **Table 4**. For dose modifications due to capecitabine and oxaliplatin see **Tables 5** and **6**.

Dose Modifications for Bevacizumab

No dose reduction of BP01/ Avastin® is foreseen for an individual patient. Skipped doses or termination of treatment will be based on observed toxicities as specified below. If adverse events occur that require holding bevacizumab, the dose will remain the same once treatment resumes.

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Any toxicities associated or possibly associated with bevacizumab treatment should be managed according to standard medical practice. Discontinuation of bevacizumab will have no immediate therapeutic effect. Bevacizumab has a terminal half-life of 21 days; therefore, its discontinuation results in slow elimination over several months. There is no available antidote for bevacizumab. Subjects should be assessed clinically for toxicity before, during, and after each infusion. If unmanageable toxicity occurs because of bevacizumab at any time during the study, treatment with bevacizumab should be discontinued.

Infusion Reaction: Infusion of bevacizumab should be interrupted for subjects who develop dyspnea or clinically significant hypotension. Subjects who experience an NCI CTCAE v. 5.0 Grade 3 or 4 allergic reaction/hypersensitivity, adult respiratory distress syndrome, or bronchospasm (regardless of grade) will be discontinued from bevacizumab treatment.

The infusion should be slowed to 50% or less or interrupted for subjects who experience any infusion-associated symptoms not specified above. When the subject's symptoms have completely resolved, the infusion may be continued at no more than 50% of the rate before the reaction and increased in 50% increments every 30 minutes if well tolerated. Infusions may be restarted at the full rate during the next cycle.

Missed doses will not be made up for. A rounding up or down of the dose is acceptable to allow practical ease of administration (±10%). Refer to **Table 4** for specific instructions on Bevacizumab Dose Modification / Adjustment due to Adverse Events.

CLINICAL ENDPOINTS:

Primary Efficacy Endpoints:

- Objective response rate (ORR) as per RECIST Version 1.1 at EOS (Day127±5 Days).
  [ORR is defined as the proportion of patients with complete response (CR) or partial response (PR) as assessed by Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.]

Secondary Efficacy Endpoints:

- ORR at Cycle 4 (Day 64± 3 Days).

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- Overall survival at EOS (Day127±5 Days).
- Progression free survival at EOS (Day127±5 Days).
- Disease control rate at EOS (Day127±5 Days).

Immunogenicity Endpoints:

- Incidence and Titres of Anti-Bevacizumab Antibodies between both groups.
  [Baseline (pre-dose before cycle 1), Cycle 3 (Day 43 ± 3 Days) after completion of chemotherapy cycle and End of Study Visit (Day 127 ± 5 Days) or at withdrawal visit.]

Safety Endpoints:

- Treatment Emergent Adverse Events (TEAEs) evaluated based on changes in clinical signs and symptoms and changes in safety laboratory values.

EVALUATION OF SAFETY:

An adverse event is defined as any untoward medical occurrence (sign, symptom, or laboratory finding), regardless of severity and whether or not attributed to the investigational product.

All adverse events, whether observed by an Investigator or Study Coordinator or reported by the subject, whether related to the study drug or not related to the study drug, shall be documented on the CRF and subject records, together with details, i.e., date of onset, the duration and intensity of each episode, the action taken, the relationship to the investigational product and the degree of severity, the seriousness and the outcome.

Safety and tolerability to treatment were evaluated according to routine laboratory tests (hematology and biochemistry), 12-lead ECGs, clinical examinations, and the incidence, severity, and type of AEs reported by the patients over the course of treatment.

- Vital Signs and Body Measurements: At all visits
- 12-lead ECG Evaluations: At all visits.
- Hematology: Hemoglobin, Platelets, RBC, ANC, Differential WBC Counts at all visits
- Serum Biochemistry: LFT: Total Bilirubin (Direct Bilirubin to be performed in patients with Gilbert's syndrome), ALP, AST, ALT; KFT: Creatinine, BUN, Albumin, Creatinine clearance (using the Cockcroft and Gault formula); Electrolytes (NA^+, K^+, Cl^-) at all visits.

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- Coagulation Profile: D-dimer, PT/INR and APTT [at screening, baseline, before each treatment cycle, and End of Study (EOS)] Urinalysis: Appearance, bilirubin, blood, color, epithelial cells, glucose, ketones, nitrite, pH, proteins, RBCs, WBCs, urobilinogen, specific gravity at all visits
- Spot UACR (Dipstick method): Screening, Visit 4 (Cycle 3), Visit 6 (Cycle 5) and EOS
- HIV, HbsAg, and HCV antibody tests: Screening
- Pregnancy test (Serum): Screening
- Pregnancy test (Urine): to be repeated at all visits from randomization until the end of Study
- 2D-ECHO / MUGA: Screening, Visit 5 (Cycle 4), End of Study Visit.
- Bone Scan – Screening
- Brain CT or MRI: Screening
- Injection site monitoring will be performed after study drug administration.

All AEs were coded using the latest Medical Dictionary for Regulatory Activities Version and grouped by treatment. The number and percentage of AEs, SAEs, AEs leading to discontinuation, AEs of Special Interest, and AEs related to the study drug will be summarized by system organ class, preferred term, and treatment group. The NCI Common Terminology Criteria for Adverse Events version 5.0 will be utilized for Adverse Event (AE) reporting. A grading (severity) scale will be provided for each AE term. The number and percentage of AEs by severity will also be summarized separately for TEAEs and all AEs. All AEs will be displayed in listings. The AEs will be summarized by severity and outcome of the event as well. Any AEs determined to be of interest or occurring frequently may be summarized separately using the same methodology as described above. Key information tables and narratives will be presented for SAEs and deaths.

A summary of the vital signs, physical examination, laboratory parameter values, and other safety values (e.g., ECG) at relevant time points as well as change from baseline will be presented. A summary of physical examination findings will be presented by visit. A summary of concomitant medications will be presented.

Safety evaluations in the study will be performed using the Safety **Analysis Set (SAF)**. The Safety Analysis Set (SAF) consists of all subjects who took at least 1 dose of study medication and will be used for safety analysis.

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A descriptive analysis comparing the rate, intensity, and severity of adverse events in both treatment groups will be performed.

EVALUATION OF IMMUNOGENICITY:

Immunogenicity will be evaluated by assessing serum levels of anti-bevacizumab antibodies in all patients of both the treatment groups.

Immunogenicity testing will be done at Baseline (pre-dose before cycle 1), Cycle 3 (Day 43 ± 3 Days) after completion of the chemotherapy cycle, and End of Study Visit (Day 127 ± 5 Days) or at withdrawal visit. Immunogenicity shall be assessed using a validated method, centrally at a laboratory with capabilities of analyzing anti-bevacizumab antibodies (screening and confirmatory) using a standard, globally accepted & validated method & following GLP principles of testing.

For the assessment of immunogenicity endpoints, a Safety Analysis Set (SAF) will be used, which will consist of all patients who received at least 1 administration of study drug. All analyses using the SAF will group patients according to the treatment received.

EVALUATION OF EFFICACY:

All patients will be assessed for improvement in clinical signs and symptoms of the disease improvement at screening and all subsequent study visits. The efficacy of the treatment will be assessed using the following criteria:

Primary Efficacy Endpoint:

- Objective response rate (ORR) as per RECIST Version 1.1 at EOS (Day127±5 Days).

[ORR is defined as the proportion of patients with complete response (CR) or partial response (PR) as assessed by Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.]

Secondary Efficacy Endpoint:

- ORR at Cycle 4 (Day 64±3 Days).
- Overall survival at EOS (Day127±5 Days).
- Progression free survival at EOS (Day127±5 Days).
- Disease control rate at EOS (Day127±5 Days).

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The efficacy evaluations will be performed using the following analysis sets for this study:

- **Intent to Treat (ITT):** The ITT set will consist of all subjects who are randomized, and receive at least 1 dose of investigational product. This will be the primary analysis set for efficacy analyses.

- **Per protocol population (PP):** The Per-Protocol set will be a subset of subjects in the ITT set and at least one Post baseline assessment without any important protocol deviations. The criteria to determine protocol deviations will be defined in the SAP. The PP set will be a secondary analysis set for efficacy analyses.

  This will constitute all the enrolled subjects who were compliant with the assigned study treatment and completed evaluation on Day 127 (Week 18) with no major protocol deviations that would affect the evaluation or interpretation of the primary efficacy endpoint. Protocol compliance will be evaluated by questioning the subjects, reviewing subject diaries for missed doses, etc.

- **Safety Analysis Set (SAF):** The SAF will consist of all patients who received at least 1 administration of study drug. All analyses using the SAF will group patients according to the treatment actually received. The SAF will be used for Safety and immunogenicity endpoints.

STATISTICAL METHODS:

Valid statistical tools [SAS (Version 9.4) or SPSS (Version 26.0) or higher] will be used for analysis in this study. A statistical analysis plan (SAP) will be prepared separately from this protocol which gives descriptions of the statistical methods, models, hypothesis, and analysis populations to be analyzed. The SAP will serve as a companion to the protocol and will serve as the de facto documentation of the proposed statistical evaluations.

Sample Size Rationale:

- ORR at Day 127±5 Days is expected to be 42% in both arms. The expected difference in proportions is 0%
- Allocation ratio = 2:1 (Test: Reference)
- Non inferiority margin of -25% is considered.

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- Power = 90%
- Significance Level of 5%
- Required sample size for BP01 = 102, for Avastin = 51

Based on the above estimate, a sample size of 153 patients would be sufficient to establish therapeutic equivalence between test and reference arms with adequate power. However, considering ~10% drop-out rate, a sample size of 168 (112 Test: 56 Reference) will be enrolled for this study.

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Exhibit-B

PART 1- Budget & Payment Schedule

Protocol Title: A prospective, Randomized, Double Blind, Multicentric, Parallel Group Phase-III Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of BP01 (Bevacizumab) Versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients."

Protocol No: ICS/CUR/2023-006

Estimated Per Subject Fee: [including all fixed costs, institutional overheads (as applicable) & other Compensation below]: Based on the ongoing discussions with site team it has been assumed that the site and PI will make all possible attempt to achieve at least 3-4 enrolments per month in the study. Accordingly, the following study budget has been offered to proportionately compensate for the efforts and resources being utilized by the site and study team members.

VISITS	PI	Co-I	CRC/ Nurse	Phlebo	Pharmacist	Patient TA	Cardiologist	Day Care +Pre medication +Food Allowance	Total
Screening (V1)	5000	2000	1500	500	0	0	1500	0	10500
Randomization / Cycle 1 (V2)	5000	2000	1500	500	500	400	0	3000	12900
Cycle 2 (V3)	5000	2000	1500	500	500	400	0	3000	12900
Cycle 3 (V4)	5000	2000	1500	500	500	400	0	3000	12900
Cycle 4 (V5)	5000	2000	1500	500	500	400	1500	3000	14400
Cycle 5 (V6)	5000	2000	1500	500	500	400	0	3000	12900
Cycle 6 (V7)	5000	2000	1500	500	500	400	0	3000	12900
EOS / FU (V8)	5000	2000	1500	500	0	400	1500	0	10900
Sub Total	40000	16000	12000	4000	3000	2800	4500	18000	100300
IOH 25%	10000	4000	3000	1000	750	700	1125	4500	25075
Grand Total	50000	20000	15000	5000	3750	3500	5625	22500	**125375**

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PRICE LIST FOR RADIOLOGY/IMAGING TESTING

Test	Frequency	Total Cost
Bone Scan (Whole Body) (includes interpretation and report)	1	12000
Brain CT (includes interpretation and report)	1	2000
Chest CT (includes interpretation and report)	1	2500
Chest CT Contrast (includes interpretation and report)	1	3000
Whole Abdomen CT (includes interpretation and report)	3	9000
Whole Abdomen CT Contrast (includes interpretation and report)	3	15000
Brain MRI (includes interpretation and report)	1	3500
Chest MRI (includes interpretation and report)	1	4500
Whole Abdomen MRI (includes interpretation and report)	3	22500
12 Lead ECG	8	1600
MUGA /2DECHO	3	6000
Chest Xray	1	200

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PRICE LIST FOR LABORATORY TESTING

NABL LAB ONLY

S.NO.	TEST	FREQUENCY	TOTAL
1	Hematology	8	30345
2	LFT: Total Bilirubin,ALP,AST,ALT	8	
3	KFT: Creatinine, BUN,Albumin,Creatinine clearance	8	
4	Coagulation Profile -D-DIMER	8	
5	PT/INR,APTT	8	
6	RT-PCR	1	
7	Serum Electrolytes NA+,K+,CL-	8	
8	Urinalysis:Appearance,Bilirubin,Blood,Colour, Epithelial Cells,Glucose, Ketones, Nitrite, pH,Protein,RBCs,WBCs,Urobilinogen,Specific Gravity,	8	
9	Spot UACR (Dipstick Method)	4	
10	HIV	1	
11	HCV	1	
12	HBsAg	1	
13	Pregnancy Test (Serum)	1	
14	Pregnancy Test (Urine)	7	

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TERMS & CONDITIONS

- The above budget is inclusive of non- procedural charges including but not limited to PI & Co-I Grant, CRC, Nurse, Phlebotomist Grant, hospital day care and premedication and Institutional overheads.
- The payment for the radiology/imaging testing will be paid on pro-rata basis. Same modality to be used for a particular subject throughout the study.
- The subject is considered as completed when the subject has completed the specified study period and is evaluated as per the Protocol.
- The above grant is for Completed subject's only. A 10% drop outrate is acceptable and only lab costs applicable till the last visit performed for drop out subjects. Reimbursement for discontinued or early termination or dropout Study Participants will be prorated based on the number of confirmed completed visits
- A sum **of Rs. 3000 per subject** will be paid as investigator fees for up to **ratio of 4:1 of Randomized: Screen Fail** of the Subjects at site. To be eligible for reimbursement of screening visit, completed screening CRF pages must be submitted to Sponsor and any additional information, which may be requested by Sponsor to appropriately document the Study Participant screening procedures.
- There are no other miscellaneous charges acceptable except the above-mentioned amount.
- Sponsor will provide study drug and chemotherapy drugs for all study visits.
- Sponsor will provide Subject file with required documents (Source templates and Diary card)
- Sponsor will provide required stationary to site
- All required data shall be filled on EDC and scan of source and radiology reports shall be uploaded along with data entry **within 5-7 days of visit completion** (per subject) up to 90% with minimum error.
- Final payments made will be only on the basis of SDV of subjects completed in the trial.
- No payments will be processed if no patients are enrolled and / or screened within two months from date of study was conducted at site
  Last one invoice of PI/Site/CRC Grants will be kept on hold until final CSR is signed.
- Any additional investigation(s) / Procedure(s) performed as per Principal Investigator's discretion will be reimbursed upon submission of hard copy of correct original invoice
- Tax deduction at source (TDS) as per the applicable regulations

PAYMENT MILESTONES

For Randomized Completed Subjects:

- Site Pass-Through costs (lab assessments, imaging, radiological charges etc.): Invoice to be submitted every 60 days from the date of FSI (First Subject Randomized) for payment of accrued amounts for randomized / completed subjects.
- PI/Site/CRC Grants: Invoice to be submitted every 90 days till close-out for payment of accrued amounts for randomized / completed subjects.

For Screen Failures Acceptable limit for payment of screen failure shall be 4:1 (Randomized: Screen Failure) subjects for each site, following invoicing milestone to apply:

- Site Pass-Through costs (lab assessments, imaging, radiological charges etc.), PI/Site/CRC Grants: Invoice to be submitted during site closeout at the site.

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For LTF/Drop-outs/Withdrawals (Max. allowable limit is Not More Than 10% of randomized subjects per site), for payment following invoicing milestones to apply:

- Site Pass-Through costs (lab assessments, imaging, radiological charges etc.): To be paid on pro-rata basis as per approved pricing, Invoicing Milestone will be Site Close-out visit.
- PI/Site/CRC Grants: Invoicing Milestone will be Site Close-out visit.

*Last one invoice of PI/Site/CRC Grants will be kept on hold until final CSR is signed.

Screen Failure Payments: As mentioned above.

Archival Fee: The Trial site/PI shall arrange for Archival of documents as per (NDCT) Rules, 2019. Fee for such archival shall be mutually decided and documented separately, by the parties herein at a later date, which shall be read as part and parcel to this agreement.

Payment Terms:

a) This EXHIBIT-B is for completed records for valid subjects. A valid subject is defined as a subject who meets eligibility requirements to enroll in the Study and does not have significant Protocol violations that would exclude his/her Data from analysis. Sponsor anticipates closure of enrollment upon randomization of a total of 168 valid subjects across all the sites participating in the study. In the event 168 total valid subjects are enrolled, further recruitment will be suspended. No payment will be made for any subject excluded from analysis because of Protocol violations within the Study personnel's control

b) Trial Site acknowledges this is a multicenter Study designed to evaluate a set number of Study subjects. When enrollment of the target number of Study subjects in the Study is complete, those sites will be notified and instructed not to continue enrolling Study subjects.

c) If required, Sponsor will, at its cost, provide, through a third party vendor, thermometer equipment valued at up to Rs. 4,000 for better clinical results and use as envisaged in the Protocol. Upon termination of the Study at Trial Site, the equipment will be taken back by the Sponsor from the Trial Site. It is clarified that the ownership of the thermometer equipment shall always belong to the Sponsor and Sponsor/ CRO shall be responsible for the costs relating to the installation, repair, maintenance, use, and insurance of the equipment during the study and shall take care of their removal upon the completion of the Study.

d) Equipment Calibration: Trial Site shall be responsible for ensuring Trial Site-owned equipment utilized by Trial Site in accordance with this Agreement is serviced and/or

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calibrated as per manufacturer's recommendation and/or more frequently as required by Sponsor. Records verifying the equipment calibration and maintenance shall be provided to Sponsor upon request for calibrations which are performed solely at the request of Sponsor, and that are not part of the recommended scheduled maintenance suggested by manufacturer, Sponsor will reimburse Trial Site for the actual cost without mark-up for each calibration Processing of payment will begin upon receipt of invoice and supporting documentation in accordance with paragraph e) below.

e) To be eligible for payments, the procedures must be performed in full compliance with the Protocol and this Agreement, and Data submitted must be complete, correct and entered into the CRF in accordance with Sponsor's instructions. Payments will be made, at a minimum, on a fortnightly basis, once the corrected invoices are received. These payments will include milestone payments, as well as all invoiced and approved costs from the prior payment cycle. Ongoing reconciliations will be performed during the course of the study. Any erroneous payments discovered will be applied to any pending or future payments due. No payments will be made until all erroneous payments have been offset. If no pending or future payments exist, Trial Site will promptly refund overpayment according to Sponsor's instructions

Original invoices pertaining to this study should be submitted for reimbursement to the following address

TO

Insignia Clinical Services Pvt. Ltd.
Unit No. 512,
05th Floor, Best Sky Tower,
Netaji Subhash Place, Pitampura,
New Delhi-110034

A copy of the invoice, together with the supporting documentation should be emailed to simran.sohal@insigniacs.com and failure to do so, might delay the payment process

Please note that invoices must contain the following information, or they will be returned, delaying payment:

- Trial Site name
- Principal Investigator name
- Protocol number
- Invoice number and date
- Date & description of services provided Supporting documentation (i.e. third-party invoices, receipts)

CRO **Trial Site** **CTMO** **Principal Investigator**

Dr. Priyani . R.
MD(Path), Ph.D, AMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Dr. D. Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

- Any claims for reimbursement of adverse events must be submitted in a separate Invoice
- Site Purchase Order (PO) number
- ICS GST Number – 07AADCI0529A1Z7
- PAN (permanent account number)
- Site (micro, small and medium enterprises) MSME number (If applicable) Site GST number (if applicable)
- HSN/SAC (Harmonized System of Nomenclature/ Service Account Code)

f) Costs from, and reimbursement for, activities and items not specifically referenced above, including, but not limited to staff costs, laboratory fees, x-rays, scales and questionnaires (quality of life, etc.), data coordinator fees, travel fees, and subject reimbursement other than any subject stipends specifically identified above, are incorporated into the per-subject payment above. No additional reimbursement for these costs is otherwise provided.

g) For the avoidance of doubt, the Principal Investigator and/or the Trial Site are responsible for providing any and all compensation benefits and/or insurance to the investigational staff. It is also understood and expressly acknowledged that the Investigator and the investigational staff are not eligible to participate in, nor are they eligible for coverage under any of the Sponsor's benefit plans, programs, employment policies, procedures or workers compensation insurance.

h) The parties agree this EXHIBIT-B is part of the Agreement and clarifies the payment schedule associated with this Agreement Payments shall be made in accordance with the provisions set forth in this EXHIBIT-B, with the last payment being made after the site completes all of its obligations under the Agreement and any exhibits thereto. The Principal Investigator acknowledges and agrees his or her judgment with respect to his or her advice to and care of each subject is not affected by the compensation the site receives hereunder. The parties agree the payee designated below is the proper payee for this Agreement and payments under this Agreement will be made only to the following payee.

Payee Name: (This should be a business name and should match the business name used to file for your tax EIN or other tax IDD number)	SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH
Tax ID number: (Tax ID number must exactly match the payee Name indicated above)	PAN No: AAATS5344P GST No: 29AAATS5344P1ZT
Contact Information: (Name , Phone No., & e-mail address)	Name: Dr. Bhuvana.K
	Phone No:99003 83738

CRO **Trial Site** **CTMO** **Principal Investigator**

Dr. Kalyani . R.
MD, Path., Ph.D., FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Adichunchanagiri University, B G Nagara

Dr. D. Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103

	E-mail: bhuvanak@sduaher.ac.in
Payee Address:	Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar, Karnataka, India Pin code - 563101

Trial Site will have 30 days from the last subject out (LSO) date of the Study to resolve the payment discrepancies, which have arisen during the course of study.

CRO / **Trial Site** / **CTMO** / **Principal Investigator**

Dr. Kalyani . R.
FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Adichunchanagiri University, B G Nagara

Dr. B. Bhuvanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

PART-2 TAXES

1. Notwithstanding anything contained in the Agreement, the Trial Site agrees that it is eligible to receive part of the consideration being the Goods and Services Tax(GST) charged in respect of the supply only after the details of such supply are uploaded by the Institution in the Form GSTR-1 (or such other form as may be notified in lieu thereof from time to time). which is subsequently reflected in Form GSTR-ZA (or such other form as may be notified in lieu thereof from time to time), made available electronically to the Sponsor, and are considered as matched with the corresponding details furnished by the Sponsor in its returns in terms of the relevant provisions of the GST Laws.

2. The Trial Site agrees to indemnify the Sponsor and keep it indemnified from and against any or all Liabilities as defined in Explanation below that may accrue or be demanded by a Taxing Authority, in respect of or in connection with the execution of scope of work or payments made due to the Trial Site, arising under the said Agreement or anything done pursuant to the same. Any such compensation towards indemnification of Liabilities by the Trial Site to the Sponsor will be made within 15 days of the Liabilities accruing / demanded raised by Tax Authorities on the Sponsor either by way of issuance of demand or show cause notice or order or decree.

Explanation -

i. 'Liabilities in this Agreement means, "any kind of taxes / duties, disallowance of input tar credit. loss, damage, legal expenses, demands, claims, costs interest penalties including in relation to compliances arising under respective Taxing Statute in course of execution of scope of work".
ii. 'Liability accruing / demanded in this Agreement means, "any liabilities proposed to be imposed either during investigation or audit or by way of issuance of show cause notice or demanded by way of issuance of order or decree by Taxing Authority"

3. The Trial Site undertakes to be compliant with the anti-profiteering provision under Section 171 of the Central Goods and Services Act. 2017

4. **Other terms:**

a. The consideration payable under this Agreement shall be exclusive of applicable Goods and Services Tax (GST) including but not limited to COST and SGST /UTGST or IGST, and or applicable cess, as the case may be.
b. The Trial Site shall periodically its tax liabilities in compliance with me GST Laws in connection with the goods/ services supplied under this Agreement such that me Sponsor is entitled to claim such credit of input tax with respect to the good/services supplied under this Agreement as permitted under the GST Laws.

CRO Trial Site CTMO Principal Investigator

Prof. Dr. Kalyani . R.
MD(Path), PhD, FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Adichunchanagiri University, B.G Nagara

Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

c. The Trial Site hereby undertakes that it will make timely payments of all taxes, duties, levies imposed by Government (including but not limited to GST), be responsible for filing of all necessary tax returns and undertake all necessary compliances in accordance with applicable statutory requirements under the relevant statute in relation to sum received from the Sponsor.

d. The Trial Site hereby undertakes that it will issue the tax invoices within the statutory time limits as prescribed under the GST laws and in the manner and with all the prescribed particulars as are required to be specified as per the GST Laws.

e. The Trial Site hereby undertakes that the address / location of the Sponsor to which the invoice will be issued by the Trial Site will be as per the address mentioned in the Purchase Order (PO) issued by the Sponsor. Separately, prior to issue of an invoice, the Trial Site shall intimate the Sponsor about the address / location of the Sponsor to which the invoice will be issued and a prior approval from the Sponsor in this respect will be taken by the Trial Site.

f. The Trial Site undertakes that a debit note/ supplementary invoice/credit note with appropriate references to the original invoice will be issued only in such circumstances as agreed between the parties.

g. Post supply of goods / services under this Agreement, the Trial Site shall cooperate with the Sponsor and provide any information that may be reasonably requested by the Sponsor in connection with claiming such credit of input tax under the GST Laws such as tax invoice or debit note issued by the Trial Site or such other taxpaying document(s) as may be required as proof of payment of applicable GST by the Institution.

h. Where, transactions in respect of which the Sponsor has claimed input tax credit are notified as unmatched vis-à-vis the corresponding disclosures made by the Trial Site in his periodic returns, the Trial Site would extend necessary assistance including inter alia carrying out revision/ rectification of its returns, to enable the Sponsor to retain such claimed credits.

i. The Trial Site undertakes that it has secured required GST Registration(s), which is/are in full force and effect and no action or claim is pending nor threatened to revoke or terminate such registration(s) or declare such registration(s) as invalid.

CRO

Trial Site

Prof. Kalyani . R.
MD(Path), Ph.D, FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

CTMO

Adichunchanagiri University, B.G.Nagara

Principal Investigator

Dr. D. Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

Exhibit-C

Statement issued by Trial Site

1. That **Dr. Lokanatha Dasappa** is one of the consultant of the Trial Site and has signed an Agreement or equivalent document to this effect.

2. The PI is obligated to assign to the Trial Site all inventions and discoveries made in the course of their Consultancy arrangement, explicitly mentioned in the Agreement signed by both the Parties.

3. Trial Site approves and agrees PI to be the investigator for the study and responsible to the conduct of the study.

For R.L Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College

Dr. Kalyani R
(Director, Research & Development Cell,
SDUAHER)

Signature _____ Date and Stamp 25/09/'24

Prof. Dr. Kalyani . R.
MD(Path), Ph.D, FAMS, FICP, FIAMS, FIMSA, FKSTA
Director
Research and Development Cell, SDUAHER
Professor & Former Head
Dept. of Pathology, SDUMC

Dr. Lokanatha Dasappa
(Principal Investigator)

Signature _____ Date and Stamp 25.09.24.

Dr. D. Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

CRO

Trial Site

Prof. Dr. Kalyani . R.
MD(Path), Ph.D, FAMS, FICP, FIAMS, FIMSA, FKSTA
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CTMO

Adichunchanagiri University, B G Nagara

Principal Investigator

Dr. D. Lokanatha
Prof. of Medical Oncology
KMC No. 24954
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	**IN-KA84823512852466W**
Certificate Issued Date	:	03-Dec-2024 04:29 PM
Account Reference	:	NONACC (FI)/ kagcsl08/ SUGGAPPA LAYOUT/ KA-GN
Unique Doc. Reference	:	SUBIN-KAKAGCSL0809879871053824W
Purchased by	:	KOUSHIK GANGULY
Description of Document	:	Article 5(J) Agreement (in any other cases)
Property Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KOUSHIK GANGULY
Second Party	:	Dr BHUMA VENGAMMA RL JALAPPA HOSPITAL KOLAR
Stamp Duty Paid By	:	KOUSHIK GANGULY
Stamp Duty Amount(Rs.)	:	500 (Five Hundred only)

सत्यमेव जयते

G S SEVA KENDRA SUGGAPPA LAYOUT BRUHAT BENGALURU MAHANAGARA PALIKE Authorized Signatory

Please write or type below this line

CLINICAL TRIAL AGREEMENT
ERGOMED – INVESTIGATOR/INSTITUTION

This AGREEMENT is put in effect on the Effective Date and is made between:

Neuraxpharm Pharmaceuticals S.L. with registered offices at Av. Barcelona, 69. 08970 Sant Joan Despí, Barcelona, Spain (hereinafter referred to as the "**Sponsor**") represented by **ERGOMED** whose

representative is duly authorized to sign this Agreement on behalf of **Sponsor**, under the Letter of Authorisation issued on 10 July 2024.

and

Ergomed Clinical Research Private Limited, with registered offices at Wing A, Level 4, Dynasty Business Park, Andheri-Kurla Road, Andheri (East) Mumbai– 400059, Maharashtra, INDIA; CIN: U73200MH2013PTC249804 (hereinafter referred to as "**ERGOMED**").

and

R.L. Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, with registered offices at Tamaka, Kolar, Karnataka 563103 (hereinafter referred to as the "**INSTITUTION**") represented **by Dr. Kalyani R, Director, Research & Development Cell, SDUAHER** and **Dr Rajesh Venkataraman, Central Trial Monitoring Organization** with business address at **Adichunchanagiri Hospital, Adichunchanagiri University at B.G Nagara, Mandya, Karnataka -571 448.**

and

Dr. Bhuma Vengamma (name of the INVESTIGATOR), with business address at **R.L. Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar, Karnataka 563103,**(hereinafter referred to as the **INVESTIGATOR**).

WHEREAS:

ERGOMED and the Sponsor enteredinto an agreement by which the Sponsor requested and ERGOMED accepted to organize and manage the conduct of the following clinical trial in the interest and for the benefit of the Sponsor: "**A Double-Blind, Randomized, Placebo and Active Controlled Study to Evaluate the Efficacy and Safety of Once Daily, Extended Release Levetiracetam as Add-on Therapy in Patients with Refractory Partial Onset Epilepsy**", Protocol „**NXPLEVE/24/P3-6**"(hereinafter: "the **Clinical Trial**");

and

ERGOMED and Sponsor wish to involve the INSTITUTION and INVESTIGATOR in the Clinical Trial in the role referred to herein and the INSTITUTION and INVESTIGATOR accept such involvement.

WHEREBY IT IS AGREED AS FOLLOWS:

Article 1

Definitions

1.1. For the purpose of this Agreement, the following expressions shall have the meanings attributed to them below:

"**Adverse Event**" Any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational

drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given.

"Affiliate" Any business entity which controls, is controlled by, or is under the common control with the Sponsor or ERGOMED. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity. For the avoidance of any doubt, Affiliate shall mean as well a subsidiary or representative and branch office in any country.

"Agreement" This agreement comprising its clauses, schedules and any appendices attached to it.

"Case Report Form" or **"CRF"** A printed, optical, or electronic document, prepared by the Sponsor and/or ERGOMED and completed by the INVESTIGATOR, designed to record all of the Protocol required information to be reported to the Sponsor on each Clinical Trial Subject.

"Clinical Trial" That portion of the clinical trial referred to and described in the Protocol, that is to be conducted, at the INSTITUTION, under the supervision and direction of INVESTIGATOR, pursuant to the Protocol and subject to the terms and conditions of this Agreement.

"Clinical Trial Product" Levetiracetam extended-release granules

"Clinical Trial Subject" A person Enrolled in the Clinical Trial who meets all of the inclusion criteria and none of the exclusion criteria set forth in the Protocol and has signed a valid IRB/EC approved Informed Consent Form.

"Data Subject" or "Data **Principal"** Any natural person whose Personal Data is processed in accordance with this Agreement and who is listed in Schedule III.

"Enrolment" Recruitment (invitation to potential participants in the Clinical Trial for screening), screening (examination of the potential participants in the Clinical Trial by INVESTIGATOR for the purpose of determining the eligibility as per Protocol criteria, and, if a potential participant in the Clinical Trial is eligible for participation, presentation and discussion of the Clinical Trial implications with the potential participants in the Clinical Trial and obtaining from the potential participant in the Clinical Trial an Informed Consent Form to participate in the Clinical Trial), and/or randomization (as defined in the GCP). Also to include "Enrol" as the verb or any other derivation of the term.

"Informed Consent Form" The form prepared by the Sponsor and/or ERGOMED in conformance with the Regulations (as hereinafter defined), in consultation with the Sponsor, ERGOMED, and the IRB/EC, approved by the IRB/EC and signed by all Clinical Trial Subjects before they begin to participate in the Clinical Trial.

"INVESTIGATOR's team"	Qualified staff, determined by INVESTIGATOR, who participates in Clinical Trial e.g. INSTITUTION's employees and/or INSTITUTION's and / or INVESTIGATOR's contractors and/or consultants.
"IRB/EC"	Institutional Review Board(s) or Ethical Committees organized in accordance with the Regulations.
"Party"	ERGOMED, INSTITUTION or INVESTIGATOR and except where otherwise provided "Parties" shall mean all of them.
"Protocol"	"A **Double-Blind, Randomized, Placebo and Active Controlled Study to Evaluate the Efficacy and Safety of Once Daily, Extended Release Levetiracetam as Add-on Therapy in Patients with Refractory Partial Onset Epilepsy**", Protocol „**NXPLEVE/24/P3-6**"as amended from time to time by Sponsor and approved by the IRB/EC and the Regulatory Authority. The Protocol, as it may be amended from time to time in accordance with Regulations, is incorporated into this Agreement by this reference as Schedule I.
"Recruitment Period"	January 2025 to June 2026, or such later date as may be directed by Sponsor and approved by the competent authorities.
"Regulations"	All laws, rules, regulations and guidelines that apply to or govern the conduct of the multi-centre Clinical Trial and/or the Clinical Trial, including without limitation the applicable Drugs and Cosmetics Act, 1940; New Drugs and Clinical Trial Rules, 2023; Medical Device Rules, 2017; Indian Council for Medical Research Guidelines for Biomedical and Health Research Involving Human Participants, 2017; Good Clinical Practices Guidelines issued by the Central Drugs Standards Control Organisation; ICH guidelines (including E6: Good Clinical Practice: Consolidated Guideline, and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CHMP/ICH/135/95; hereinafter: "**GCP**"), together with the requirements in Clinical Trial Directive 2001/20/EC (4 April 2001) and the related guidance, guidelines and directives), the most recent version of Standard BS EN ISO 14155, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' ("**Helsinki Declaration**"), all relevant laws of the European Union if directly applicable or of direct effect, all Indian laws and all relevant regulations and ordinances and all relevant laws and regulations regarding data protection and privacy, especially the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 - General Data Protection Regulation or "**GDPR**"; Information Technology Act, 2000; Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011; Digital Personal Data Protection Act, 2023 ("**DPDPA**"); (together "**Data Protection Laws**"); and anti-bribery and ethical business conduct, and the requirements of the applicable regulatory authorities and the ethics committee and the policies of the INSTITUTION, as any of the foregoing may be amended from time to time, including the Clinical Trial Regulation EU 536/2014.

"**Regulatory Authority**" Any federal or state regulatory authority or government official or authority including the Central Drugs Standard Control Organization.

"**Serious Adverse Event**" An untoward medical occurrence during the Clinical Trial resulting in death or permanent disability, or hospitalisation of the ClinicalTrialSubject where the Clinical Trial Subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the Clinical Trial Subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defector life-threatening event.

"**Services**" The services of research and other services to be performed by the INSTITUTION and INVESTIGATOR in accordance with the Protocol and under the terms of this Agreement in order to carry out the Clinical Trial.

"**Timelines**" The dates set out in Schedule II hereto as may be amended by agreement between the Parties.

Article 2

Rights and obligations of the Parties

2.1. Pursuant to the terms and conditions of this Agreement, INSTITUTION through the efforts of INVESTIGATOR agrees to conduct the Clinical Trial according to the Protocol. INSTITUTION and INVESTIGATOR agree to use their best endeavours to recruit approximately four (4) Clinical Trial Subjects to participate in the Clinical Trial according to the Protocol and in accordance with the Timelines.

INSTITUTION shall ensure that the INVESTIGATOR uses her best efforts to Enrol only Clinical Trial Subjects who satisfy the Enrolment criteria according to the Protocol and shall not knowingly Enrol any participants which in her best professional judgment do not adequately meet the criteria for Clinical Trial Subjects.

The Sponsor or ERGOMED may request INSTITUTION to stop Enrolment at any time and for any reason.

2.2. INSTITUTION and INVESTIGATOR agree to perform the work required under the Protocol and this Agreement and to conduct the Clinical Trial with reasonable care and skill and in accordance with the Protocol, this Agreement, agreed standard operating procedures ("**SOPs**") and Regulations.

By signing the Agreement, INSTITUTION and INVESTIGATOR acknowledge that they have received and reviewed the full text of Protocol (as herein attached as Schedule I).

2.3. INSTITUTION and INVESTIGATOR shall protect the rights and welfare of Clinical Trial Subjects participating in the Clinical Trial in accordance with the Protocol.

2.4. The Parties shall obtain and maintain any and all licenses, permits, approvals required under the Regulations. Where the INVESTIGATOR obtains and maintains any licenses, permit, or approvals a copy of the same shall be provided to ERGOMED.

Specifically, INVESTIGATOR shall provide relevant information on the Clinical Trial and obtain a signed Informed Consent Form from each potential participant in the Clinical Trial (or his/her legal guardian, as appropriate) before initiating any Clinical Trial specific procedures.

Any proposed modifications to any Informed Consent Form must be approved by both the IRB/EC and ERGOMED or the Sponsor before being used for the Clinical Trial.

All original signed Informed Consent Forms shall be retained by the INVESTIGATOR and be available for the inspection by Sponsor, ERGOMED, their representatives and any agency or their designee.

2.5. ERGOMED shall submit to IRB/EC and the Regulatory Authority for the Clinical Trial approval.

INSTITUTION shall immediately notify ERGOMED and Sponsor if the IRB/EC approval of the Clinical Trial is suspended, terminated, or made subject to other sanctions by any government agency. INVESTIGATOR shall submit all required reports to the IRB/EC and obtain continuing review and approval by the IRB/EC as required by applicable Regulations.

2.6. INSTITUTION and INVESTIGATOR each represent and warrant that the INVESTIGATOR has the necessary expertise to perform the Clinical Trial, and that INVESTIGATOR meets and shall continue to meet the conditions set out in the applicable Regulations, especially in the GCP.

INVESTIGATOR further represents that INVESTIGATOR's medical license is in good standing; that INVESTIGATOR has never had a medical license suspended or revoked or otherwise restricted; that INVESTIGATOR has never been disqualified or otherwise been restricted in conducting clinical studies by any regulatory authorities and that INVESTIGATOR is not currently the subject of any disciplinary actions by any state or federal agency.

2.7. The INSTITUTION and INVESTIGATOR represent and warrant that the Clinical Trial shall be conducted in accordance with Protocol approved by the IRB and the Regulatory Authority.

The Sponsor or ERGOMED may request the Protocol to be amended from time to time. The INSTITUTION and INVESTIGATOR may apply for an amendment to the Protocol to the IRB and the Regulatory Authority.

Notwithstanding the foregoing, in case of any administrative or logistic changes or minor amendments to the Protocol or deviations from the Protocol to eliminate immediate hazard to the Clinical Trial Subject, the INSITUTION shall notify the IRB and Regulatory Authority in writing of administrative or logistic changes or minor amendmentswithin 30 (thirty) days.

If an amendment to the Protocol is initiated by the INSTITUTION or INVESTIGATOR, approval from ERGOMED and/or the Sponsor shall be obtained in writing prior to notifying the IRB and the Regulatory Authority.

2.8. INSTITUTION and INVESTIGATOR shall arrange for any other relevant personnel required to carry out the Protocol and shall ensure that at all times during the Clinical Trial there is enough personnel to support the Clinical Trial. In addition to the Article 2.11., the

INSTITUTION and / or the INVESTIGATOR shall inform ERGOMED of any change in the INVESTIGATOR's team. The INSTITUTION and INVESTIGATOR shall be solely responsible for such personnel and Sponsor and ERGOMED shall not be responsible or liable for the personnel appointed by the INSTITUTION and INVESTIGATOR and such personnel shall at no point in time be construed as employees of the Sponsor and ERGOMED.

2.8.1. The INSTITUTION shall comply with all applicable employment and occupational health and safety laws and regulations, including those related to employment practices, wages, and worker classification (such as meal and rest break laws, wage notices, separation pay, and overtime laws) including but not limited to Minimum Wages Act, 1948; Contract Labour (Regulation & Abolition) Act, 1970; Workmen's Compensation Act, 1923; Employees' Provident Funds and Miscellaneous Provisions Act, 1952 as may be amended and replaced from time to time.

2.9. INSTITUTION represents and warrants that it possesses all facilities, personnel and resources necessary to properly conduct the Clinical Trial; that any laboratory work performed at INSTITUTION shall be performed at a laboratory that is certified under the applicable Regulations; and that INVESTIGATOR's team is qualified and has the training necessary to comply with the Protocol and applicable Regulations as well as the appropriate time to deliver the Services under this Agreement.

2.10. ERGOMED may, at its sole option, arrange for the availability of a study coordinator, duly qualified by training and / or experience, to manage the administrative functions at the Clinical Trial site.

2.11. INSTITUTION and INVESTIGATOR shall perform the Clinical Trial efficiently and within the Timelines set out in Schedule II and the Protocol. INSTITUTION and INVESTIGATOR acknowledge and agree that when rendering the Services time is of the essence. INVESTIGATOR shall give written notice to ERGOMED as soon as a delay in the Timelines can be anticipated.

2.12. INVESTIGATOR shall personally conduct the Clinical Trial and supervise the work of the INVESTIGATOR's team. INVESTIGATOR and INSTITUTION shall not delegate their obligations from this Agreement to any third party without the prior written approval of ERGOMED and competent authorities, where required. INVESTIGATOR and INSTITUTION shall be responsible for supervising any third party to whom they delegate Clinical Trial related duties and shall remain at all times fully and solely liable to ERGOMED for any performance undertaken by such third party.

2.13. ERGOMED has the right to replace INVESTIGATOR if there is information available to ERGOMED that the INVESTIGATOR does not perform her obligations as set out in this Agreement.

2.14. If the INVESTIGATOR and / or the INSTITUTION respectively retains the services of any third party to perform Clinical Trial related duties and functions, INVESTIGATOR and / or the INSTITUTION respectively should: (i) inform ERGOMED thereabout; (ii) ensure this third party is qualified to perform those Clinical Trial related duties and functions, as per Regulations; (iii) implement procedures to ensure integrity of such performed Clinical Trial related duties and functions and any data generated and (iv) remain at all times fully and solely liable to ERGOMED and the Sponsor for any performance undertaken by any such third parties for the quality, completeness and fulfilment of the work.

2.15. INVESTIGATOR shall timely prepare and maintain adequate and accurate case histories of each Clinical Trial Subject Enrolled in the Clinical Trial, recording all observations and other data pertinent to the Clinical Trial.

INVESTIGATOR shall collect clinical data related to the Clinical Trial in accordance with Regulations in a timely and organized manner that shall allow ERGOMED a complete and thorough analysis of the clinical findings of the Clinical Trial. INVESTIGATOR shall review and sign the forms used for data collection in a timely manner, including Case Report Forms.

INVESTIGATOR shall follow Clinical Trial Subjects in accordance with the Protocol, and INVESTIGATOR shall actively seek to contact Clinical Trial Subjects who discontinue and do not complete all necessary Protocol requirements. Upon completion of the Clinical Trial (whether prematurely or otherwise) INVESTIGATOR shall co-operate with Sponsor and ERGOMED in producing a report of the Clinical Trial detailing the methodology and results and containing an analysis of the results and drawing appropriate conclusions.

2.16. INSTITUTION shall ensure that INVESTIGATOR fully complies with adverse event provisions of the Protocol. The INVESTIGATOR and the INSTITUTION shall promptly ensure that adequate medical care is provided to the injured Clinical Trial Subject in case of any adverse event occurring the during the Clinical Trial. The Sponsor shall bear the cost of medical care extended to the Clinical Trial Subjects.

INVESTIGATOR shall promptly contact ERGOMED and Sponsor to report any adverse event experienced by any Clinical Trial Subject as and when required by the Regulations and the Protocol.

INVESTIGATOR shall submit to ERGOMED and the Sponsor a summary of the adverse event, summary of the medical care provided along with all associated documentation (e.g. lab reports, death or injury summary from the attending medical practitioner, operative reports etc.) for each adverse event. INVESTIGATOR shall respond to all requests for follow-up information from ERGOMED. The INVESTIGATOR shall also assist ERGOMED and the Sponsor for preparation of any reports for submissions to the Regulatory Authority in accordance with applicable Regulations.

In case of Serious Adverse Events, the INVESTIGATOR shall within twenty-four hours of occurrence of such incidents, shall notify the Regulatory Authority, IRB, ERGOMED and the Sponsor in writing. The INVESTIGATOR shall submit a detailed report of the Serious Adverse Event to the Regulatory Authority, the chairperson of the IRB, head of the INSTITUTION where the Clinical Trial has been conducted, ERGOMED and the Sponsor within fourteen days of the occurrence of the Serious Adverse Event.

2.17. The Sponsor shall be responsible for providing compensation to the Clinical Trial Subjects as determined by the IRB in case of Serious Adverse Events in accordance with Regulations.

2.18. In addition to the obligation contained under Section 4.2 below, the INVESTIGATOR shall conduct the Clinical Trial in compliance with the Protocol and applicable Regulations. The INVESTIGATOR shall document and provide a rationale for any deviation from the Protocol and applicable Regulations and, when possible, describe the immediate remediation measures taken to re-establish the safety and rights of the Clinical Trial Subjects. The INVESTIGATOR shall contact ERGOMED and report any suspected serious breach immediately and no later than twenty-four hours after the event comes to the knowledge of the INVESTIGATOR and/or INVESTIGATOR's team. Any reporting to the relevant regulatory authorities shall be performed per local regulatory requirements and by the responsible party. The INSTITUTION

shall have implemented a procedure to ensure timely identification of a suspected serious breach committed by the INVESTIGATOR, INVESTIGATOR's team, and the INSTITUTION's and/or INVESTIGATOR's service providers.

2.19. INSTITUTION shall promptly inform Sponsor and ERGOMED of any intended or actual inspection, written inquiry and/or visit to the trial site at the INSTITUTION by any Regulatory Authority and forward to Sponsor and ERGOMED copies of any correspondence from any such regulatory authority relating to the Clinical Trial.

INSTITUTION shall use all reasonable endeavours to ensure that Sponsor and ERGOMED may have a representative present during any such visit. INSTITUTION and INVESTIGATOR agree that during inspection by any regulatory authority concerning the Services or Clinical Trial any of them shall not disclose information and materials that are not required to be disclosed to such regulatory authority, without the prior written consent of ERGOMED, which consent shall not be unreasonably withheld or delayed.

2.20. INSTITUTION shall permit Sponsor and ERGOMED to examine the conduct of the Clinical Trial and the premises of INSTITUTION upon 3 (three) days' advance notice during regular business hours to determine whether the Clinical Trial is being conducted in accordance with the requirements set out in this Agreement.

2.21. INSTITUTION shall immediately notify Sponsor and ERGOMED if INVESTIGATOR is no longer able for whatever reason to act as INVESTIGATOR.

2.22. INSTITUTION shall ensure that the preparation, storage and/or testing of any Clinical Trial Product during the course of the Clinical Trial at the INSTITUTION is carried out in accordance with the Protocol and all the Regulations.

INSTITUTION shall bear all risk of loss or damage to the Clinical Trial Product provided by ERGOMED or Sponsor while the Clinical Trial Product is in the control or possession of INSTITUTION.

2.23. INSTITUTION and INVESTIGATOR acknowledge that the Sponsor is and shall at all times remain the sole owner of the Clinical Trial Product.

ERGOMED or Sponsor shall provide INSTITUTION with the required quantities of the Clinical Trial Product, at no charge, for the INSTITUTION to conduct the Clinical Trial.

Neither INSTITUTION nor INVESTIGATOR shall permit the Clinical Trial Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Clinical Trial Product shall, at Sponsor's option and expense, either be returned to Sponsor or disposed of in accordance with the Protocol or Sponsor's instructions. Detailed records of stocks and use of the Clinical Trial Product shall be maintained by the INSTITUTION and shall be submitted to ERGOMED or the Sponsor upon request.

2.24. Neither the INSTITUTION nor INVESTIGATOR shall during the term of this Agreement conduct any other trial which might hinder their ability to conduct the Clinical Trial in line with the Protocol.

2.25. Upon Sponsor's request, INVESTIGATOR shall complete and return to ERGOMED or the Sponsor in a timely manner, financial certification or disclosure forms or any updates thereof, as applicable, provided to the INVESTIGATOR by ERGOMED or the Sponsor.

INSTITUTION and INVESTIGATOR shall ensure that other members of INVESTIGATOR's team, performing any functions related to the Clinical Trial also complete and return all such financial certification/disclosure forms, if so required by the Sponsor.

2.26. According to the applicable Regulations in force and as per agreement with the Sponsor regarding Clinical Trial archiving period INSTITUTION and INVESTIGATOR shall retain all Clinical Trial records for 25 (twenty-five) years after the end of the Clinical Trial.

INSTITUTION and/or INVESTIGATOR, as applicable, shall contact ERGOMED and/or Sponsor at least 90 (ninety) days before the planned destruction of any Clinical Trial records, at which time ERGOMED or Sponsor may require that INSTITUTION and/or INVESTIGATOR deliver such records to ERGOMED and/or Sponsor, at the Sponsor's expense.

INSTITUTION and/or INVESTIGATOR shall notify ERGOMED and/or Sponsor immediately in writing of any accidental loss or destruction of Clinical Trial records.

Article 3

Compensation and expenses

3.1. As compensation for the conduct of the Clinical Trial as referred to in this Agreement by INSTITUTION and INVESTIGATOR, ERGOMED shall pay to the INSTITUTION the gross fee, GST excluded (if applicable) as indicated in Schedule II herein attached and made an integral part of this Agreement. This gross fee includes any and all taxes that may be applicable anywhere anytime and it is specifically agreed that any such taxes shall be the sole responsibility of the INSTITUTION and of the INVESTIGATOR who shall both timely pay all such taxes for which they are liable. INSTITUTION shall have the responsibility and the obligation to make proper and timely disbursements of funds to all appropriate parties involved in the Clinical Trial.

3.2. It is agreed that payment of the sums due under this Agreement shall be payable by ERGOMED by wire transfer at the bank account indicated in the INSTITUTION's invoice and within 30 (thirty) days from the invoice receipt.

3.3. In case of the Sponsor's material failure to meet its obligations towards ERGOMED, ERGOMED retains the right to withhold payments to the INSTITUTION and the INVESTIGATOR until Sponsor satisfies its obligations.

3.4. Prices in Schedule II are GST excluded.

3.5. The INSTITUTION shall issue all invoices under this Agreement to Ergomed Clinical Research Private Limited and deliver tositepayments@ergomedgroup.com.

3.6. Unless otherwise agreed in writing and approved by Sponsor, payments of the sums due under this Agreement shall be made according to the attached Schedule II.

3.7. If a dispute arises between the Parties in respect of any part of an invoice, ERGOMED shall: (i) notify INSTITUTION promptly of the particulars of the dispute, and (ii) may withhold payment of the disputed part of the invoice provided that ERGOMED and the INSTITUTION and INVESTIGATOR respectively endeavour promptly and in good faith to resolve the dispute.

3.8. In undertaking to perform the Services for ERGOMED, it is understood that INSTITUTION, INVESTIGATOR and INVESTIGATOR's team act as independent contractors without the

capacity to legally bind ERGOMED or the Sponsor and that INVESTIGATOR and INVESTIGATOR`s team are doing so as an employee of the INSTITUTION and not as an employee of ERGOMED.

Article 4

Regulatory Review, Opinion from Ethics Committee

4.1 The INSTITUTION shall ensure that the IRB holds a valid registration as per applicable Regulations during the tenure of the Clinical Trial.

4.2 Until all Parties have obtained all required documentation from the IRB/EC (where necessary) and all required approvals (in writing) regarding the terms and conditions of Clinical Trial, including the Informed Consent Form, related instructions for use and the Protocol from the competent IRB / EC, ERGOMED and/or Sponsor shall not supply the Clinical Trial Product to INSTITUTION, and INSTITUTION and INVESTIGATOR shall not Enrol any Clinical Trial Subject and shall ensure that neither administration of the Clinical Trial Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Clinical Trial Subject.

4.3 All modifications to the Protocol shall be made by the Sponsor and implemented by the INVESTIGATOR after receipt of necessary regulatory or IRB/EC approvals. Neither INSTITUTION nor INVESTIGATOR shall consent to any change in the Protocol requested by a relevant EC without the prior written consent of the Sponsor. INSTITUTION shall promptly forward a copy of any such change in the Protocol requested by a relevant IRB/EC to the Sponsor and ERGOMED.

4.4 INSTITUTION and INVESTIGATOR shall promptly forward to ERGOMED and Sponsor copies of all correspondence to or from regulatory authorities and IRB/ECs which concern the Clinical Trial.

Article 5

Data Protection

5.1 For the purpose of this Agreement the terms Processing, Controller, Processor, Recipient, Personal Data and Personal Data Breach, shall have the same meaning ascribed to them in Data Protection Laws, especially in GDPR.

5.2 The Parties agree to adhere to the principles of confidentiality in relation to Clinical Trial Subjects and at all times comply with applicable Data Protection Laws, especially GDPR and DPDPA when Processing Personal Data in connection with this Agreement. The Personal Data protection measures during the Processing and description of Personal Data Processing are described in Schedules III and IV.

5.3 INVESTIGATOR Processes Clinical Trial Subjects' Personal Data in full detail. Clinical Trial Subjects' Personal Data has to be pseudonymised before providing it to ERGOMED and/or Sponsor, i.e. Clinical Trial Subjects are given an identifier by which they are known in a system, which is typically a number – key-coded data. List with the codes and the Clinical Trial Subjects' details is kept only with INVESTIGATOR in order to link the Clinical Trial Subjects to their Personal Data.

Unless pseudonymised, Clinical Trial Subjects' Personal Data shall not be disclosed to ERGOMED or to Sponsor by INVESTIGATOR or INSTITUTION save where this is required to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by a Clinical Trial Subject in connection with the Clinical Trial.

Consequently, ERGOMED and Sponsor shall not disclose the identity of Clinical Trial Subjects to third parties without prior written consent of the Clinical Trial Subject in question except as permitted by and in accordance with Regulations.

INVESTIGATOR shall be the point of contact for any Clinical Trial Subject's data protection related requests (including, but not limiting, to fulfil the Clinical Trial Subject's GDPR rights) concerning the Parties or Sponsor in connection with the Clinical Trial. INVESTIGATOR shall be primarily responsible to handle such requests (including sharing such requests with Sponsor and ERGOMED with compliance with the Regulations, specifically the pseudonymization of Clinical Trial Subject's personal data, where required) and communicate with Clinical Trial Subjects. Sponsor and ERGOMED shall provide reasonable assistance where required to ensure compliance with Clinical Trial Subject's rights under applicable Data Protection Laws.

5.4 INVESTIGATOR hereby confirms that she fully understands and has been properly informed that the conclusion and the performance of this Agreement and the conduct of the Clinical Trial as per the Regulations require the Sponsor and ERGOMED to Process her Personal Data. Depending on Sponsor's decision to file for submission for marketing application, necessary Processing may include the transfer of her Personal Data to countries outside India in accordance with applicable Regulations. By entering into this Agreement, the INVESTIGATOR explicitly agrees with such transfers of her Personal Data to the extent necessary for the conclusion and the performance of this Agreement and the conduct of the Clinical Trial as per the Regulations.Such Personal Data may include names, contact information, work experience, qualifications, publications, resumes, educational background, information on performance and professional capabilities and applicable invoicing details.

INSTITUTION and INVESTIGATOR agree to inform the INVESTIGATOR's team about the Processing of INVESTIGATOR's team Personal Data and to establish proper arrangement of their relations with the INVESTIGATOR's team for such Processing. Depending on Sponsor's location and its decision to file for submission for marketing application, Processing necessaryfor the conclusion and the performance of this Agreement and the conduct of the Clinical Trial as per the Regulations may include the transfer of their Personal Data to countries outside the EU/EEA, which do not ensure adequate level of Personal Data protection as per GDPR. INSTITUTION and INVESTIGATOR shall ensure that INVESTIGATOR's team is aware that their Personal Data shall be Processed for the below mentioned purposes. Any person who does not fully agree with the Processing described should not be involved in any capacity in the INVESTIGATOR's team.

ERGOMED shall provide the INVESTIGATOR and INVESTIGATOR's team with the Personal Data information notice that contains information about their Personal Data Processed and their rights (e.g. access right, portability, rectification) so that Sponsor and / or ERGOMED comply with their obligation under applicable Data Protection Laws.

5.5 The Sponsor and ERGOMED Process Personal Data of the INVESTIGATOR and INVESTIGATOR's team for the following specific purposes, where:

- the Sponsor is the Controller:

(i) ensuring proper conduct of the Clinical Trial;
(ii) review by a regulatory authority, Sponsor, ERGOMED or their agents;
(iii) publication on www.clinicaltrials.gov, other public websites and public portals for clinical documents of EMA and other relevant agencies that inform about clinical trials and participating investigators and corresponding clinical trial results;
(iv) satisfying legal or regulatory requirements e.g. anti-corruption compliance.

- ERGOMED is the Controller:
(i) maintaining in databases to facilitate selection of investigators and sites in future clinical trials;
(ii) conclusion and performance of this Agreement;
(iii) ERGOMED's legal obligations as far as such exist or may be imposed under the Regulations to ERGOMED (for example, tax obligations);
(iv) for the establishment, exercise or defence of legal claims.

ERGOMED's, INSTITUTION's and INVESTIGATOR's legal basis for Processing in the role of the Processor is the performance of a contract.

Article 6

Intellectual Property

6.1. The Parties hereby agree that the Sponsor shall at all times retain ownership of any know-how, trade secrets, developments, discoveries, inventions, innovations or improvements (whether or not patentable) conceived or first reduced to practice, or deriving therefrom, in the performance of Services under this Agreement, in the performance of the Clinical Trial, or as a result of using data from the Clinical Trial by INSTITUTION, its employees or INVESTIGATOR (hereinafter: the "**Intellectual Property**") and the INSTITUTION and INVESTIGATOR have no rights to any such Intellectual Property.

For the avoidance of doubt, the INSTITUTION and INVESTIGATOR hereby grant to Sponsor any and all right, title and interest in any and to any Intellectual Property. INVESTIGATOR and INSTITUTION shall assign and deliver to Sponsor all documents and do all such things as may be necessary or appropriate to vest in Sponsor all rights, title and interest in and to such Intellectual Property. INVESTIGATOR and INSTITUTION shall promptly disclose to the Sponsor any such Intellectual Property.

Upon the request of the Sponsor INVESTIGATOR and INSTITUTION shall assist the Sponsor in the preparation, filing and prosecution of such patent applications; INVESTIGATOR and INSTITUTION further agree to execute and deliver any and all instruments necessary to effectuate the ownership of such patent applications and to enable the Sponsor to file and prosecute such patent applications in any country.

6.2. INSTITUTION and INVESTIGATOR agree that any and all works, recommendations, advices, observations and conclusions, rendered, obtained, generated, conceived or derived, directly or indirectly, by INSTITUTION and/or INVESTIGATOR during the course of the performance of Services under this Agreement, in performance of the Clinical Trial, or as a result of using data from the Clinical Trial, including, without limitation, clinical and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer database or computer readable form) shall be Sponsor's absolute and exclusive property, who shall be free to use it as it deems fit for any purpose whatsoever.

INSTITUTION and INVESTIGATOR agree that they assert no claim to rights in technology and materials owned by ERGOMED or the Sponsor.

6.3. INSTITUTION or INVESTIGATOR may be allowed to present and publish data resulting from the Clinical Trial pursuant to the Sponsor's publication policies and upon obtaining prior expressed written approval from the Sponsor for any such presentation or publication.

Any material prepared for publication or presentation shall be submitted to the Sponsor for review and comment at least 60 (sixty) days prior to submission for publication. INSTITUTION and/or INVESTIGATOR shall modify the publication or presentation material according to the comments provided by the Sponsor.

6.4. INSTITUTION and/or INVESTIGATOR further agree to delete information identified by ERGOMED or the Sponsor as confidential, prior to submitting such material for publication or presentation. During the period for review of a proposed publication or presentation material, the Sponsor shall be entitled to request a delay of publishing such materials for a period of up to 6 (six) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property.

INSTITUTION and/or INVESTIGATOR shall not unreasonably withhold or delay their consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, the Sponsor's proprietary information and/or intellectual property rights and know-how might otherwise be compromised or lost.

6.5. If the Clinical Trial is multi-centre, any publication based on the results obtained at the INSTITUTION (or a group of sites) shall not be made before the first multi-centre publication. In case of presentation or publication of such data INSTITUTION and INVESTIGATOR shall be bound by the confidentiality of Article 7 of this Agreement and subject to preserving Sponsor's rights in Articles 6.1 and 6.2. herein.

6.6. INSTITUTION and INVESTIGATOR shall not, and shall ensure that their respective personnel do not, engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Clinical Trial and the Clinical Trial Product without the prior written consent of the Sponsor. This provision does not prohibit publication, presentation or other public disclosure in accordance with Sections 6.3.

Article 7

Confidentiality

7.1. INSTITUTION and INVESTIGATOR shall hold in strict confidence any and all information (i) acquired by the INSTITUTION and/or INVESTIGATOR from ERGOMED and/or the Sponsor in reference to the Clinical Trial Product, the Sponsor or ERGOMED, or the Services performed under this Agreement or the Clinical Trial and (ii) developed by the INSTITUTION and/or INVESTIGATOR in the performance of the Services under this Agreement or the Clinical Trial (hereinafter: "**Confidential Information**").

7.2. INSTITUTION and INVESTIGATOR undertake to permit access to the Confidential Information only to those employees of the INSTITUTION or members of the INVESTIGATOR's team who reasonably need access to such information for the carrying out of the duties under this Agreement and who have signed confidentiality agreements containing,

or are otherwise bound by, confidentiality obligations at least as restrictive as those contained herein.

INSTITUTION and INVESTIGATOR agree to handle and shall ensure that members of INVESTIGATOR's team:

(i) handle Confidential Information with the reasonable degree of care;
(ii) take precautions as necessary and appropriate to guard the confidentiality of Confidential Information and any inadvertent disclosure thereof;
(iii) use such Confidential Information only for the performance of their obligations under this Agreement.

7.3. This Article shall not apply to information:

(i) which was known to INSTITUTION or INVESTIGATOR prior to its receipt from ERGOMED or the Sponsor, and INSTITUTION or INVESTIGATOR is able to so demonstrate through bona fide written records of such receipt,
(ii) which is or lawfully becomes generally available to the public as evidenced by objective public record,
(iii) which is lawfully acquired from third parties who have a right to disclose such information, or
(iv) which INSTITUTION or INVESTIGATOR is required by law to release, provided that INSTITUTION or INVESTIGATOR gives advance written notice of such requirement so that Sponsor has the opportunity to object to such disclosure.

7.4. Nothing herein shall be construed as prohibiting the Sponsor from reporting on this Clinical Trial to a governmental or regulatory agency or from exercising its right in its Confidential Information as it deems appropriate in its sole discretion.

Article 8

Insurance and Indemnification

8.1. INSTITUTION shall defend, indemnify, save and hold harmless the Sponsor, ERGOMED, their affiliated entities and respective affiliates, subsidiaries, directors, officers, employees, contractors, stockholders, agents, and successors and assigns from and against any and all claims, demands, suits, actions, causes of action, losses, damages, fines and liabilities, including court costs and reasonable attorneys' fees ("**Losses**") resulting from or arising out of any third party claims, actions or proceedings relating to any INSTITUTION's and/or the INVESTIGATOR's and/or the INVESTIGATOR's team's:

(i) failure to follow any Regulations, including applicable federal, state or local laws, regulations, and guidelines, or to conform to reasonable and prudent clinical practices, including GCPs as applicable to clinical studies for the Clinical Trial Product;
(ii) wrongful or negligent acts or omissions, or wilful malfeasance or misuse of the Clinical Trial Product;
(iii) failure to comply with the Approved Protocol;
(iv) failure to report Adverse Events and Serious Adverse Events within prescribed timelines;
(v) failure to provide adequate and prompt medical care to Clinical Trial Subjects during adverse events;

(vi) failure to follow the Protocol or other written recommendations or instructions provided to the INSTITUTION and/or the INVESTIGATOR and/or the INVESTIGATOR's team by ERGOMED or the Sponsor.

8.2. INVESTIGATOR shall maintain insurance coverage. The INVESTIGATOR shall provide ERGOMED with a certificate of insurance within 30 (thirty) days of the date of the Agreement. (This clause may not be applicable to Indian Investigators)

8.3. ERGOMED shall ensure that the Sponsor obtains appropriate insurance cover or provides an indemnity satisfactory to the INSTITUTION and INVESTIGATOR and for providing compensation and medical care to injured Clinical Trial Subjects in respect of its potential liability under the Clinical Trial.

ERGOMED shall produce to the INSTITUTION, on request, copy of an adequate insurance policy covering Sponsor's liability vis-à-vis Clinical Trial Subject in compliance with applicable Indian law.

8.4. ERGOMED shall maintain an appropriate insurance coverage in respect of its potential liability under this Agreement. ERGOMED shall defend, indemnify, save and hold harmless the INSTITUTION and the INVESTIGATOR from and against any and all Losses resulting from or arising out of any third party claims, actions or proceedings relating to any ERGOMED's wrongful or negligent acts or omissions.

8.5. The INSTITUTION shall maintain professional liability insurance coverage and general liability insurance coverage (including contractual liability) that does not exclude clinical studies as well as the DPDPA liability, sufficient to cover the INSTITUTION's indemnification obligations hereunder. If the policy is a claims-made policy, the INSTITUTION shall extend the coverage period of such insurance coverage, for an additional 5 (five) years after completion of the Clinical Trial. The INSTITUTION shall provide ERGOMED with a certificate of insurance within 30 (thirty) days of the date of the Agreement. (This clause may not be applicable to Indian Institutes)

8.6. INSTITUTION and INVESTIGATOR acknowledge that the Sponsor has engaged ERGOMED to manage the Clinical Trial, so ERGOMED has performed no independent research or analysis regarding the safety or efficacy of the Clinical Trial Product, materials or treatment procedures that are to be administered pursuant to the Clinical Trial and, therefore, ERGOMED makes no warranties, expressed or implied concerning the Clinical Trial Product, materials, treatment procedures, results to be obtained in administering the Clinical Trial Product, or the Clinical Trial Product's fitness for any particular purpose.

8.7. ERGOMED expressly disclaims any liability in connection with the Clinical Trial Product caused by,or allegedly caused by, the use or misuse of the Clinical Trial Product other than liability for death, personal injury or loss of or damage to property which liability is the result of gross negligence or wilful misconduct on the part of ERGOMED.

8.8. Nothing in this Article 8 may be construed so as to restrict or exclude the liability of INSTITUTON or INVESTIGATOR in relation to death or personal injury caused by the negligence of such Party or its employees respectively or to restrict or exclude any other liability of INSTITUTION or INVESTIGATOR which cannot be so restricted or excluded in law.

8.9. INSTITUTION and INVESTIGATOR are obliged to immediately, in written form, inform ERGOMED of any claim on existence of any personal injury, death or damages, and shall allow

the Sponsor and/or ERGOMED to resolve such claim (including settlement deal) in accordance with applicable laws and shall cooperate with the Sponsor or ERGOMED in resolving of such claim.

Sponsor and ERGOMED shall have exclusive control with respect to resolving such claim or petition, including any settlement, however with limitation that such settlement shall not include recognition of the responsibility of the INSTITUTION and/or the INVESTIGATOR and their associates without their prior written approval, which shall not be withheld without valid reason.

Article 9

Anti-Corruption (Anti-Kickback and Anti-Bribery)

9.1. The INVESTIGATOR and the INSTITUTION agree that their judgment with respect to the advice and care of each Clinical Trial Subject shall not be affected by the compensation they receive under this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

9.2. The INVESTIGATOR and the INSTITUTION agree that they shall not bill any Clinical Trial Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Clinical Trial for which they have received compensation from ERGOMED.

9.3. Each Party, in performing this Agreement, represents and warrants that it shall:

a) fully and absolutely comply with the provisions of any applicable legislation on anti-bribery/anti-corruption prevention as well as with the principles of international anti-bribery/anti-corruption legislations such as Prevention of Corruption Act, 1988, OECD Anti Bribery Convention or Combating Bribery of Foreign Public Officials in International Business Transactions, UK Bribery Act, US Foreign Corrupt Practices Act, which are in force from time to time ("**Anti-Bribery Regulations**");

b) adopt all necessary measures to prevent violation to the Anti-Bribery Regulations;

c) not, in the conduct of the performance of the Services under this Agreement, offer, pay, give, or promise to pay or give, directly or indirectly, any payment or gift of money or thing of value to: (a) any government official to influence any acts or decisions of such official or to induce such official to use his/her influence with any government to effect or influence the decision of such government in order to assist the Party in its performance of the obligations under this Agreement or to benefit any of the Parties; (b) any political party or candidate for public office for such purpose; or (c) any person if either Party knows or has reason to know that such money or thing of value shall be offered, promised, paid, or given, directly or indirectly, to any official, political party, or candidate for such purpose.

9.4. The defaulting Party shall hold harmless and indemnify the other Parties and the Sponsor from any and all claim, expense, fine, sanction, obligations or consequences that may arise from violation of this Article and/or the Anti-Bribery Regulations.

9.5. A violation or a threatened violation of this Article and/or the Anti-Bribery Regulations shall constitute a material breach under this Agreement and in addition to other rights or remedies under this Agreement or at law, the non-defaulting Party may terminate this Agreement with

immediate effect if the defaulting Party breaches any of the representations or warranties contained in this Article.

Article 10

Term and Termination

10.1. This Agreement shall become effective on the date of its signing by all Parties and if signed on the different dates then on the latest signature date("**Effective Date**") and shall remain in full force and effect until the full and satisfactory completion of the Services by the INSTITUTION and INVESTIGATOR.

10.2. ERGOMED may terminate this Agreement prior to its expiration with a written notice to the other Parties and a notice period of not less than 30 (thirty) calendar days.

10.3. ERGOMED may terminate this Agreement prior to the full and satisfactory completion of the Services by the INSTITUTION and INVESTIGATOR by written notice and immediate effect for any of the following reasons:

A. In case the Sponsor has terminated the relevant Agreement with ERGOMED and / or has ceased any further activity on the Clinical Trial and / or has requested to stop Enrolment regardless of the reason given to ERGOMED by the Sponsor;

B. Continuous and / or repetitive and /or material breach of any of the INSTITUTION's and / or INVESTIGATOR's obligations stipulated herein. For the purpose of this Agreement, the following shall, among other, be considered as the material breach of this Agreement:

(i) INVESTIGATOR and/or INSTITUTION prevent access to ERGOMED's employees or contractors or any third persons authorized by ERGOMED and / or the Sponsor to any and all original medical records necessary to verify entries on Clinical Trial Case Report Forms;

(ii) INVESTIGATOR, her associates, or any other person engaged in this Clinical Trial (excluding Clinical Trial Subjects) are unavailable upon reasonable notice by ERGOMED and/or the Sponsor, to meet with ERGOMED's and/or the Sponsor's representative during the course of the Clinical Trial, as necessary, to discuss information relevant to the Clinical Trial;

(iii) Case Report Forms have not been legibly completed and / or forwarded by the INVESTIGATOR to ERGOMED or to its designated representative, as appropriate within 60 (sixty) days of each Clinical Trial Subject's completion date.

C. In case INVESTIGATOR does not recruit any Clinical Trial Subject within 60 (sixty) days from the day of the initial visit;

D. In case the regulatory and / or IRB/EC: (i) has not issued the permit or approval for conducting of the Clinical Trial; or (ii) loss of such permit or approval;

E. Determination by ERGOMED and/or the Sponsor that the INVESTIGATOR, after a reasonable opportunity, is unable, for any reason to act as INVESTIGATOR and/or to

satisfactorily perform the Clinical Trial as required by the Protocol and a suitable INVESTIGATOR replacement is not made timely.

10.4. In the event that ERGOMED chooses to exercise its right to terminate this Agreement, the INVESTIGATOR shall, immediately upon receipt of ERGOMED's notice to terminate, cease Enrolling Clinical Trial Subjects into the Clinical Trial and shall discontinue conducting Clinical Trial procedures, to the extent medically possible.

10.5. The rights and obligations of the Parties under any provision of this Agreement, which by its term is intended to survive beyond the term of this Agreement, including but not limited to Article 5 (Data Protection), Article 6 (Intellectual Property), Article 7 (Confidentiality) and Article 8 (Insurance and Indemnification), shall continue notwithstanding the termination or expiration of this Agreement for any reason.

10.6. In the event of early termination, the sum payable under this Agreement shall be limited to pro-rated fees based on actual work performed pursuant to the Protocol.

10.7. INSTITUTION and INVESTIGATOR shall return to ERGOMED any unused Clinical Trial Product and all Clinical Trial materials shall, at the Sponsor's option and expense, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor's written instructions.

Article 11

Final Provisions

11.1. Neither Party may delegate their obligations or assign their rights hereunder without the prior written consent of the Sponsor. ERGOMED may assign this Agreement with Sponsor's prior written consent and without the consent of INSTITUTION or INVESTIGATOR.

11.2. Any and all additions and/or amendments to this Agreement shall be in writing, numbered, dated and signed by the authorized representatives of all Parties.

11.3. In the case of inconsistency between the Protocol and the other terms of this Agreement, or any other document incorporated therein, the terms of the Protocol shall prevail to the extent applicable to the medical treatment of Clinical Trial Subjects but no further. In respect of other inconsistencies, the Agreement shall prevail.

11.4. Any and all disputes arising out of or in connection with the Agreement shall be settled by an amicable effort of the Parties.

11.5. Any dispute, which is not amicably settled by such efforts of the Parties, shall be finally resolved under the Rules of the Indian by 1 (one) arbitrator appointed pursuant to such Rules. The seat of such arbitration shall be in Tamaka, Kolar, Karnataka, India. The language of arbitral proceedings shall be English.

11.6. This Agreement and all disputes thereof shall be governed by and construed in accordance with the laws of India.

11.7. If any provision of this Agreement should be deemed invalid or legally unenforceable, such provision shall not affect the validity and/or enforceability of any other provision(s) of this

Agreement or the Agreement as a whole. The Parties shall, in such case, replace the invalid provision with a valid one that best expresses their original intent.

11.8. This Agreement is being executed in 3 (three) identical copies, of which each Party shall keep 1 (one) copy.

11.9. The Parties agree that Sponsor is an intended third party beneficiary of this Agreement, with full benefits and full rights of enforcement. Except for the Sponsor, the Parties do not intend that any term of this Agreement shall be enforceable by any person who is not a Party to this Agreement.

11.10. In this Agreement, the words "including" and "includes" mean "including without limitation."

11.11. All notices, statements, demands, requests, consents, communications and certificates from anyParty hereto to the other shall be made in writing unless specified to the contrary herein and sent by fax, certified mail, return receipt requested, hand delivered or byFedEx®or similar overnight delivery service for which a receipt is made to the Parties, addressed as follows:

(a) If intended for ERGOMED

Ergomed Clinical Research Private Limited
91 Springboard Business Hub Private Limited
9th Floor, Sadanand Business Centre, Sr. No.104/1, NH 48, Service Road,
Baner, Pune Maharashtra 411045

with copy to: legal@Ergomedgroup.com

(b) If intended for Sponsor:

NeuraxpharmPharmaceuticals S.L.
Av. Barcelona, 69. 08970 Sant Joan Despí
Barcelona, Spain
with copy to: fjurado@neuraxpharm.com

(c) If intended for INSTITUTION:

R.L. Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College
Tamaka, Kolar, Karnataka 563103
with copy to: dir.research@sduaher.ac.in

Dr Rajesh Venkataraman,
Adichunchanagiri Hospital,
Adichunchanagiri University
B.G Nagara, Mandya, Karnataka -571 448.
With copy to: drrajesh.ahrc@gmail.com

(d) If intended for INVESTIGATOR:

Dr. Bhuma Vengamma
R.L. Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College
Tamaka, Kolar, Karnataka 563103

with copy to: vicechancellor@sduaher.ac.in)

or such other addresses as either Party hereto may from time to time direct by service of notice to the other Party as provided above. Any such notices, statements, demands, requests, consents, communications or certificates shall be deemed given on the date received.

11.12. The Parties agree that this Agreement may be executed by way of electronic signatures and that the electronic signature has the same binding effect as a physical signature. For the avoidance of doubt, the Parties agree that this Agreement, or any part thereof, shall not be denied legal effect, validity or enforceability solely on the ground that it is in the form of an electronic record.

Signature page follows

ERGOMED

SIGNED on behalf of **ERGOMED**:

Name: Kaushik Ganguly
Title: Office Director | Sr. Project Director

05 Dec 2024
Date

SIGNED by **ERGOMED** on behalf of **Sponsor**:

Name: Kaushik Ganguly
Title: Office Director | Sr. Project Director

05 Dec 2024
Date

SIGNED by the **INSTITUTION**:

Name: Dr. Kalyani R
Title: Director
Research& Development Cell,
SDUAHER

11/12/'24
Date

SIGNED by the **INVESTIGATOR**:

Name: Dr Bhuma Vengamma
Title: Vice-Chancellor, SDUAHER

11th Dec 2024.
Date

ERGOMED

SCHEDULE I – PROTOCOL

- Provided under a separate cover -

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SCHEDULE II – PAYMENT TERMS AND BUDGET`

1. Enrollment target

a. The INVESTIGATOR shall randomize a minimum of four (4) and up to eight (8) Clinical Trial Participants ("**Participants**") in the Clinical Trial as agreed and authorized by SPONSOR through ERGOMED. The INVESTIGATOR shall not randomize any Participants above the enrolment target, unless expressly authorized in writing by the SPONSOR, through ERGOMED.

b. SPONSOR, through ERGOMED, may increase the enrolment target through a written notification sent to the INSTITUTION and INVESTIGATOR which includes the updated enrolment target. The Parties agree that such changes will not require any formal amendments to this Agreement.

c. The INSTITUTION and INVESTIGATOR acknowledge that enrollment of Participants may be competitive among all Clinical Trial Sites, and as result, the INSTITUTION and INVESTIGATOR shall cease screening and enrolling Participants at any time upon SPONSOR's direct request, or through ERGOMED.

2. Compensation and Payment terms

a. As compensation to the INSTITUTION and INVESTIGATOR for conducting the Clinical Trial, SPONSOR, through ERGOMED acting as its paying agent, shall make payments each quarter by electronic wire transfer to SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH ("Payee") in line (1) with the amounts and in the currency listed in **Appendix 1 – Clinical Trial Budget** ("**Budget**"), and (2) with the Payment terms defined herein.

b. SPONSOR, through ERGOMED, shall generate within 15 business days of the end of each calendar quarter a proforma invoice covering activities completed at the site based on EDC data entered by the INSTITUTION or INVESTIGATOR, and verified by ERGOMED, which will be sent to the Payee for verification and approval.

c. If the Payee does not raise any queries to SPONSOR through ERGOMED within 10 business days of receipt, SPONSOR will consider the proforma invoice as approved. Any queries raised by the Payee will be resolved by SPONSOR, through ERGOMED, and by the Payee in good faith in line with Article 3 of this Agreement.

d. Upon approval, SPONSOR through ERGOMED, will process and initiate the payments for such activities within 30 calendar days at the rates set forth in the Budget and based on the terms of this Schedule II.

e. For activities payable upon receipt of an invoice, SPONSOR through ERGOMED, will pay the Payee within 30 calendar days of receipt of a correct invoice from the Payee, subject to a verification of the invoice by SPONSOR, through ERGOMED.

f. Payee will only be compensated for services that have been properly performed in accordance with the Protocol and this Agreement, and payments are dependent upon completion of CRFs/eCRFs, reports, and other documents pursuant to this Agreement being submitted in a timely and satisfactory manner.

g. SPONSOR, through ERGOMED, will not pay for any visits performed in relation to any Participants who do not conform to the Protocol's inclusion and exclusion criteria or in relation to whom serious violation(s)of the Protocol have been made, if the violation(s) resulted in the withdrawal of the Participant from the Clinical Trial. Payments for Participants who were deemed to have been in violation, may be made up to the point of when the violation occurred, at the sole discretion of the SPONSOR.

h. All payments shall be performed in line with the following payment terms (**"Payment terms"**):

i.	**Per Participant Costs:**	Payments will be made on a per Participant per visit basis for visits completed as per EDC data entered during the preceding quarter.
ii.	**Screen Failure costs:**	Failures at V1 Screening Visit (Onsite) shall be paid as per the Screen Failure rate in the Budget, for any Participant(s) undergoing screening procedures but not randomized to receive the Clinical Trial Product. Payments for screen failures will be limited to one (1) screen failure for every two (2) Participants randomized, up to a limit of four (4) screen failures. Once reached, it will be paid at a rate of one (1) screen failure for every three (3) of Participants randomized. This limit of payable Screen Failures may be increased by written notification sent to the INSTITUTION and INVESTIGATOR by the SPONSOR through ERGOMED, which includes the updated Screen Failure limit. The Parties agree that such changes will not require any formal amendments to this Agreement. Payment of Screen Failure costs shall be made following receipt of a correct and itemized Invoice, subject to SPONSOR's verification through ERGOMED.
iii.	**Conditional procedures**	Conditional procedures as per the Budget will be reimbursed to the Payee on a per subject per procedure basis for conditional procedures completed in line with the Protocol and this Agreement. Payment shall be made in accordance with the Budget upon receipt of a correct and itemized Invoice detailing Conditional Procedures completed during the preceding quarter, subject to SPONSOR's verification through ERGOMED.
iv.	**Participant travel reimbursements:**	Sponsor, through ERGOMED, will provide reimbursement for reasonable and documented Participant travel costs incurred by Participants during visits up to the amounts set in the Budget, upon receipt of an invoice detailing actual amounts reimbursed by the Institution to each Participant, subject to SPONSOR's verification through ERGOMED.

		Reasonable costs/expense are defined as standard class public transport, private hire vehicles (taxis), use of a private vehicle (the latter at Local Government Approved Rate(s)), parking, meals and incidentals.
v.	**Early withdrawal reimbursement:**	An early withdrawal is a Participant who (1) completes Visit 4 and (2) withdraws from participation in the Clinical Trial prior to Visit ("**Early Withdrawal**"). Payment of the Early Withdrawal Fee shall be made in accordance with the Budget following receipt of a correct and itemized Invoice, subject to SPONSOR's verification through ERGOMED. Because some of the procedures required by Protocol for Early Withdrawals may have already been performed as part of a standard visit, only those Early Withdrawal procedures not already included in a visit will be reimbursed.
vi.	**Safety Follow-up visits:**	If a Participant experiences a SAE between Visit 4 and Visit 8 , the Subject must be brought back for a follow-up. If Visit 9/ Safety Follow-up is performed at the Site rather than via a phone call, the Institution will be paid for the Safety Follow-up visit in line with the Budget, upon receipt of a correct and itemized Invoice.
vii.	**Unscheduled visits:**	An Unscheduled Visit means a Participant visit which is not expressly set forth in the Clinical Trial Plan nor in the Procedures of the Protocol but is otherwise required for the Clinical Trial. SPONSOR will pay through ERGOMED for unscheduled visits approved by the SPONSOR, at the rate determined in the Budget. Payments will be performed following receipt of a correct and itemized Invoice detailing Unscheduled Visits completed during the preceding quarter. Under no circumstances shall Institution be paid for more than one (1) unscheduled visit per randomized subject.
viii.	**IRB Fees:**	Local IRB/EC Fees will be paid to the Payee on a pass-through basis upon receipt of a correct and itemized invoice from Payee. Following approval by SPONSOR through ERGOMED, any subsequent re-submissions, amendments, or renewals will be reimbursed upon ERGOMED's receipt of appropriate documentation and invoice.
ix.	**Start-up Fee**	A one-time Start-up Fee will be paid to Payee upon (1) receipt and approval of all regulatory documents, (2) signature of this Agreement and (3) following the Site's activation by SPONSOR, through ERGOMED.

		Payment of the Start-up Fee shall be made in accordance with the Budget following receipt of a correct and itemized Invoice, subject to SPONSOR's verification through ERGOMED.
x.	**Storage Fees:**	A one-time long-term Document Storage/ Record retention Fee will be paid to Payee in line with the Budget upon receipt of an invoice at Study close-out.
xi.	**Overhead costs:**	All fees in the Budget are inclusive of any overhead costs as incurred by the Institution where applicable.

i. Final payment will be made to the Payee by SPONSOR, through ERGOMED, when INSTITUTION and/or INVESTIGATOR have cumulatively:

   i. Completed the Clinical Trial;
   ii. Satisfactorily accounted for all unused Clinical Trial Product, materials, supplies, and Equipment;
   iii. Completed CRF / eCRF and for each Clinical Trial Subject in the Clinical Trial;
   iv. Satisfactorily answered all of SPONSOR and/or ERGOMED inquiries regarding the Clinical Trial; and
   v. Received confirmation from SPONSOR directly or through ERGOMED that all applicable conditions above have been satisfied in accordance to this Agreement.

j. Final invoices need to be submitted to SPONSOR, through ERGOMED, for payment no later than within 30 calendar days from the moment SPONSOR directly or through ERGOMED confirmed to INSTITUTION and INVESTIGATOR that all applicable conditions listed above in Schedule II - section 2 i) have been satisfied. SPONSOR, through ERGOMED, will pay the final invoices within 30 calendar days of receipt of a valid invoice.

k. The Payee will have 30 calendar days from the Final Payment, to inform SPONSOR, through ERGOMED, of any payment discrepancies for consideration. SPONSOR reserves itself the right not to pay through ERGOMED any invoices or discrepancies after this period.

3. Taxes

a. All agreed upon amounts are NET, and Goods and Services Tax (GST)/Harmonized Sales Tax (HST) is excluded. The Institution acknowledges that the services supplied to SPONSOR are exempt for GST/HST purposes. Alternatively, if the services provided by the INSTIUTION are not exempt (for GST/HST purposes), the supply by the INSTITUTION to SPONSOR is subject to a zero rate of GST/HST as export services. The payment will not be subject to a withholding tax. In the limit of applicable regulation, it is the responsibility of the PAYEE to declare this income and SPONSOR is not liable for any taxes due.

b. All other taxes, costs, tariffs, duties, social contributions and fixed amounts are included in the payments detailed within Schedule II. The INSTITUTION, INVESTIGATOR, and/or PAYEE are solely responsible for the timely payment of all taxes, costs, tariffs, duties, social contributions and

fixed amounts levied by relevant local, federal, or national authorities for which the INSTITUTION, INVESTIGATOR or PAYEE are liable.

4. Payee details

PAYEE Details	
Type:	INVESTIGATOR / INSTITUTION
Name:	Sri Devaraj Urs Academy of Higher Education and Research
Address:	Tamaka, Kolar, Karnataka, India
Tax ID Nr:	xxxx
PAYEE Bank Account details	
Bank Name:	Kotak Mahindra Bank
Bank and Branch ID Number:	SDUMC branch, ID is 8269
Bank account number / IBAN number	2849611362
BIC / Swift number:	KKBKINBB
Name and details of PAYEE contact responsible for managing invoices and payments:	
First & Last Name:	Dr. Bhuvana K
Job Title:	Chief Co-ordinating Officer Clinical Trial Centre, SUDAHER, Kolar
Email address:	bhuvanak@sduaher.ac.in
Phone number:	9900383738

a. All payments made by SPONSOR, through ERGOMED, as set forth in this AGREEMENT shall be payable solely to the designated PAYEE above. Any payments made to the PAYEE that are due to any other party performing services in connection with this Clinical Trial shall be settled solely between the PAYEE and such a Party.

b. The INSTITUTION and INVESTIGATOR certify that the above Payee is the proper Payee to receive payments under this Agreement.

5. Invoicing

a. Any invoices due under this Agreement shall be issued and sent to:

Issued to Sponsor:	Neuraxpharm Pharmaceuticals S.L. Av. Barcelona, 69. 08970 Sant Joan Despí (Barcelona), Spain Tax ID: B08165789
Sent to ERGOMED:	ERGOMED CLINICAL RESEARCH LIMITED 1 Occam Court, Surrey Research Park, Guildford, GU2 7HJ United Kingdom

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To expedite payments, please send an electronic invoice to the following ERGOMED email address:	sitepayments@ergomedgroup.com

b. Instructions for Processing of Payments

Invoices must include the following information:

- Invoice reference number
- Payee Name (as shown in this Schedule II)
- Payee Address
- Payee Tax ID number
- Protocol number
- Site number
- Date & itemized description of services provided/ invoiced
- Applicable supporting documents/ third party invoices
- Total amount payable

ERGOMED will process on behalf of SPONSOR all payments electronically. Such electronic payments will be sent directly to the Payee's bank account as provided above.

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Appendix 1 – Clinical Trial Budget

Budget Information

	Standard	Conditional	Overall		
Total Cost per Patient:	410,672.44	15,975.00	426,647.44	**Overhead Percent:** 25.00%	**Location:** India

Currency: INR - Indian Rupee

Selected Activities: 234753.95 per patient

Name	OH?	Total Quantity	Screen	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Early Terminat ion	Unsched	Total	Selected Cost
Eligibility Criteria	Y	2.00	1.00			1.00									1,270.00	635.00
Informed Consent Form	Y	1.00	1.00												1,439.00	1,439.00
Demographic Data	Y	1.00	1.00												2,226.00	2,226.00
Relevant Medical History	Y	1.00	1.00												1,900.00	1,900.00
Prior/Concomitant Medications (including ASM)	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	6,216.00	518.00
Physical Examination	Y	7.00	1.00			1.00		1.00	1.00	1.00			1.00	1.00	25,914.00	3,702.00
Neurological Examination	Y	7.00	1.00			1.00		1.00	1.00	1.00			1.00	1.00	21,070.00	3,010.00
Vital Signs	Y	8.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00	1.00	12,488.00	1,561.00
Height	Y	1.00	1.00												880.49	880.49
Weight	Y	3.00	1.00							1.00			1.00		2,641.46	880.49
Electrocardiography	Y	8.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00	1.00	4,800.00	600.00
Safety Laboratory Tests (Hematology)	Y	8.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00	1.00	11,360.00	1,420.00
Safety Laboratory Tests (Chemistry)	Y	8.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00	1.00	25,520.00	3,190.00
Safety Laboratory Tests (Urinalysis)	Y	8.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00	1.00	320.00	40.00
Urine Drug Screen	Y	1.00	1.00												720.00	720.00
HBsAg	Y	1.00	1.00												520.00	520.00
HCV	Y	1.00	1.00												650.00	650.00
HIV	Y	1.00	1.00												520.00	520.00
Randomization	Y	1.00				1.00									716.00	716.00
Access to the Subject Seizure Diary (eDiary) and training	Y	6.00	1.00			1.00		1.00	1.00	1.00		1.00			9,636.00	1,606.00
Subject Seizure Diary Completion	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
Collection of Subject Seizure Diary Data	Y	7.00				1.00		1.00	1.00	1.00		1.00	1.00	1.00	7,021.00	1,003.00
Assessment of Quality of Life in Epilepsy (QoLIE-31 Version 2 OR QOLIE-AD-48)	Y	4.00	1.00			1.00				1.00			1.00		7,124.00	1,781.00
Risk of Suicidality (CSSR-S)	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	44,172.00	3,681.00
AEs Collection	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	6,216.00	518.00
IMP Treatment Compliance	Y	7.00				1.00	1.00	1.00	1.00	1.00	1.00	1.00			14,042.00	2,006.00
TSQM	Y	3.00						1.00	1.00	1.00					3,345.00	1,115.00
MMAS (8-item)	Y	3.00						1.00	1.00	1.00					4,386.00	1,462.00
End of Study / ET Documentation	Y	3.00										1.00	1.00	1.00	14,841.00	4,947.00
Telephone Visit	Y	4.00		1.00	1.00		1.00				1.00				2,800.00	700.00
															234,753.95	

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Selected Other Direct Costs : 93784 per patient

Name	OH?	Total Quantity	Screen	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Early Termination	Unscheduled	Total	Selected Cost
Physician Salary (w/o Exam Costs)	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	44,712.00	3,726.00
Patient Reimbursement, Per Visit	Y	7.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00		10,500.00	1,500.00
Study Coordinator; Per Visit	Y	12.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	34,668.00	2,889.00
Study Drug Accountability	Y	1.00								1.00					2,368.00	2,368.00
Distribution of IMP	Y	3.00				1.00		1.00	1.00						1,536.00	512.00
															93,784.00	

Selected Conditional Activities and Itemized Other Direct Costs: 12780 per patient

Name	OH?	Total Quantity	Screen	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Early Termination	Unscheduled	Total	Selected Cost
Pregnancy Test (Serum)	Y	3.00	1.00			1.00				1.00					3,990.00	1,330.00
Pregnancy Test (Urine)	Y	6.00				1.00		1.00	1.00	1.00		1.00	1.00		600.00	100.00
PCR Test for COVID	Y	7.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00		4,550.00	650.00
Antigen Test for COVID	Y	7.00	1.00			1.00		1.00	1.00	1.00		1.00	1.00		3,640.00	520.00
															12,780.00	

Patient Cost For Standard Items

	Screening Screen	Treatment Visit 2	Treatment Visit 3	Treatment Visit 4	Treatment Visit 5	Treatment Visit 6	Treatment Visit 7	Treatment Visit 8	Treatment Visit 9	Treatment Visit 10	Treatment Early Termination	Treatment Unscheduled	Total
Costs Charged with Overhead	40,112.98	12,032.00	12,032.00	34,614.00	14,038.00	34,059.00	34,059.00	38,576.49	14,038.00	29,205.00	34,966.49	30,805.00	328,537.95
Overhead at 25%	10,028.24	3,008.00	3,008.00	8,653.50	3,509.50	8,514.75	8,514.75	9,644.12	3,509.50	7,301.25	8,741.62	7,701.25	82,134.49
Selected Cost Per Visit	50,141.22	15,040.00	15,040.00	43,267.50	17,547.50	42,573.75	42,573.75	48,220.61	17,547.50	36,506.25	43,708.11	38,506.25	**410,672.44**

Patient Cost For Conditional Items

	Screening Screen	Treatment Visit 2	Treatment Visit 3	Treatment Visit 4	Treatment Visit 5	Treatment Visit 6	Treatment Visit 7	Treatment Visit 8	Treatment Visit 9	Treatment Visit 10	Treatment Early Termination	Treatment Unsched	Total
Costs Charged with Overhead	2,500.00			2,600.00		1,270.00	1,270.00	2,600.00		1,270.00	1,270.00		12,780.00
Overhead at 25%	625.00			650.00		317.50	317.50	650.00		317.50	317.50		3,195.00
Selected Cost Per Visit	3,125.00			3,250.00		1,587.50	1,587.50	3,250.00		1,587.50	1,587.50		**15,975.00**

Overall Patient Cost

	Screening Scree	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Visit	Treatment Early Termination	Treatment Unsch	Total
Costs Charged with Overhead	42,612.98	12,032.00	12,032.00	37,214.00	14,038.00	35,329.00	35,329.00	41,176.49	14,038.00	30,475.00	36,236.49	30,805.00	341,317.95
Overhead at 25%	10,653.24	3,008.00	3,008.00	9,303.50	3,509.50	8,832.25	8,832.25	10,294.12	3,509.50	7,618.75	9,059.12	7,701.25	85,329.49
Selected Cost Per Visit	53,266.22	15,040.00	15,040.00	46,517.50	17,547.50	44,161.25	44,161.25	51,470.61	17,547.50	38,093.75	45,295.61	38,506.25	**426,647.44**

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Site Level Other Direct Costs

Name	OH?	Selected Cost	Comment
Study Set-Up	N	30,000.00	Paid upon site activation
Archiving Fee	N	225,000.00	Paid upon Study close-out
Participant travel and meal reimbursements:	N	Actual costs	Actual costs up to 1500 INR per visit. Costs above this amount require

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SCHEDULE III
DESCRIPTION OF PERSONAL DATA PROCESSING

1. Introduction

(i) INSTITUTION and INVESTIGATOR shall process Personal Data as determined in this Schedule III on behalf of ERGOMED (the Sponsor's processor) as ERGOMED's sub-processors. Nothing in this Agreement derogates or prevents the INSTITUTION or INVESTIGATOR to keep Clinical Trial and medical documentation as prescribed by the applicable mandatory Regulations, nor excludes their obligations and responsibilities as Controllers when they Process Personal Data of their employees, contractors, sub-contractors orClinical Trial Subjects.

(ii) INSTITUTION and INVESTIGATOR should comply with the requirements for collection, storage and processing under the Data Protection Laws.

(iii) The technical and organizational measures regarding the security of the Personal Data Processing are specified in Schedule IV herein.

2. Categories of Data Subjects

The Personal Data concerns the following categories of Data Subjects:

- INVESTIGATOR and INVESTIGATOR's team;
- Clinical Trial Subjects.

3. The duration of the Processing (retention period)

The processing activities based on this Agreement shall be performed during the term of the Agreement <*if possible state exact number of years here*>. Retention period for all Categories of Personal Data is defined by the Sponsor. It starts from the Effective Date of this Agreement and last for _____ years after closure of the Clinical Trial. <Please insert the period as under the Article 2.23.> (PLEASE VERIFY THIS SERIAL NUMBER, IT COULD BE 2.26)

4. The source of Personal Data:

- of the INVESTIGATOR and INVESTIGATOR's team: Data Subject;
- of Clinical Trial Subjects: Data Subject and the INVESTIGATOR;

5. The Recipients of Personal Data of all Categories of Data Subjects:

- the regulatory authority;
- IRB/EC;
- publicly accessible trial registries and databases;
- Sponsor's and ERGOMED's contracted service providers;
- Sponsor's and ERGOMED's Affiliates involved in research, development and commercialization of medical products and their contracted service providers;
- Sponsor's contract partner(s) in case they take over the development and/or commercialization of medical products;
- insurance company, legal and/or medical advisors or consultants engaged by all entities mentioned above.

6. Categories of Personal Data

a. INVESTIGATOR's and INVESTIGATOR team's: Personal Data is listed in Personal Data information notice.

b. Clinical Trial Subject:

(i) Processing by the INVESTIGATOR and INSTITUTION:
- surname, first name, patronymic, matronymic and contact details (address, telephone, mobile, fax, e-mail address);
- health data;
- other Personal Data needed for the conduct of the Clinical Trial.

(ii) Processing by ERGOMED and Sponsor:
- Personal Data incl. health data –
  - pseudonymised for: ERGOMED and Sponsor
  - full detail when at the investigational site for: assigned ERGOMED's and Sponsor's staff (e.g. monitors, site managers, study physician, auditors) for verification of clinical trial procedures and/or data, without violating the confidentiality of the Clinical Trial Subject.

7. Processing activities

The Personal Data shall be subject to the following Processing activities: collecting, recording, systemizing, accumulating, storing, rectifying (updating, modifying), retrieving, using, transferring (distributing, providing, accessing), blocking, erasing or removing.

8. In accordance with the Article 2.11 of this Agreement, ERGOMED hereby confirms that it has authorised INSTITUTION and INVESTIGATOR, in the course of providing its clinical research organisation services to the Sponsor, to engage subcontractors ("**Sub-processor(s)**") and to transfer to its Sub-processors, on ERGOMED's behalf, the Personal Data. INSTITUTION and INVESTIGATOR are obliged to beforehand inform ERGOMED of any intended changes concerning the involvement, addition or replacement of Sub-processors, and ERGOMED is entitled to object such Sub-processor. Furthermore, the same Data Protection Laws obligations as imposed in this Agreement on INSTITUTION and INVESTIGATOR by ERGOMED shall be imposed on that Sub-processor by way of a contract and INSTITUTION and INVESTIGATOR are fully responsible for Sub-processor's non-compliance with the Data Protection Laws.

9. INSTITUTION and INVESTIGATOR warrants and represents that they shall:

(i) Process the Personal Data only in accordance with the Data Protection Laws and ERGOMED's written instructions as specified in this Agreement or as may be issued in writing by ERGOMED from time to time, unless required to do so by European Union or European Union Member State law to which INSTITUTION and INVESTIGATOR and/or the INVESTIGATOR's team and/or the Clinical Trial Subject is subject; in such a case, INSTITUTION and INVESTIGATOR shall inform ERGOMED of that additional legal requirement before Processing, unless that law prohibits such information on important grounds of public interest. Should INSTITUTION and INVESTIGATOR be unable for any reason to ensure its compliance with any duties stipulated by the Data Protection Laws, this Agreement or ERGOMED's instructions, INSTITUTION and INVESTIGATOR shall immediately notify ERGOMED, who may suspend the Processing of the Personal Data.

(ii) promptly, and in any case no later than 24 (twenty-four) hours after discovering or suspecting a Personal Data Breach, (i) notify responsible ERGOMED's monitor and data protection officer at DPO@ergomedplc.com of such Personal Data Breach; (ii) investigate

the Personal Data Breach and provide responsible ERGOMED's monitor with detailed information about the Personal Data Breach; and (iii) take reasonable steps to mitigate the effects and to minimize any damage resulting from the Personal Data Breach. If INSTITUTION and INVESTIGATOR are unable to provide the notice within 24 (twenty-four) hours, they shall provide ERGOMED with reasons for the delay. Where necessary, INSTITUTION and INVESTIGATOR shall assist ERGOMED or Sponsor when notifying relevant party about Personal Data Breach and/or when communicating to the data subjects.

(iii) immediately inform ERGOMED if, in INSTITUTION's and/or INVESTIGATOR's opinion, ERGOMED's instructions violate any Data Protection Laws or other Regulations. INSTITUTION and INVESTIGATOR shall be entitled to suspend and refuse the execution of ERGOMED's instructions that are in violation of the Data Protection Laws or other regulation until ERGOMED confirms that there is no such violation or modifies its instructions.

(iv) provide ERGOMED with all necessary materials, documents, assessments and other information to enable ERGOMED to confirm that INSTITUTION and INVESTIGATOR have complied with their obligations under the Data Protection Laws and this Agreement. Moreover, where necessary, INSTITUTION and INVESTIGATOR shall help Sponsor in conducting data privacy impact assessment as well as prior consultation procedure, or any other activity required by EGROMED or Sponsor in order to demonstrate their compliance with GDPR. INSTITUTION and INVESTIGATOR shall allow for and contribute to GDPR audits to ensure compliance with the Data Protection Laws. GDPR audits shall be carried out during customary business hours following a prior announcement of 7 (seven) working days.

(v) notify ERGOMED promptly and in any event within 1 (one) working day of receiving any communication, complaint, inquiry, or request from any third party, including a regulatory authority or a Data Subject, relating to the Personal Data Processing by INSTITUTION and INVESTIGATOR. INSTITUTION and INVESTIGATOR shall not respond to that request except on the documented instructions of ERGOMED or Sponsor or as required by applicable Regulations to which the INSTITUTION and INVESTIGATOR are subject, in which case INSTITUTION and INVESTIGATOR shall to the extent permitted by applicable Regulations inform ERGOMED.

(vi) to comply with their obligations under the Data Protection Laws. In that light, INSTITUTION and INVESTIGATOR shall take appropriate technical and organisational security measures to safeguard the Personal Data against unauthorised or unlawful access, modification and against accidental loss or destruction of, or damage to the Personal Data, unauthorised transfer or other unauthorised Processing of any Personal Data or any other misuse of the Personal Data, as specified in Schedule IV herein.

(vii) Ensure that all persons engaged by INSTITUTION and INVESTIGATOR and its employees respect confidentiality obligation defined in Article 7.

In case of earlier termination of this Agreement or its regular expiry, INSTITUTION and INVESTIGATOR have to retain all Personal Data that is subject of this Agreement (ISF and medical records related to the Clinical Trial and Clinical Trial Subjects entered into CRF), as defined by Sponsor and required by Regulations, only to the extent and for such period as required by applicable Regulations.

INSTITUTION and INVESTIGATOR shall ensure the confidentiality of all such Personal Data and shall ensure that such Personal Data is only retained as necessary for the purpose(s) specified

by Sponsor requiring its storage and for no other purpose. This Personal Data has to be archived at the site as per applicable regulatory requirements and in line with Sponsor's agreement.

10. INSTITUTION and INVESTIGATOR shall only transfer the Personal Data from any jurisdiction to any other jurisdiction (the European Economic Area ("EEA") constituting a single jurisdiction for this purpose) as necessary to provide the Services under this Agreement or where otherwise instructed by ERGOMED, unless required to do so by law to which INSTITUTION and INVESTIGATOR are subject; in such a case INSTITUTION and/or INVESTIGATOR shall informERGOMED of that legal requirement before Processing, unless that law prohibits such information on important grounds of public interest.

11. INSTITUTION and INVESTIGATOR shall indemnify ERGOMED for any damage suffered by ERGOMED and/or any affiliate of ERGOMED as a consequence of or ensuing from breach by the INSTITUTION and INVESTIGATOR and/or their Sub-processors to perform the obligations under this Agreement relating to data protection. For the purposes of this Article, damage shall mean: (i) fines and other penalties imposed by a supervisory authority or other government agency; (ii) compensation claimed by third parties and; (iii) reasonable costs connected with the execution of this Article.

ERGOMED

SCHEDULE IV
TECHNICAL AND ORGANIZATIONAL SECURITY MEASURES

1. *Certification*- Obtain and implement the IS/ISO//IEC 27001 standard. If the INSTITUTION does not have an IS/ISO//IEC 27001 certification, a comprehensive information security policy may be adopted by the INSTITUTION and subsequently approved by ERGOMED or the Sponsor.

2. *Physical security and access control* - Rights to access and operate the automatic data processing system shall be available only to INSTITUTION's employees, INVESTIGATOR and members of INVESTIGATOR's team who shall be trained in handling of the Personal Data and who shall directly handle such Personal Data. Such persons shall only have access to the Personal Data corresponding to their respective authorisations, which shall be granted solely to such persons. INSTITUTION and INVESTIGATOR shall ensure that the IT systems utilized for the Processing of the Personal Data only allow authorised users access to the data limited to their individual authorisation rights.

3. *Confidentiality* - INSTITUTION and INVESTIGATOR shall at all times keep confidential all Personal Data it Processes pursuant to this Agreement. INSTITUTION and INVESTIGATOR may disclose the Personal Data to its employees, members of INVESTIGATOR's team, officers, representatives or advisers who need to know such information for the purposes of carrying out its obligations under this Agreement provided that such employees, officers, representatives or advisers are required to maintain the confidentiality of the Personal Data in accordance with the terms of this Agreement.

4. *Availability control* - INSTITUTION and INVESTIGATOR shall ensure that the Personal Data cannot be unintentionally lost or destroyed. Without limitation to the foregoing, INSTITUTION and INVESTIGATOR shall implement an antivirus protection system for all equipment used in the Processing of the Personal Data and a data security backup system.

5. *Transfer control* – INSTITUTION and INVESTIGATOR shall ensure that during any transfer of the Personal Data it cannot be read, copied, modified or deleted without authorisation.

6. *Input control* – INSTITUTION and INVESTIGATOR shall implement a system to log who enters the Personal Data into the system used in the Processing of the Personal Data and by whom the Personal Data is removed from such systems.

7. *Separation of data processing for different purposes* – INSTITUTION and INVESTIGATOR shall ensure that any Personal Data collected for different purposes is processed separately.

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INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

सत्यमेव जयते

Certificate No.	:	IN-GJ52697797643585X
Certificate Issued Date	:	07-Feb-2025 09:38 AM
Account Reference	:	IMPACC (AC)/ gj13280311/ GULBAI TEKRA/ GJ-AH
Unique Doc. Reference	:	SUBIN-GJGJ1328031117092482398045X
Purchased by	:	CBCC GLOBAL RESEARCH LLP
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CBCC GLOBAL RESEARCH LLP
Second Party	:	SRI DEVARAJ URS MEDICAL COLLEGE
Stamp Duty Paid By	:	CBCC GLOBAL RESEARCH LLP
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

ADVOCATE & NOTARY + PRAGNA A. DAVE + A.C.C. KANKARIYA AHMEDABAD

IN-GJ52697797643585X

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Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate
3. In case of any discrepancy please inform the Competent Authority.

SHCIL

NOTICE

- **The contents of this e-stamp certificate can be verified at www.shcilestamp.com, Stock Holding mobile application "EStamping" or at Stock Holding Branch/ Centre (the details of which are available at www.stockholding.com).**
- **Any alteration to this certificate renders it invalid and would constitute a criminal offence.**
- **Kindly contact Stock Holding Branch / Centre in case of discrepancy.**
- **For information related to e-Stamping you may write to us on our email id estamp.ahmedabad@stockholding.com or visit our Branch/Centre.**

સૂચના

- આ ઈ-સ્ટેમ્પ પ્રમાણપત્રની વિગતો www.shcilestamp.com દ્વારા અથવા સ્ટોક હોલ્ડિંગની "ઈસ્ટેમ્પિંગ" મોબાઈલ એપ્લિકેશન અથવા સ્ટોક હોલ્ડિંગની શાખા / કેન્દ્ર (જેની વિગતો www.stockholding.com પર ઉપલબ્ધ છે) પર જઈ ને ચકાસી શકાય છે.
- આ પ્રમાણપત્રમાં કરેલ કોઈપણ ફેરફાર અમાન્ય છે અને તે ફોજદારી ગુનો બને છે.
- આ ઈ-સ્ટેમ્પ પ્રમાણપત્રમાં કોઈપણ વિસંગતતા જણાય તો સ્ટોક હોલ્ડિંગની શાખા / કેન્દ્ર પર સંપર્ક કરવો.
- ઈ-સ્ટેમ્પિંગ સંબધિત જાણકારી માટે અમને **estamp.ahmedabad@stockholding.com** પર ઈ-મેઈલ કરવો અથવા અમારી શાખા / કેન્દ્ર ની મુલાકાત લેવી.

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**"), made and effective as of the dated signature at the end of this Agreement ("**Effective Date**"), is by and among;

CBCC Global Research ("**CBCC**"), an Indian Company having its principal place of business at TURQUOISE-IV, 6th Floor, Sardar Patel Ring Rd, opp. Apple Woods, Near Shantipura circle, Ahmedabad, Gujarat 382210, India **represented by** Dr. Sandeep Singh.

And

Dr. Lokanatha D ("Principal Investigator"), having his principal business address at R L Jalappa Hospital And Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar, Karnataka 563103 India

And

R L Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College ("Institution") having its principal business address at R L Jalappa Hospital And Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar, Karnataka 563103 India represented by Dr Kalyani, Director, Research and Development Cell, Sri Devaraj Urs Academy of Higher Education and Research and Dr Rajesh Venkataraman, Consultant Clinical Trials, Sri Devaraj Urs Academy of Higher Education And Research, Tamaka, Kolar, Karnataka, India - 563103

Hereinafter, the Institution, the Principal Investigator and CBCC are individually referred to as the "Party" or collectively referred to as the "Parties".

PREAMBLE

WHEREAS, CBCC has been contracted by Sponsor to perform certain services in connection with the multicenter clinical trial (the "Clinical Trial" or "Study") described in the protocol entitled "A randomized, open label, multi-center, two-treatment, two-period, two-sequence, fully replicate, cross-over, multiple dose, steady-state, bioequivalence study of Olaparib Tablets 150 mg (2*150 mg tablets) of Alembic Pharmaceuticals Limited, India with Lynparza® 150mg Filmtabletten Olaparib (2*150 mg tablets) of AstraZeneca AB, SE-151 85 Södertälje, Schweden, in adult patients with carcinoma of the ovary, breast, prostate or adenocarcinoma of

the pancreas under fasting condition." attached hereto and incorporated herein as Schedule I (the "Protocol") to evaluate the safety and efficacy of Sponsor's drug named in the Protocol (the "Investigational Product"),

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

Whereas the Institution has adequate infrastructure to conduct the Study and allows the Principal Investigator and CBCC to conduct the Study.

NOW THEREFORE, the undersigned Parties have agreed upon the rights and obligations set forth below, which shall apply between them in connection with the performance of the Clinical Trial.

1. SCOPE OF WORK

This Agreement allows the Parties to specify distinct Clinical Trial activities to be performed by the Principal Investigator and Institution for the Study.

1.1. Clinical Trial Conduct

a) The Principal Investigator shall conduct the Clinical Trial at the Institution according to the Protocol provided to the Principal Investigator, which may be amended from time to time in writing by the Sponsor.

b) In the event of a conflict between the terms of this Agreement and the Protocol, the terms of the Protocol shall govern for any matter regulated by applicable laws and regulations and, as to all other matters, this Agreement shall govern.

c) The Institution will allocate highly qualified and trained personnel, equipment, materials (except as otherwise may be provided herein) and facilities as are necessary or useful to perform the Clinical Trial.

d) In performing the Clinical Trial, each Party shall fully comply with all applicable laws and regulations, and all terms and conditions of the Protocol and this Agreement.

e) Principal Investigator and the Institution agree that in performing their obligations under this Agreement, they shall comply with all the applicable laws, rules, regulations guidelines and standards, without limitation to the relevant ICH guidelines and standards and all applicable laws

relating to confidentiality and privacy, prescribed under the Directives of the Institutional Ethics Committee.

f) The Principal Investigator and the Institution will, during the Term, be granted role specific access to a third-party data management platform (the "**Platform**") and shall be responsible for and required, as part of their services, for inputting all correct and applicable information relating to the Study into such Platform within the required deadlines and in accordance with any Platform access or use requirements as may be specified from time to time by the CBCC and/or the third party management Platform provider. CBCC will have the delegated responsibility from the Sponsor for the supervision and monitoring of the Principal Investigator and the Institution and for ensuring the data integrity of the inputted clinical site data entered into the Platform. [Good Clinical Practices (GCP), Good Laboratory Practices ("**GLP**"), the ICH Guidelines and all applicable local, national and international laws, rules, regulations and guidelines including, but not limited to, General Data Protection Regulation ("**GDPR**") and all regulations made thereunder or other legislation implementing or amending the same and any other applicable legislation on the protection of personal data and privacy and with the standard of care customary in the area of clinical research for the pharmaceutical industry will be followed as per the agreement].

1.2. Principal Investigator

a) The work to be performed hereunder shall be performed solely by or under the supervision of the Principal Investigator:

- The Principal Investigator shall take primary responsibility for performing the Clinical Trial at the Institution according to the Protocol, the Good Clinical Practice Guidelines ("**GCP**"), the terms of this Agreement, and the current standard of care of Institution customary in the area of clinical research for the pharmaceutical industry ("**Standard of Care**") along with all applicable statutory provisions;
- The Principal Investigator shall ensure that the standard operating procedures have been documented and are in compliance with GCP and applicable regulations.
- The Principal Investigator represents and warrants that he/she is:
  (i) Qualified by training and experience to perform the Clinical Trial and has special expertise in the field of clinical research relating to the Clinical Trial;

(ii) Has provided CBCC with a true and correct copy of Principal Investigator's current curriculum vitae (CV).

b) If the Principal Investigator is unable to continue with the Clinical Trial, the Principal Investigator and the Institution shall promptly notify the CBCC in writing within 15 days and propose a substitute in place of the Principal Investigator. CBCC, upon consultation with the Sponsor shall have the right to either approve any such substitute or terminate this Agreement within 30 days upon receipt of notification from the Principal Investigator if the proposed substitute is not acceptable to the Sponsor. If accepted by the Sponsor, the substitute Principal Investigator will sign this Agreement for approval and will become a party to this Agreement.

c) During the performance of the Clinical Trial, the Principal Investigator is responsible for, but not limited to, the following aspects:

- Provision of required study documents (eg. curriculum vitae(s), Investigator Undertaking, medical registration certificates and / or other relevant documents evidencing qualification of Investigator (s) and sub-Investigator (s), confirmation of adequate site facilities, etc);
- Progress reporting (including recruitment figures) to the Ethics Committee and CBCC on a regular basis;
- Ensuring access by monitors, auditors and regulatory authorities to the Principal Investigator and other project facilities, original study materials, drug records, subject records, case records and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study – related monitoring, audit and inspections with or without prior intimation to access and review study documents;
- To allow any regulatory audit by DCGI or any applicable regulatory authorities within 25 years of submission of the dossier and ensure compliance of any regulatory deficiency raised by such authorities in a reasonable period of time. If the Institution or Principal Investigator is to submit any information to such regulatory authorities' agencies, such submission shall not be made without CBCC's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval;

- Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
- Inform the Ethics Committee of the Study updates and Study closure;
- Maintenance of drug accountability records, Study documents including Study drug acknowledgement receipts, Study supply receipts, payment receipts, EC approvals etc;
- Handling and storage of the Investigational Products (as hereinafter defined) according to the Protocol;
- Storage of the Investigator site file containing Essential Documents (As per ICH - GCP) and all the Clinical Trial related data for a period as per the scope after completion of the Study. Charges for archival shall be borne as mentioned under **Schedule-II**. The Principal Investigator and/or the Institution shall inform CBCC/Sponsor in writing in the event of relocation or transfer of archiving responsibilities. On completion of the archival period, the Principal Investigator/Institution must notify, in writing, the CBCC for the further management of Study documents and follow CBCC's instructions. CBCC, in turn, will obtain confirmation from Sponsor on further management of Clinical Trial documents. The CBCC, on behalf of Sponsor may direct the Principal Investigator/Institution either to forward the documents to a third-party location identified by the CBCC at CBCC or Sponsor's cost or to destroy the documents at the site, subject to any retention obligations imposed by applicable law on the Principal Investigator/Institution. The record of either the third party archival or destruction must be maintained at the Institution and a copy forwarded to CBCC.
- The Principal Investigator is responsible for training and supervision of sub-Investigators and other site Study team member on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying CBCC of such change in a timely manner.
- The Principal Investigator shall participate in teleconferences required by CBCC/the Sponsor to update the Investigational Product information and resolve issues, if any.
- Principal Investigator/Institute will intimate to CBCC about any inspection(s) from any regulatory authorities for the Study, within 24 business hours of their notification. The

Principal Investigator shall provide adequate medical care to the Study Subject(s) (as defined in Clause 1.7) in case of any adverse events during the Subject's participation in the Clinical Trial. CBCC in turn will notify Sponsor of inspection by regulatory authorities.

- It shall be the duty of the Principal Investigator to report all serious adverse events as per the current regulatory requirement and any applicable laws.

1.3. Ethics Committee Approval

The Principal Investigator shall ensure that the Ethics Committee is registered under CDSCO as per current regulatory requirements and any applicable laws. The Principal Investigator shall also ensure that prior to enrolling any Subjects in the Clinical Trial, the Ethics Committee has approved in writing the conduct of the Clinical Trial at the Institution under the supervision of the Principal Investigator. If the Ethics Committee alters or withdraws its approval of the Clinical Trial in any manner, or of the participation of the Principal Investigator or any Co-Investigators in the Clinical Trial, the Principal Investigator shall promptly notify CBCC/Sponsor in writing. The Principal Investigator shall comply with the terms and conditions laid down in the Ethics Committee approval.

1.4. Communication and Reporting to Competent Authorities

CBCC shall assume responsibility for interaction with and reporting to applicable country regulatory authority and the Ethics Committee as required and/or permitted by applicable laws and guidelines. The Principal Investigator retains responsibility for standard Clinical Trial-related communication and reporting to the Ethics Committee in accordance with standard procedure of the Ethics Committee, Good Clinical Practice guidelines and all other applicable regulatory requirements.

1.5. Informed Consent

a) The Principal Investigator shall ensure that adequate information is given to the Study Subject (or guardian or legal representatives, if applicable) both in oral and written form in a language that the Study Subject fully comprehends and in a manner that is non-technical.

b) The Principal Investigator shall ensure that the Study Subject's Informed Consent is signed, dated and obtained from each Subject participating in this Clinical Trial. The signed and dated consent must be obtained prior to the first procedure set forth in the Protocol and Study Subjects will be allowed sufficient time to decide whether or not they wish to participate in the Clinical Trial.

c) The Principal Investigator shall keep the original Informed Consent Form in the Study Subject's permanent records held by the Institution and hand over a copy to the Study Subject.

d) The Principal Investigator shall ensure that the Study Subject's information sheet and the Informed Consent Form has been approved by the Ethics Committee and they shall be furnished to the Licensing Authority appointed by the Central Government to perform the duties of the licensing authority.

e) The Principal Investigator shall be responsible for responding to all Study Subjects' (as defined below) questions relating to the Study.

1.6. Study Team

The Principal Investigator may appoint other individuals as Co-investigators who are appropriate to assist in the conduct of the Clinical Trial in accordance with the Protocol, provided that (i) the Principal Investigator shall be required to act in accordance with proper professional judgment in making all such appointments; and (ii) the Principal Investigator shall be responsible for all acts, omissions or breaches of this Agreement by such Co-investigators. The Principal Investigator shall be responsible for leading the team of Co-investigators, who in all respects shall be bound by the same obligations as the Principal Investigator, and the Principal Investigator shall keep informed in detail all Co-investigators about all such obligations as they may exist from time to time. The Principal Investigator may also appoint other staff such as site coordinator, phlebotomist etc. for Study related activities. Further, the Principal Investigator shall be responsible for ensuring that the Co-investigator and all staff and personnel within the Institution who participate in the Clinical Trial, have read and understood the Protocol and they are qualified, experienced and trained for conducting the Clinical Trial.

1.7. Study Subject Enrollment

a) The Principal Investigator shall not start enrolling Study Subjects prior to receiving written approval from the Ethics Committee (or equivalent) as well as written authorization from CBCC to do so. The Principal Investigator shall use his best efforts to promptly enroll Study Subjects in the Clinical Trial who meet the eligibility criteria set forth in the Protocol ("**Study Subjects**"), consistent with Standard of Care.

b) CBCC reserves the right to limit the recruitment of further Study Subjects or to cease the recruitment at the site, for reasons relating to the appropriate management of the Clinical Trial, including, without limitation, where the worldwide or applicable national recruitment targets for the Clinical Trial have been reached. Upon receipt of written notice from the CBCC to cease recruitment, the Principal Investigator shall immediately cease further recruitment of Study Subjects.

1.8. Investigational Product

a) The Sponsor/CBCC or designee shall be responsible for providing the Principal Investigator the Investigational Products (Study Drugs) free of charge to conduct the Clinical Trial at the Institution. The Investigational Products provided hereunder are investigational in nature and are not covered by any valid market authorization. The Sponsor/CBCC or designee shall be responsible for providing the supportive Clinical Trial supplies required for the Clinical Trial to be conducted at the site.

b) The Principal Investigator shall:

- not distribute the Investigational Products to any other person or entity,
- allow access of the Investigational Products to persons within its organization having a "need to know",
- use the Investigational Products only on Study Subjects under the Principal Investigator's supervision,
- not analyze, decompose, amend or modify the properties of the Investigational Products, and
- Principal Investigator and Institution shall not use the Investigational Product past the labeled expiration date.
- Shall retain the Investigational products as per the regulatory requirement in consultation with CBCC/Sponsor.

c) The Institution and/or the Principal Investigator shall promptly provide to CBCC all required documentation with respect to the usage and the return of the Investigational Product. After completion or premature termination of the Clinical Trial, the Institution and/or the Principal Investigator shall return unused Investigational Product pursuant to the procedures provided by CBCC and/or Sponsor to the CBCC and/or Sponsor.

1.9. Monitoring of Study

The Principal Investigator and the Institution shall permit CBCC and/or CBCC designee(s)/representative access to the Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, case report forms ("**CRF**"), Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with his obligations. If any governmental entity should audit or inspect the Institution with respect to the Study, the Principal Investigator and/or the Institution shall provide CBCC and the Sponsor with immediate notice and shall provide an opportunity for the Sponsor and CBCC or their designee to be present during such governmental audit.

1.10. Adverse Events & Compensation

a) The Principal Investigator shall ensure that Adverse Events and, Serious Adverse Events ("**AE/ SAE**") whether expected or unexpected are reported in writing to CBCC, the Institution, the Sponsor, regulatory and the Ethics Committee in a timely manner and as defined in the Protocol or equivalent. The Principal Investigator shall strictly adhere to the applicable regulatory laws for conducting Clinical Trial the current regulations of the licensing authority, New Drugs and Clinical Trials Rules, 2019/Medical Device Rules 2017 (of the applicable guidelines and law in India) and provisions of ICH- GCP. The review of serious adverse events shall be undertaken by CBCC in close coordination with the Principal Investigator.

b) The Sponsor agrees that only the Sponsor/CBCC and neither, the Principal Investigator nor the Institution, is responsible for the costs of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to Study Subjects in the Clinical Trial which in the reasonable judgment of the Principal Investigator are determined to result from participation in the Clinical Trial, except for such costs that arise directly from:

- the negligent activities, reckless misconduct or intentional misconduct of the Principal Investigator or his staff, CBCC or its staff or the Institution or its staff; or

- their failure to adhere to the terms of the Protocol.

This clause is not intended to create any third-party contractual benefit for any participants in the Clinical Trial.

1.11. No Reimbursement for Sponsor Paid Drug or Services

The Principal Investigator and the Institution agree that, if the Investigational Product and/or other services are paid for or provided without charge by the Sponsor or CBCC, the Principal Investigator, the Institution and/or any other vendor subcontracted or engaged by the Principal Investigator/Institution shall not separately bill or seek reimbursement for such Investigational Product and/or services from any third party including, without limitation, the Study Subject, any private provider of Insurance or state program.

1.12. Deviation to Protocol

The Principal Investigator shall not deviate from the approved Protocol unless the Study Subject's status deems this essential. Any deviation and the reason(s) for such deviation to the Protocol shall be recorded and reported by the Principal Investigator to CBCC and to the Ethics Committee, as applicable.

2. COST AND PAYMENT

2.1. Consideration

a) In consideration of the services provided under this Agreement, CBCC will be responsible for all fees payable to the Institution and/or the Principal Investigator on a per subject basis as set forth in the Payment **Schedule II** of this Agreement. The per subject fee structure detailed in **Schedule II** of this Agreement shall remain unchanged for the duration of the Study, unless otherwise agreed in writing by all Parties. All payments towards the Principal Investigator and the Institution services shall be payable in Indian Rupees and will be paid within forty-five (45) days of receipt and approval of an invoice by CBCC. CBCC or the Sponsor shall not be obligated to any person or entity to pay any amounts not explicitly set forth in **Schedule II** of this Agreement. The Principal Investigator and the Institution shall be jointly and severally responsible for the payment of any or all taxes that may apply to any payment it receives, including without limitation, for

paying any value-added tax, sales tax, or similar tax imposed by the taxation authorities in any jurisdiction.

b) **Cost per Subject:** Payments will be made on invoices received in INR and will be released based on data entered in subject electronic case report forms (eCRF's). All payments will be on a pro rata basis. For Study Subjects who do not complete the Clinical Trial (Screen failure, early termination, drop – out, etc.), the payment schedule will be evaluated according to the number of days/visits completed by such Study Subject.

c) The Institution shall generate invoice/request for payment on a monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). The final payment and Archival Fees will be made by CBCC at the time of site close out visit or immediately after site close out visit or as agreed.

d) Other Parties appointed by the Principal Investigator (such as, Radiology, Local Laboratory, ECHO, ECG, etc.) will be managed and paid by the Principal Investigator.

e) The Ethics Committee fee will be paid by CBCC and is separate from the Per-Subject fee.

f) **Screen Failures:** The Institution/Investigator will be paid for (1) Screen Failure (as defined below) for every (2) subject(s) who are randomized. Institution will be reimbursed as per procedure basis in accordance with the rates set forth in the Budget for a maximum of (04) screen failures. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the pre-screening and/or screening visit but does not randomize into the Study. Payment for Screen Failures will be payable to Institution based upon the receipt of correct and itemized invoices or on a quarterly basis in conjunction with the Institution's other payment invoices.

g) If a Study Subject was randomized in the Study deviating from the 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 in such an event and only if performed according to the Protocol.

h) **Unscheduled Visits:** An Unscheduled Visit means a subject visit which is not expressly set forth in the Protocol, but is otherwise required for the Study. Unscheduled Visits will be reimbursed on a per procedure basis in accordance with the rates set forth in Budget. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval

before procedure is performed. Amount of compensation for a procedure not included in Budget will be approved at the time written approval is provided.

2.2. The Institution and the Principal Investigator shall review the payment details generated by CBCC that shall accompany each payment and shall inform CBCC in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. At the completion of the Study, the Institution and the Principal Investigator shall ensure that any such discrepancies that may exist are brought to the attention of the CBCC no later than one month after the Study database is locked. The Parties shall work diligently and in good faith to resolve any such discrepancies.

2.3. Overpayment/ Underpayment

If, at the date of Study termination, the total amount paid to the Principal Investigator/Institution exceeds the amount to which the Principal Investigator/Institution is entitled, the Principal Investigator/Institution shall return the overpayment to CBCC within forty-five (45) days following termination of the Study, delivery to CBCC of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to CBCC of all items provided which will be listed separately.

2.4. Reasonable Efforts

The Principal Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum eligible Subjects in the study. The recruitment will be competitive among participating sites.

2.5. Relationship of Parties

Sponsor shall be responsible for all payments to the Principal Investigator / Institution pursuant to this Agreement. As it relates to the payment of fees hereunder, CBCC is only responsible for (a) receiving, reviewing and approving the invoices received from Principal Investigator/ Institution, and (ii) the transfer of funds to the Principal Investigator/ Institution upon receipt of the funds from Sponsor.

2.6. Institution Payment for Investigational Products and Other Expenses.

The Institution acknowledges that the Product being investigated in the Clinical Trial is being provided by the Sponsor free of charge, for exclusive use on Study Subjects.

3. REPORTS, ACCESS

3.1. Access to the Principal Investigator

The Sponsor and CBCC shall have reasonable access (at mutually agreeable times and locations) to the Principal Investigator for the purpose of discussing progress reviews, internal reporting and other matters related to the Clinical Trial, including on site monitoring at intervals specified in the monitoring plan agreed by CBCC and the Sponsor.

3.2. Records and Reports

a) The Institution and/or the Principal Investigator shall prepare and maintain complete, accurately written records, accounts, medical notes, reports, and data including all supporting documentation for each Study Subject ("**Source Documents**") in accordance with all applicable laws. The Principal Investigator shall prepare and submit to the CBCC all CRF's and all additional documentation for each Study Subject as required by the Protocol and shall promptly resolve all data queries from the Sponsor and CBCC. The Principal Investigator shall ensure that any data or supportive documentation provided to the Sponsor and CBCC does not include any information that would personally identify a Study Subject.

b) Study Subjects CRFs and all other records and reports relating to the Clinical Trial shall be available for inspection or copying by the Sponsor and CBCC, as soon as reasonably possible. The Institution shall allow access of original Study Subject medical records, and any documentation related to the Clinical Trial, for monitoring by the Sponsor and CBCC or their representative, possible audit or inspection by the Sponsor, CBCC, relevant competent authorities and other regulatory agencies.

c) All records and reports required by this Agreement, or prepared in connection herewith such as the Investigator Site File containing essential documents and source data must be maintained by the Institution and the Principal Investigator in a secure place at the Institution/Principal Investigator's cost for a period of at least Twenty five (25) years after the later of:

- the termination or expiration of this Agreement;

- the completion of the Clinical Trial; or
- As required by the applicable laws.

d) In the event that the Principal Investigator is to destroy the Investigator Site File or source data, the Principal Investigator shall inform CBCC and the Sponsor in writing prior to destruction to confirm it is acceptable for them to be destroyed.

4. CONFIDENTIAL INFORMATION

4.1. Definition of Confidential Information.

a) The term "Confidential Information" shall include, but is not limited to reports, notes, analyses, memoranda, models, prototypes, drawings, plans, diagrams, photographs, test results, formulae, algorithms, research records, laboratory results, clinical results, laboratory methods and procedures, clinical methods or procedures, whether such information is communicated to recipient orally, in writing or any other hard copy such as computer discs or is learned by recipient or prepared by recipient in the course of or after the end of its relationship with the provider.

b) Confidential Information does not include information which:

- prior to or subsequent to the time of disclosure, Confidential Information is independently known to the recipient, as evidenced by written documentation;
- prior to or subsequent to the time of disclosure, Confidential Information has legitimately entered the public domain, as evidenced by written documentation;
- subsequent to the time of disclosure, Confidential Information becomes or is made available to the recipient by a third party having the lawful right to do so, as evidences by written documentation;
- is independently developed by the recipient or its agents or employees by persons who did not receive the Information, as evidenced by written documentation; and
- is disclosed to others by the Provider without restrictions concerning disclosure and/or commercial use.

4.2. Term of Confidentiality

Each Party agrees that during the Term of the Agreement, and for a period of ten years thereafter, (i) it will not use Confidential Information owned by any of the other Parties except for the purpose of carrying out this Agreement; (ii) it will maintain the Confidential Information in confidence and not disclose the same to anyone other than to their respective employees and agents who have a need to know the Confidential Information for the purpose of completing the Clinical Trial and provided the disclosing party advises all employees and agents having access to any Confidential Information of its confidential nature and the recipient's obligations under this Agreement; (iii) it will safeguard all Confidential Information by using a reasonable degree of care that is not less than the degree of care used by the recipient in safeguarding its own Confidential Information.

4.3. Use of Confidential Information

a) Each Party agrees to keep the disclosed Confidential Information in strict confidence and not to disclose or otherwise use the Confidential Information for any other purpose. Accordingly, the recipient agrees to treat the Confidential Information, which it receives as it would its proprietary information and to take all reasonable precautions to prevent the unauthorized disclosure to any third party of the Confidential Information, which it received hereunder.

b) All tangible or hard copies containing the Confidential Information, which is or will be in the possession of any recipient hereunder, shall be returned to the disclosing Party at the first request.

c) The Confidential Information shared with any recipient hereunder will not be disclosed to any other Parties without prior written permission of the disclosing Party.

d) The recipient will not develop any modification, improvement, alteration, technology, idea, concept or design based on the information disclosed without the prior written consent of the disclosing Party;

5. DATA PROTECTION

Each of the parties agrees and ensure that required and appropriate measures shall be taken for protection of personal data and privacy.

6. INVENTIONS AND PATENT RIGHTS

6.1. Disclosure of Inventions, Reports and Results

The Institution and the Principal Investigator shall promptly and fully:

a) disclose to the Sponsor/CBCC in writing all improvements, developments, discoveries and inventions, whether or not patentable, conceived or first reduced to practice, either alone or with others, in connection with the performance of the Clinical Trial or relating to the Investigational Product and/or Confidential Information ("**Inventions**"); and

b) Disclose and deliver to the Sponsor/CBCC all results of the Clinical Trial ("**Results**") and all reports, records and other materials prepared by the Institution or the Principal Investigator, either alone or with others, in connection therewith or relating to the Investigational Product or Confidential Information ("**Reports**").

6.2. Ownership of Inventions, Reports and Results

All Inventions, Reports and Results are, and shall always be, the exclusive property of the Sponsor. All rights, title and interest of the Institution and the Principal Investigator in and to such Inventions, Reports and Results shall be automatically assigned to and shall belong exclusively to the Sponsor without any additional compensation than the ones listed in **Schedule II** of this Agreement. The Institution and the Principal Investigator, to the extent necessary (and at Sponsor's expense) will execute such documents as are reasonable and customary to perfect in and transfer to the Sponsor the ownership rights of the Institution and the Principal Investigator. Notwithstanding the foregoing, the Institution and the Principal Investigator shall have the right to publish the Results in accordance with clause 7 of this Agreement.

7. PUBLICATIONS

7.1. The data and Results from this Clinical Trial are the property of the Sponsor. As the Clinical Trial is a multi-Centre study, the Parties agree that, consistent with international standards for scientific and medical publications, the data from all centers will be analyzed collectively and reported as such (which including the Results and Reports shall be hereinafter the "**Study Outcome**"). CBCC, the Institution and the Principal Investigator (including its affiliates, employees, agents, authorized sub-contractors and consultants as applicable) shall not make any publications of the Study Outcome or refer to in whole or in part of the Study Outcome without first obtaining the prior written consent of the Sponsor and shall

not use the Sponsor's name in connection with any publication without the Sponsor's prior written consent.

7.2. Sponsor shall have the right to access and use all data, results and the Study Outcome generated during the Clinical Trial. The Clinical Trial site will not use the clinical related data without the written consent of Sponsor for any other purpose than for Clinical Trial completion. The Principal Investigator, CBCC, the Institution shall properly refer to the Sponsor in all publications or presentations resulting from the performance of the Clinical Trial and provided the provisions of Clause 7.1 have been adhered to. No Party may use the name of any other Party in any advertising or other form of publicity without the written permission of the Party whose name is to be used.

8. INDEMNITY AND INSURANCE

8.1. Sponsor Indemnification

CBCC on behalf of Sponsor shall indemnify the Principal Investigator and the Institution, (including the Principal Investigator's and the Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, incurred by the Investigator Indemnitees as a result of any claim(s), lawsuit(s), loss(es) action(s), demand(s) or judgment(s) against them arising out of the conduct of the Clinical Trial pursuant to the Protocol ("Claims"); provided however the CBCC/Sponsor will not be responsible for and assumes no liability for any loss, claims, or demands to the extent arising from any of the following:

a) the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to:
   - the terms of the Protocol and /or this Agreement including any amendments thereto; or
   - applicable international, provincial, or local laws; or
   - the written instructions relative to the use of the Investigational Product

b) in no event shall the collective, aggregate liability (including without limitation, contract, tort or breach of statutory duty) of the Sponsor under this Agreement exceed the amount of fees paid to the Investigator Indemnitees under this Agreement.

8.2. Institution Indemnification

The Institution shall indemnify, defend and hold harmless the Sponsor and CBCC (including the Sponsor's and CBCC's affiliates, contractors, agents, fellows, employees and servants) (collectively "**Sponsor Indemnitees**") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by the Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees and/or any Investigator Indemnitees failure to adhere to the terms of the Protocol and/or this Agreement, or applicable international, provincial or local laws or the written instructions relative to the use of the Investigational Product. The Principal Investigator and the Institution shall carry professional Indemnity Insurance and such other insurance required to indemnity under this clause, for the Term of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. The Principal Investigator and the Institution shall provide the copy of insurance as and when required by CBCC and the Sponsor.

8.3. Serious Adverse Event Reimbursement

Notwithstanding any other terms contained in this Agreement, the Sponsor/CBCC will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Study Subject's SAE in accordance with the provisions of Clause 1.10.

9. DEBARMENT

Debarment and Exclusion: The Institution and the Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. The Institution and the Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and have not violated any applicable anti-kickback or false claims laws or regulations. During the Term of this Agreement and for three (3) years after its termination, the Principal Investigator and the Institution will notify CBCC and the Sponsor promptly in writing to the extent possible within two (2) business days if either of this certification needs to be amended in material issues related to the medical licensure of any associated researchers. The Institution and the Principal Investigator will cooperate with CBCC and /or Sponsor regarding any responsive action necessary.

10. TERM AND TERMINATION

10.1. Term

This Agreement shall, subject to the early termination provisions as specified hereunder, have a term of three years from the Effective Date unless extended or terminated earlier by mutual written agreement of the Parties (the "**Term**") Notwithstanding the foregoing, all obligations which are by their nature continuing, including, without limitation, such obligations contained in Clauses 4 through 8, the effect of termination provisions of this Clause 10 and Clauses 12 and 14 shall survive the expiration or termination of this Agreement.

10.2. Early Termination

a) The CBCC may terminate this Agreement during the Term with or without cause upon providing written notice to the other Parties.

b) The CBCC may terminate this Agreement for a breach of this Agreement upon thirty (30) days' written notice specifying the nature of the breach. "Breach" shall be defined as failure to comply with any material provision of this Agreement. If such breach has not been substantially cured within the thirty (30) day period, the CBCC may terminate this Agreement. In the event of termination, the Parties shall promptly meet to prepare a close-out schedule, and the Principal Investigator/Institution shall cease performing all work not necessary for the orderly close-out of the Clinical Trial or required by applicable laws or regulations. The CBCC may terminate this Agreement immediately upon provision of written notice if any of the Parties becomes insolvent or files for bankruptcy.

c) The Institution or the Investigator may also terminate this Agreement [Immediately, if in its reasonable judgment such termination is necessary to protect the health, safety and welfare of any Study Subject, by giving 24 hours written notice of termination to the other Parties.]

d) In addition to the early termination rights as set out above, if applicable, CBCC or the Sponsor reserves the right to terminate the Clinical Trial by the provision of immediate notice in the case of (i) below and by thirty (30) days' notice in the case of (ii) and (iii) below to the other Parties where such termination is necessary if:

(i) In the interest of subject/patient safety;

(ii) In order to comply with the requirements of any government agency, board, or department; and

(iii) In order to comply with the decision of the IEC/ IRB.

In the event of any early termination, and except in the event of early termination pursuant to Clause 10.2(c), CBCC shall reimburse the payee designated in **Schedule III** of this Agreement for all contractual commitments and financial obligations reasonably and necessarily incurred by the Institution in performing this Agreement prior to such termination and to the extent such financial obligations or contractual commitments cannot be cancelled by the Principal Investigator/Institution and the Principal Investigator and Institution shall cease incurring any further costs.

e) Upon receipt of a notice of termination, the Principal Investigator and the Institution shall immediately cease:

- enrolling Study Subjects in the Clinical Trial; and
- Conducting procedures in connection with the Clinical Trial, to the extent medically advisable, on Study Subjects.

Such termination shall not commence until Study Subjects can be transitioned out of the Clinical Trial without suffering any adverse medical effects. Unless otherwise directed by the Sponsor/CBCC, the Institution and the Principal Investigator shall immediately return:

- all Results, Reports and Inventions; and
- all unused Investigational Products to the Sponsor/CBCC if the Clinical Trial is terminated, suspended, discontinued or completed; unless the return of Investigational Product would jeopardize the rights, safety, or welfare of a Study Subject.

11. COVENANTS AND WARRANTIES

11.1. The Institution and the Principal Investigator represent and warrant that the services covered by this Agreement are not in violation of any other agreement with other Parties or of any restrictions of any kind to which either is bound.

11.2. The Institution and the Principal Investigator each represent and warrant that:

a) they have not been found by the US FDA or the relevant international competent authority officials to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations;

b) no form FDA-483 (or equivalent international requirement) has been issued to either Institution or Principal Investigator with respect to any site at which the Principal Investigator has served as a clinical investigator; and

c) they have not been terminated from any investigation or research project for reasons other than completion of the research project.

The Institution and the Principal Investigator agree that if any of the events listed in a), b), or c) above should occur, they shall notify the Sponsor/CBCC in writing within three business days of each such occurrence.

12. NO WARRANTIES

CBCC, the Principal Investigator and the Institution makes no warranties, express or implied, as to any matter whatsoever, including, without limitation, the results of the Clinical Trial or any invention, process or Investigational product, whether tangible or intangible, conceived, discovered, or developed under this Agreement. The provisions of this clause shall survive termination of this Agreement.

13. FORCE MAJEURE

A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, terrorism or government action (a "**Force Majeure Event**") provided the affected Party gives the other Party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected Party will be unable to perform its obligations under this Agreement. The affected Party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other Party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that either Party may terminate this Agreement if such Force

Majeure Event continues for a period of forty-five (45) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event.

14. MISCELLANEOUS

14.1. Unless otherwise specified, this Agreement, together with the **Schedules** of this Agreement, embodies the entire understanding among the Parties with regards to the subject matter hereof, and any prior or contemporaneous agreements between the Parties relating to the subject matter hereof, either oral or written, are hereby superseded.

14.2. No amendments or changes to this Agreement, including without limitation, changes to the Protocol or to the **Schedules** of this Agreement, shall be effective unless made in writing and signed by the authorized representatives of the Parties.

14.3. This Agreement shall be governed by the applicable laws of India with jurisdiction and place of delivery being India.

14.4. If any provision of this Agreement is determined to be unenforceable or prohibited by any applicable laws, such provision shall be ineffective only to the extent of such unenforceability or prohibition without invalidating the remainder of such provision or the remaining provisions of this Agreement. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and the successor to substantially the entire business and assets of the respective Parties hereto.

14.5. Notice

a) All notices, requests, demands or other communication required or permitted to be given under this Agreement shall be in writing, in English language (including by facsimile and/or email) and shall be effective upon delivery to the intended Party (whether by personal delivery or registered post or courier of international repute or facsimile or email) at the address, and shall be marked to the attention of the person, indicated hereunder, unless the contrary is proved, be deemed to be delivered and duly served at the time of delivery, if made or delivered by hand, with acknowledgement of receipt thereof; on the 5th (fifth) business day after the date of posting by

registered post or courier; when confirmation of its transmission has been recorded by the sender's facsimile machine, if made or delivered by facsimile; or when dispatched and a receipt of delivery confirmation is received, if made or delivered by email:

If to **CBCC**, at:

Address: TURQUOISE-IV, 6th Floor, Sardar Patel Ring Rd, opp. Apple Woods, Near Shantipura circle, Ahmedabad, Gujarat 382210, India
E-mail Address: Sandeep.singh@cbcc.global

Kind Attention: Dr. Sandeep Singh

Phone No.: +91 97264 34201/02/03

If to **Principal Investigator**, at:

Address: R L Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar- 563103, Karnataka, India
E-mail Address: drlok61@gmail.com
Kind Attention Dr. Lokanatha D
Phone No.: +91-9845695589

If to **Institution**, at:

Address: R L Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar- 563103, Karnataka, India
E-mail Address: dir.research@sduaher.ac.in
Kind Attention: Dr Kalyani R
Phone No.: +91 9448402775
&
Dr Rajesh Venkataraman,
Consultant Clinical Trials,
Sri Devaraj Urs Academy of Higher Education And Research,
Tamaka, Kolar, Karnataka – 563103.
With copy to: drrajesh.ahrc@gmail.com

If any notices, requests, demands or other communication required or permitted to be given under this Agreement is received by the intended Party (as aforesaid) after the normal business hours or on a non-business day, then the same shall, unless the contrary is proved, be deemed to be delivered and duly served on the succeeding business day.

b) Any change to the particulars of any Party, as set out above (i.e., the address, the e-mail address, the facsimile number and the phone number), shall also be notified to all the other Parties in the manner mentioned herein, otherwise, such changes shall not be effective and binding on such other Parties.

14.6. The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the construction or interpretation of this Agreement. This Agreement may be executed and delivered in one or more counterparts, each of which when executed and delivered shall be deemed to be an original but all of which when taken together shall constitute one and the same Agreement.

14.7. The Principal Investigator and the Institution may not assign this Agreement to any other Party, nor may it subcontract any of its services hereunder, without CBCC's and Sponsor's prior written consent. Any attempted assignment without CBCC's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement. CBCC may assign this agreement to sponsor or its designee upon written notice to the institution / Principal Investigator. Nothing in this section 14.7 shall be constructed to limit CBCC' ability for any claim that arises out of any action or omission by CBCC that occurred during the period in which CBCC was a party to this agreement, i.e. before assignment hereof.

14.8. This Agreement may be executed by the Parties and transmitted in a scanned version, with the same effect as if the Parties had delivered an executed original Agreement. Each of the Parties may request, at its own election, an original copy of the Agreement. None of the Parties shall be bound to this Agreement until all of the Parties have executed an original or scanned pdf version counterpart.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

CBCC- Representative:

NAME: DR. SANDEEP SINGH

Signature: _____ Date: 07/Feb/2025

Principal Investigator:

NAME: DR. LOKANATHA D

Signature: _____ Date: 18. feb. 2025

Institution Representative:

Name: DR KALYANI R

Signature: _____ Date: 18/02/'25

Title: Director, Research and Development Cell,
Sri Devaraj Urs Academy of Higher Education and Research

Schedule I – Protocol

Study Title: A randomized, open label, multi-center, two-treatment, two-period, two-sequence, fully replicate, cross-over, multiple dose, steady-state, bioequivalence study of Olaparib Tablets 150 mg (2*150 mg tablets) of Alembic Pharmaceuticals Limited, India with Lynparza® 150mg Filmtabletten Olaparib (2*150 mg tablets) of AstraZeneca AB, SE-151 85 Södertälje, Schweden, in adult patients with carcinoma of the ovary, breast, prostate or adenocarcinoma of the pancreas under fasting condition.

Study Number: CO240007

Schedule II: Study Budget

Evaluation				Period 1					Period 2						
Type of Visit	Screening Part 01	Stabilization Period (at least 15 days prior to randomization)	Screening Part 02 (Within 07 days prior to randomization)	Day 1	Day 4	Day 5	Day 6	Day 7	Day 8	Day 11	Day 12	Day 13	Day 14	End of study safety assessment	Total
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Investigator	4000	4000	4000	4000	3500	4000	4000	4000	3500	3500	4000	3500	3500	4000	53500
Study Coordinator	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	35000
Study Nurse	300	300	300	300	300	300	300	300	300	300	300	300	300	300	4200
Phlebotomist	350	350	350	350										350	1750
Social worker / Research Assistant	500	500	500	500	500	500	500	500	500	500	500	500	500	500	7000
12 lead ECG	550		550											550	1650
Chest X-Ray	800														800
D-dimer	2000		2000											2000	6000
Hospitalization						6000	6000	6000			6000	6000	6000		36000
Patient Reimbursement	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	14000
														Total Cost	159900
														Intitutional Overhead (25%)	39975
														Total Cost Per Completed Patient (Including Institutional Overhead)	199875

Payment will be prorated based on number of Days/visits completed.

Hospitalization Cost includes medication & any other resources used during the IP administration and hospital stay from Day 5 to Day 7 (Period 1) and Day 12 to Day 14 (Period 2).

GST is subjected to the submission of GST compliant invoice & copy of GST registration certificate.

D-dimer will be performed for patients with metastatic castration-resistant prostate cancer (mCRPC) at local laboratory.

Local Laboratory charges except D-dimer will be paid if used during the study. Local Lab should be NABL accredited

Chest X-ray PA view (posterio-anterior view) If no thoracic imaging is performed within 06 months prior to screening

Archival Cost of **INR 2,00,000 /-** will be paid at the time of site close out visit for archival of study documents for **25 years.** If needed archival facility can be arranged at third party as per sponsor requirement. Archival cost will be not applicable in the case of no enrollment at site.

Schedule III - Payee Details

Study Title : A randomized, open label, multi-center, two-treatment, two-period, two-sequence, fully replicate, cross-over, multiple dose, steady-state, bioequivalence study of Olaparib Tablets 150 mg (2*150 mg tablets) of Alembic Pharmaceuticals Limited, India with Lynparza® 150mg Filmtabletten Olaparib (2*150 mg tablets) of AstraZeneca AB, SE-151 85 Södertälje, Schweden, in adult patients with carcinoma of the ovary, breast, prostate or adenocarcinoma of the pancreas under fasting condition.

Protocol Number : CO240007

Investigator : Dr. Lokanatha D

Site Address : R.L, Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar- 563103, Karnataka, India

Payment Details:

Payee Name	Sri Devaraj Urs Academy of Higher Education and Research
Payee Address	Tamaka, Kolar, Karnataka, India
Bank Name and Address	Kotak Mahindra Bank Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar
Cheque/Draft (in favor of)	Sri Devaraj Urs Academy of Higher Education and Research
Sort Code	-
Account Number	2849611362
PAN Card Number	AAATS5344P
GST Number	29AAATS5344P1ZT
IFSC Code	KKBK0008269
BIC	-
IBAN	-
Contact person for payments	Dr. Bhuvana K, Chief Co-ordinating Officer, Clinical Trial Centre, SDUAHER, Kolar. Email Address: bhuvanak@sduaher.ac.in Contact Number: +91 99003 83738

Terms and Conditions

The total consideration for the Services or Goods provided by the Principal Investigator and Institution is mutually decided and shall be as laid down in the agreement as applicable.

Point be taken care of while preparing the invoice.

Tax invoice number (it must be generated consecutively, and each tax invoice will have a unique number for that financial year and the invoice number should not exceed 16 digits including numeric, alphabetical, and special characters)

The Principal Investigator and Institution should mention the MSME number as applicable on invoices.

Name of CBCC Global Research LLP contact point on every Invoice.

Company Name and Bill to address – As per GST certificate

Description of the goods/services as per Agreement

Tax identification number (PAN) and GST number of both parties- This should reflect correctly on every Invoice.

Select the Tax component correctly with a breakup of amounts of Tax if applicable (e.g. Bifurcation if tax as per CGST, SGST, IGST as applicable).

The invoice value should match per Agreement value, or payment milestone mentioned in the Agreement.

Signature of the supplier on Invoices.

Bank details- as per original details shared to CBCC Global Research LLP (Cancelled Cheques) at the time of signing of Agreements. In case of any changes in Bank details, you are requested to share the new Bank details along with Cancelled cheques and official requests from the Principal Investigator and Institution.

CBCC Global Research LLP shall be entitled to deduct from any sums due hereunder any withholding taxes and other statutory duties which are mandatory to be deducted according to the applicable laws in force on the date of payment or invoice booking, whichever is earlier.

The Principal Investigator and Institution shall issue a valid tax invoice/debit or credit note in the format prescribed under the relevant Good and Service Tax (GST) Act and rules framed thereunder ("GST Law") including (e-invoicing requirement). If the services provided by the Vendor or Service provided are taxable under GST, the Principal Investigator and Institution shall ensure that the contents prescribed by the GST Law like GST number along with HSN code for services and QR code/IRN number (if applicable) are reflected on the face of the invoice. Further, the tax invoice/debit or credit note shall be uploaded on the GSTN portal within the prescribed timelines. Principal Investigator and Institution shall incorporate the transaction with CBCC Global Research LLP under the Agreement in the periodical statutory returns filed by it within the prescribed time as required under the relevant and applicable GST Law and shall ensure that all taxes due as per the said return has been duly remitted in the manner prescribed under applicable law. Non–compliant invoices will be rejected with reasons and the Principal Investigator and Institution shall be required to send the revised invoice/debit or credit note. This is mandatory to ensure compliance with GST. If GST is exempted, necessary certificates and declarations are to be provided to CBCC Global Research LLP.

Any mismatches reported by the GSTN portal if due to an error by the Principal Investigator and Institution shall be reconciled and resolved by the Principal Investigator and Institution within the prescribed time. In all such cases where CBCC Global Research LLP is not able to avail input tax credit of GST amount paid or denied to CBCC Global Research LLP on account of mismatches on GSTN portal, non-payment of GST to government or non-filing of GST returns or non-uploading of invoice within due timelines or uploading invoice with incorrect GSTIN of CBCC Global Research LLP or other reasons attributable to any failure on Principal Investigator and Institution part including (e-invoicing requirement), then the Principal Investigator and Institution agrees that CBCC Global Research LLP shall have the right to set-off any such amounts (along with interest and penalty payable to government authorities) from any amounts that is already due or will become due and payable to the Principal Investigator and Institution under this Agreement or any other agreement. Further, CBCC Global Research LLP also reserves the right to recover the amount from the Principal Investigator and Institution for which the input tax credit of GST could not be availed and any interest and penalty so charged by a government on CBCC Global Research LLP for such default of the Principal Investigator and Institution by raising a debit note, Principal Investigator and Institution will be responsible to make payment against such debit note within 7 days from date of issuance of debit note.

The Principal Investigator and Institution agrees that if at any later date, any error is found in the invoice, the same shall be rectified by the Principal Investigator and Institution by issuing a debit/credit note as applicable.

The Principal Investigator and Institution shall further indemnify, hold harmless and defend at its costs, expense CBCC Global Research LLP, its directors, officers and employees, its affiliates in relation to: (a) any claims from applicable tax authorities including interest/penalty or any amounts levied upon/paid by CBCC Global Research LLP due to the default, error or non-compliance of the

Principal Investigator and Institution; (b) any loss/denial of input tax credit to CBCC Global Research LLP due to non-compliance of GST regulation by The Principal Investigator and Institution or due to late submission of invoices by The Principal Investigator and Institution ; (c) any interest and/or penalty levied/paid by CBCC Global Research LLP to tax authorities in relation to loss/denial of input tax credit to CBCC Global Research LLP as mentioned in above point; and/or (d) non-compliance of obligations set out hereinabove in respect to GST Law and under other applicable laws.

The Principal Investigator and Institution shall provide their correct PAN and a self-declaration that they are not a specified person, as provided in Sec 206AB or Sec 206CCA of the Income Tax Act 1961, as the case may be, for the purpose of deduction/collection of TDS/TCS at a higher rate.

The payment by the CBCC Global Research LLP is exclusive of all taxes, duties, levies or other governmental fees for which the Principal Investigator and Institution will be responsible for accounting to the applicable governmental authorities. All payments made hereunder will be made in INR or applicable currency as per the signed agreement. Any overpayment by CBCC Global Research LLP shall be credited or refunded to CBCC Global Research LLP by the Principal Investigator and Institution within thirty (30) days of reconciliation.

CBCC Global Research LLP may suspend payment of an invoice if it raises a bona fide dispute as to the accuracy of any invoice submitted by the Principal Investigator and Institution.

The Principal Investigator and Institution shall keep and maintain complete and accurate books and records in sufficient detail to determine amounts owed to the Principal Investigator and Institution hereunder and shall be made available for inspection, copying and audit by CBCC Global Research LLP, upon reasonable notice by CBCC Global Research LLP, for the sole purpose of determining the accuracy of amounts invoiced.

Documentation Requirements.

Company/Trust Registration as applicable

GST Certificate as applicable

PAN Card copy

Bank Cancelled Cheque copy.

MSME certificate as applicable