

CLINICAL TRIAL AGREEMENT

Ki3 Private Limited
No.5/3, Jayalakshmi Street, Radha Nagar,
Chrompet, Chennai - 600 044
(AS SPONSOR)

AND
Dr. S. Ratnasamy
Director
Sri Venkateshwaraa Medical College Hospital and Research Centre
Ariyur, Puducherry 605102

(AS SITE)

AND
Dr. K Suresh MBBS, MD, Professor and HOD,
Department of General Medicine,
Sri Venkateshwaraa Medical College Hospital and Research Centre

DATED: 7th April 2025

THIS CLINICAL TRIAL AGREEMENT executed on the day of 7th April 2025

by and between

Ki3 Private Limited, a company, registered in accordance with the laws of the Republic of India, having its office at No.5/3, Jayalakshmi Street, Radha Nagar, Chromepet, Chennai - 600 044, hereinafter referred to as the "**SPONSOR**", on behalf of the manufacturer, Apex Laboratories Private Limited.

And

Dr. S. Ratnasamy
Director
Sri Venkateshwaraa Medical College Hospital and Research Centre
Ariyur, Puducherry 605102

And

Dr. K Suresh MBBS, MD,
Professor and HOD,
Department of General Medicine,
Sri Venkateshwaraa Medical College Hospital and Research Centre

Here in after referred to as the "**Site Investigator**" / "**Principal Investigator**".

The Sponsor, Site and Investigator are collectively referred to as "*Parties*" and individually referred to as "*Party*" where the context so necessitates.

WHEREAS,

- A. Ki3 Private Limited, the Sponsor is in the business of providing Clinical Trial Services, and will act on behalf of the test substance manufacturer; Apex Laboratories Private Limited. India, for this study entitled "**A Phase 3 prospective, comparative, placebo controlled, clinical study to evaluate the efficacy and safety of Zincovit ACTIVE Instant Rehydration Solution in fatigue/stress**".
- B. The Site, Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry is engaged in treatment of patients & conducting clinical trials and the PI is **Dr. K Suresh MBBS, MD**. Designation Professor and HOD at Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry - 605102 to execute the study under discussion.
- C. The Director is the Head of the Institute, and has the authority to permit the study under discussion, at his/her site.
- D. The hospital is engaged in healthcare delivery, teaching and clinical research.

In view of the above, the Parties hereto have agreed to conduct Clinical Trial on such terms and conditions as stated below.

NOW THEREFORE, in consideration of the mutual promises and conditions stated herein, and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

1. Definitions and Interpretations

1.1 In this Agreement:

“**Adverse Event**” shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject during the Clinical Trial.

“**Applicable Laws**” shall mean any applicable statute, law ordinance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

“**Case Report Form**” shall mean the case record form in electronic format for each Subject in the form and manner provided by the Sponsor.

“**Clinical Trial**” shall mean a clinical trial conducted as per the Protocol.

“**Clinical Trial Documents**” shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Report Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor or site may, from time to time, provide.

“**Disability**” shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of God, inclement weather or other reason or cause beyond that Party’s reasonable control.

“**Dispute Notice**” shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

“**Drug**” or “**Clinical Trial Drug**” shall mean the chemical compound invented by the Manufacturer, excluding a Vehicle, in respect of which the Clinical Trial is being conducted.

“**Drugs Act**” shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

“**Effective Date**” shall mean the date of execution of this Agreement on which date it shall come into effect’ (execution date is stated at the start of the Agreement).

“**Ethics Committee**” shall mean the ethics committee formed by the Site and in accordance with the Applicable Laws to review and approve all types of research

proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

“**ICH GCP Guidelines**” shall mean the International Conference on Harmonization- Good Clinical Practice issued by Helsinki Declaration in June 1964 with applicable updates and amendments thereof.

“**ICH**” shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“**Indian GCP**” shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research.

“**Information Brochure**” shall mean the information brochure of the Manufacturer.

“**Informed Consent Form**” or “**ICF**” shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

“**Investigational Devices**” shall mean the test and reference devices as mentioned in the protocol and supplied by the Manufacturer, in respect of which the Clinical Trial is conducted.

“**Subject**” shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

“**Protocol**” shall mean **Protocol No. Zincovit IRS/04/24** as provided by the Sponsor.

“**Screen Failure**” shall mean the screen failure as defined in the Protocol.

“**Serious Adverse Event**” or an “**SAE**” includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

“**Services**” shall mean the services detailed in Schedule ‘A’.

“**Site Indemnitee**” shall mean the Site and its employees and its associated staff.

“**Sponsor**” shall mean Ki3 Private Limited who has been deputed and authorized by the manufacturer to facilitate this Clinical Trial, at the site.

“**Sponsor Property**” shall mean all data and information generated or derived by Site arising out of any services performed by Site.

“**Standard Operating Procedures**” or “**SOP**” shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

2. Statement of Work

- 2.1. The Investigator and Site agree to conduct the study in accordance with Protocol No. **Zincovit IRS/04/24** (the “**Protocol**”) titled “**A Phase 3 prospective, comparative, placebo controlled, clinical study to evaluate the efficacy and safety of Zincovit ACTIVE Instant Rehydration Solution in fatigue/stress**”. The Investigator and Site agree to conduct the Study and perform the work under this agreement in cooperation with all other agents of the Sponsor.
- 2.2. The Protocol shall be considered final after it has been signed by each of Manufacturer and Investigator, and approved by the Institutional Review Board/Independent Ethics Committee (“**IRB/IEC**”). Any amendments to the Protocol shall be made only upon the prior written

consent of the Sponsor and subsequent approval of the IRB/IEC.

- 2.3. Prior to commencing the enrolment of subjects in the Study, Investigator shall submit the following to Sponsor: executed signed Clinical Trial Research Agreement, executed signature page of the Protocol, current curriculum vitae of the Investigator, all sub-investigators and other personnel involved with the conduct of the Study, copies of current medical licenses of participating investigators, Investigator Undertaking form, IRB/IEC approval to conduct the Study, composition of the IRB/IEC, IRB/IEC approved subject informed consent, other Study documents required by Sponsor prior to enrolment.

3. Conduct of the Study

- 3.1. Investigator and/or Site and Sponsor shall be responsible for the following:

- 3.1.1. Upon request, Investigator shall inform Sponsor of the recruitment status of the Study. Sponsor may, in its sole discretion, extend the enrolment period at any time by delivering a notice of extension. If an insufficient number of subjects have been enrolled at the Investigator's Institution over a period of three (3) months from the date of initiation, based on the number of subjects for recruitment as agreed to between the parties and as outlined in Section 3.1, Sponsor may notify Investigator to terminate further recruitment of subjects at the Site. Site/Sponsor may elect to either terminate the Study or the Site or both at any time for safety reasons, or if no patients have been enrolled. In the event of termination, Site and Investigator shall follow the guidance of the Sponsor with respect to completing participation of subjects enrolled on the date of such notice.

- 3.1.2. Investigator shall exercise independent medical judgment as to the compatibility of each subject with Protocol requirements. Prior to the screening and treatment phases of the Study, Investigator shall ensure a medical professional competent to answer questions concerning the Study, obtains from each subject an informed consent, approved by the IRB/IEC. The informed consent shall be signed by the subject or a Legally Authorized Representative (LAR) and the signature of the subject or LAR witnessed.

- 3.1.3. Investigator or appropriately qualified designee shall review and sign all informed consents. Investigator shall review and sign all Study related forms and Case Report Forms (CRFs) to ensure their accuracy and completeness and provide these forms and any other Study data or samples to Sponsor in the format and manner agreed by the parties. Site and Investigator shall use their reasonable efforts to meet the time schedules set forth in the Protocol and this Agreement. Investigator agrees to resolve any discrepancies or errors in the informed consents and CRFs and cooperate with the monitor and any audit requirements pertaining to original case records, laboratory reports and other raw data sources underlying the data recorded on the CRFs, as may be required by Sponsor, Drugs Controller General of India ("DCGI"), or other regulatory authorities, as the case may be.

- 3.1.4. Immediately after it comes to the attention of Investigator, Investigator shall adhere to timelines of initial and follow-up SAE reporting, analyzed, narrative after due analysis, to DCGI and EC as per the New Drugs and Clinical Trials Rules 2019 & GCP guidelines. The Investigator shall be responsible for making available all other safety information, as directed by the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

- 3.1.5. Sponsor shall inform Investigator of any new developments and information pertaining to the drug under Study. Investigator shall inform all subjects of such new developments and information immediately after receipt of such information from Sponsor.

- 3.1.6. Sponsor shall not be liable for the failure of Investigator to inform subjects of new developments and information, particularly with respect to developments and information concerning health and safety of the Study drug.
- 3.1.7. Investigator will ensure that all Study personnel are appropriately qualified and educated on the Study conduct as outlined in the Protocol.
- 3.1.8. **Regulatory Agency Audit:** The Investigator shall inform Sponsor and Manufacturer within twenty-four (24) hours of being notified of a regulatory agency audit (if notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no notice is given by the applicable regulatory agency). The Investigator and the Site shall provide Sponsor with a copy of all Clinical Trial specific observations made during a regulatory audit at the Investigator and/or the Site's facilities, immediately upon receipt of such information. The Investigator shall cooperate fully with Sponsor in any such investigation, and in the implementation of appropriate action plans for such observations.
- 3.2. Sponsor shall be responsible for the following:
- i. **Clinical Trial Supplies:** Providing all the Test and Reference Products, case report forms and any other relevant document in advance or on time to the PI and/or the Site on behalf of Manufacturer.
 - ii. **Other Duties:** Training on Study Protocol with related procedures, Site Monitoring, Medical and Safety Monitoring, Clinical Data Management, Statistical Programming, Clinical Study Report preparation & IP logistics management.

4. Representations, Warranties and Covenants

- 4.1. Sponsor represents, warrants and covenants to the Institution and Investigator as follows:
- (a) **Formation/Power and Authority:** Sponsor is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.
 - (b) **Compliance with Applicable Law:** Sponsor represents and warrants that it is in full compliance always and shall continue to comply always with all Applicable Laws of India.
 - (c) **Debar:** Sponsor certifies that it has not been debarred under any applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial. Sponsor agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the term.
- 4.2. The Site represents, warrants and covenants to the Sponsor as follows:
- (a) **Formation/Power and Authority:** The clinical study site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.
 - (b) **Compliance with Applicable Law:** The Site represents and warrants that it is in full

compliance always and shall continue to comply always with all applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to conduct the study as per protocol (or shall receive approval of the ethics committee before implementing the protocol), agrees to enroll Subjects up to such higher numbers as agreed upon with Sponsor in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Ability to conduct the Trial: The Site hereby represents and warrants that it has manpower, infrastructure, and facilities necessary for the conduct of the Trial as per the Protocol, New Drugs and Clinical Trials Rules, 2019 and GCP guidelines.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other applicable Laws.

The Site agrees that it shall promptly notify Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, of the study.

The Site agrees not to employ or otherwise engage during the term any individual who will be rendering services to the Investigator and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

Upon Sponsor's request from time to time, the Site shall certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

4.3. The Investigator represents, warrants and covenants to Sponsor as follows:

Power and Authority: The Investigator hereby represents that he/she is duly registered in accordance with the applicable Laws, and has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform his/her obligations hereunder in accordance with the terms and conditions hereof.

Ethics Committee: The Investigator representing that he/she is duly authorized by the Ethics Committee of the Site to conduct the study as per protocol (or shall receive approval of the ethics committee before implementing the protocol), agrees to enrol Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with Sponsor in writing from time to time to meet the subject selection criteria described in the Protocol.

Debar: The Investigator represents that he/she has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

The Investigator agrees that he/she shall promptly notify Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

Upon Sponsor's request from time to time, PI shall certify in writing, the PI compliance with the foregoing provisions of this paragraph.

4.4. Institution and Investigator each represents to the best of its/his/her knowledge that none of Institution, Investigator or any of their/his/her personnel performing the Study is under investigation by DCGI or any other regulatory authority, shall notify Sponsor immediately upon any inquiry or the commencement of any proceeding concerning any such person(s).

- 4.5. Investigator and Institution shall properly perform and direct the Study in accordance with the Protocol, good clinical practices (GCP) and all applicable regulatory requirements. Institution or Investigator shall notify Sponsor and the IRB/IEC of any failure to comply with or deviations from the Protocol immediately after it comes to the attention of Institution or Investigator.

5. Records, Audits and Storage

- 5.1. Investigator shall comply with all reporting requirements contained in the Protocol. Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to Sponsor in the CRFs and all required reports. Investigator shall provide Sponsor or Designee, with direct access to source data and documents for monitoring, audits, IRB/IEC reviews and regulatory inspections upon reasonable notice and during business hours, and provide copies of all reports provided to the IRB/IEC listing the title of the Protocol, any Protocol revision date and the date of approval.
- 5.2. Upon termination of the Study by any party for any reason whatsoever, or on completion of the Study, Investigator shall furnish a Final Report acceptable to Sponsor.
- 5.3. Investigator shall maintain accurate and complete records in accordance with good clinical practices and all applicable laws and regulations and send one set of hard and soft copy to Sponsor
- 5.4. From time-to-time Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as Sponsor so elect, comprise: (a) inspection of the Investigator's records relating to the rendering of services to or for the Clinical Trial including adherence to Protocol; (b) review of the Investigator and compliance with licensures and certifications as per the Applicable Laws; and (c) the Investigator's adherence to Applicable Laws, including, but without limitation, Indian GCP and ICH GCP Guidelines.
- 5.5. The Principal Investigator shall return all records and documents pertaining to this Clinical Trial to the Sponsor at the end of completion of patient recruitment and all clinical trial related activities are completed. The Sponsor shall retain these documents at its own facility or at third party facility as long as it is deemed appropriate.
- 5.6. The Investigator shall retain its source documents pertaining to the trial subjects for a period of at least two (2) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (any other applicable regulation) (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which any applicable regulatory authorities are so notified. Following the Retention Period, as instructed by Sponsor, the Investigator will either forward such records to Sponsor, or retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send Sponsor proof of such destruction.
- 5.7. If the sponsor so requires, the Investigator shall maintain storage of Investigational product for the minimum time of years as required by the sponsor ("Retention Period").
- 5.8. In the event Sponsor requires storage of samples or data beyond the minimum storage outlined in this section, Investigator agree to continue to store the data and samples until the parties have agreed on payment terms and conditions. Time shall be of the essence in respect to coming to an agreement on further storage.

6. Clinical Data

All clinical data, including CRFs, underlying data and all scientific and technical information generated as a result of the Study shall be promptly and fully provided to Sponsor, subject to any regulatory requirements pertaining to patient privacy. Such data is the sole and exclusive property of Sponsor and may be freely utilized by Sponsor. Site and Investigator agree to provide Sponsor/ designee access to the data to examine and make copies of such data (excluding any personal identifying information of the Study subject) upon reasonable notice and during normal business hours.

7. Inventions

In addition to the rights referred to in Section 7, any inventions or discoveries arising out of the work performed under this Agreement will be disclosed promptly to Sponsor and will become the property of Sponsor. Institution and Investigator agree, on behalf of the personnel involved or affiliated with the Study, to execute, acknowledge and deliver at Sponsor's expense all such papers and documents as may be necessary, and to perform such other actions as Sponsor may reasonably request, to secure, verify or reflect such ownership or to secure proprietary protection in the name of Sponsor for such inventions or discoveries.

8. Publicity

- 8.1. Subject to Section 10, Site, Investigator and Sponsor agree to obtain prior written permission from each other before using the name, symbols or marks of the other in any form of disclosure in connection with the Study, unless required by law or to carry out the purpose of this Agreement. No party shall, without the prior written consent of the other, use the name of the other parties or any of the personnel involved or affiliated with it, in any press release, advertising, promotional literature, or any other publicity matters.
- 8.2. The Investigator and Institution may, without the consent of the Sponsor, disclose the existence of this Agreement, identify the parties to this Agreement, disclose the title or a general description of the Study, the duration of the Study, and the nature and amount of funding and/or other support provided by the Sponsor for the Study in the Institution's customary publications or otherwise in satisfaction of the Institution's reporting requirements.

9. Publication

The Publication right of this study is with the Sponsor/ Manufacturer. However, Drafting, corrections and final approval of manuscript will be performed by all the investigators, and industry authorized scientific writer. Before sending it to any Journal for publication, this study has to be discussed with the Sponsor and get a written confirmation of the manuscript.

10. Declaration

Institution and Investigator warrant that this Study will be performed in compliance with the Protocol, good clinical practice, requirements of the IRB/IEC, New clinical trials regulations 2019 and all applicable DCGI and local laws, regulations, governmental and institutional

guidelines governing or pertaining to clinical trials and studies, and any is thereto or any successor document thereof.

11. Insurance

Sponsor shall maintain all adequate human clinical trial insurance covering the subjects, during the term.

Sponsor shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site and the Investigator.

12. Indemnification

11.1 Indemnity: The Sponsor, on behalf of manufacturer shall indemnify, defend and hold harmless the Site, the Investigator, the Site Indemnitees and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees or the Site, or the Investigator, in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Investigator to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

11.2 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Investigator, the Site, the Clinical Trial as contained in the Clinical Trial Agreement.

11.3 Entire Obligation:

The foregoing terms constitute the entire indemnification obligation of Sponsor in relation to the Study.

13. Manufacturer shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement.

14. Independent Contractors

The parties to this Agreement agree that Site and Investigator are independent contractors in relation to Sponsor and shall not be construed for any purpose whatsoever as a partner, agent, employee, servant, joint-venturer or representative of Sponsor. The employees or agents of Site or Investigator shall not be considered to be the employees of Sponsor and neither Site nor Investigator shall enter into any contract or agreement with a third party, other than patients in accordance with this Agreement, which purports to obligate or bind Sponsor. Sponsor shall not be responsible for any fiscal (tax) implications of whatever sort or nature, which may arise as a result of payments made pursuant to this Agreement.

15. Conflict of Interest

15.1 Investigator certifies that:

- a) There is no conflict of interest between Investigator and any other party that would inhibit or affect the performance of the work specified in this Agreement;
- b) The performance of the work specified in this Agreement does not violate any other agreement Investigator may have with any other party; and
- c) No gifts or other benefits have been offered to any family members.

15.2 Investigator further certifies that Investigator will promptly advise Sponsor in writing in the event any conflict of interest that arises during the Term of this Agreement.

16. Survival

The provisions of sections 3, 5, 12, 17, 19, 24 & 25, shall survive termination of this Agreement.

17. Governing Law

This Agreement shall be governed by and construed in accordance with the Laws of the Republic of India within the jurisdiction of the courts of Chennai, India and will have exclusive jurisdiction over any disputes under this agreement without giving effect to its conflict of laws.

18. Counterparts

This Agreement may be signed in any number of counterparts which, when taken together will constitute one and the same Agreement. Counterparts may be executed in either original or faxed form and the parties adopt any signatures received by a receiving fax machine as original signatures of the parties, provided that any party providing its signature in such manner shall promptly forward to the other party an original of the signed copy of this Agreement, which was so faxed.

19. Entire Agreement

This Agreement, including all Schedules and any Addendums from time to time, represents the entire understanding of the parties with respect to the matter contained herein and supersedes all previous agreements and undertakings with respect thereto. In the event of any discrepancies in respect of a particular matter conflicts with a provision contained in this Agreement or the Protocol, the Agreement shall prevail. Any change, amendment or modification to the Protocol or this Agreement, including any Schedules hereto, requires and shall have the prior written approval from Sponsor.

20. Assignment

No part of this Agreement may be assigned, delegated, or subcontracted by any party to any other person or third party without the prior written approval of the other parties.

21. Disclaimer

The Investigator and the Site shall carry out the Study in accordance with the Protocol.

However, neither the Investigator nor the Site promises success in achieving any particular result. The Investigator and the Site make no representations, conditions, or warranties, either express or implied, with respect to the results of the Study.

22. Force Majeure

Noncompliance by any party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labour disturbances, shortage of materials, failure of public utilities or common carriers) or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention.

23. Study Subject Information

- 23.1. If the identity of any Study subject participating in the Study is disclosed to the Sponsor, its agents or employees, the Sponsor shall:
 - 23.1.1. ensure that such information is deleted or destroyed;
 - 23.1.2. not disclose such information to any third parties; and
 - 23.1.3. Notify the Institution of such disclosure.
- 23.2. The Sponsor acknowledges that the Institution is a public body subject to the provisions of the Indian law and that the collection, use, disclosure and release of personal information under this Agreement is governed thereby.

24. Confidential Information

- 24.1. All information provided to Site and Investigator by Sponsor during the course of the Study including, but not limited to, the Study Protocol, preclinical data, formulae, manufacturing and toxicology information and any other information on the Study drug, CRFs, all oral and written information and information sent or stored electronically (the "Confidential Information"), will be kept confidential and confined to the personnel affiliated with or involved in the Study. Such Confidential Information shall be marked in writing as "Confidential" or if disclosed orally or in other than documentary form shall be reduced to writing within thirty (30) days thereafter. The obligation to maintain confidentiality shall survive the completion or early termination of this Agreement and shall remain in effect for a period of Three (3) years following the completion or early termination of the Study.
- 24.2. All reports and information, including all clinical data, about the Study or its progress will also constitute Confidential Information of Sponsor and will not be provided by either Site or Investigator to any party other than Sponsor and, in confidence, the IRB/IEC, without the prior written approval from Sponsor/ except as otherwise permitted under this Agreement.
- 24.3. Confidential Information shall exclude any information:

- a) already possessed by the Investigator or Site prior to receipt from the Sponsor, other than through prior disclosure by the Sponsor, as evidenced by the Investigator's or Site's business records;
- b) that is in or becomes part of the public domain through no act or failure to act by the Site or Investigator and without breach of the Agreement;
- c) obtained by the Investigator or Site from a third party with a valid right to disclose it, provided that said third party is not under a confidentiality obligation to the Sponsor;
- d) independently developed by employees, agents or consultants of the Investigator or Institution who had no knowledge of or access to the Sponsor's information, as evidenced by the Institution's or Investigator's business records;

25. Term and Termination

- 25.1. This Agreement shall commence on the Effective Date and shall continue in effect until Sponsor satisfactorily receives all completed and corrected CRFs, reports and other documentation required by the Protocol and final payment is made (the "Term").
- 25.2. Unless otherwise provided herein, Sponsor reserves the right to terminate this Agreement without cause upon thirty (30) days' written notice. In this event, any amounts due to Site under this Agreement shall be limited to pro-rated fees based on actual work performed pursuant to the Protocol and reasonable general and administrative expenses and non-cancellable expenses related thereto, to the actual date of termination.
- 25.3. Site or Investigator may terminate this Agreement at any time on thirty (30) days' prior written notice to Sponsor or designee prior to the time subjects commencing taking the Study medication. During such thirty (30) day period, Site and Investigator shall continue to perform those services reasonably requested by Sponsor and will be entitled to payment therefore. In the event Site or Investigator wishes to terminate the Study after subjects have commenced taking the Study medication, Investigator agrees to either find a replacement Investigator or terminate recruitment. Site and Investigator agree to cooperate fully with any replacement in respect of matters pertaining to the Study. Institution agrees not to substitute another investigator as Investigator of this Study without the prior written consent of Sponsor or Designee.
- 25.4. All parties shall have the right to terminate the Study at any time for safety reasons on notice to the other parties. In such instance, Institution and Investigator shall ensure that no Study subject receives the Study drug after receiving the notice of termination from the Sponsor. Investigator shall ensure that subjects return all Study medication and Study materials that they may have in their possession to Investigator. Investigator shall continue to monitor subjects as required by the Protocol and regulatory authorities and provide appropriate therapy and follow-up for subjects, for health and safety reasons.

Signature page follows

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

Ki3 Private Limited (CRO)

No.5/3, Jayalakshmi Street, Radha Nagar, Chrompet, Chennai - 600 044

Signature:

Gayathri Sivakumar

Date:

17/05/25

Print Name:

Dr Gayathri Sivakumar

Print Title:

Director

Seal:



The Director & CEO

Sri Venkateshwaraa Medical College Hospital and Research Centre, Ariyur, Puducherry 605102

Signature:

S. w6
27/05/25

Date:

Print Name:

Dr. S. Ratnasamy

Print Title:

Director

Seal:

DIRECTOR
Sri Venkateshwaraa Medical College
Hospital & Research Centre
Ariyur, Puducherry - 605 102

SCHEDULE A

PAYMENT SCHEDULE

Description of charges	Cost per subject
PI	1500
Travel allowance – 4 visits	1000
Screening (CBG, Serum electrolyte, urea and creatinine)	1000
During study (electrolytes 48 th hrs)	545
Hospital (10% of PI, Screening and Lab)	405
CTC or CRA	500
Total	4950

S. V. S.
27/5/20

DIRECTOR
Sri Venkateshwaraa Medical Colleg.
Hospital & Research Centre
Ariyur, Puducherry - 605 102