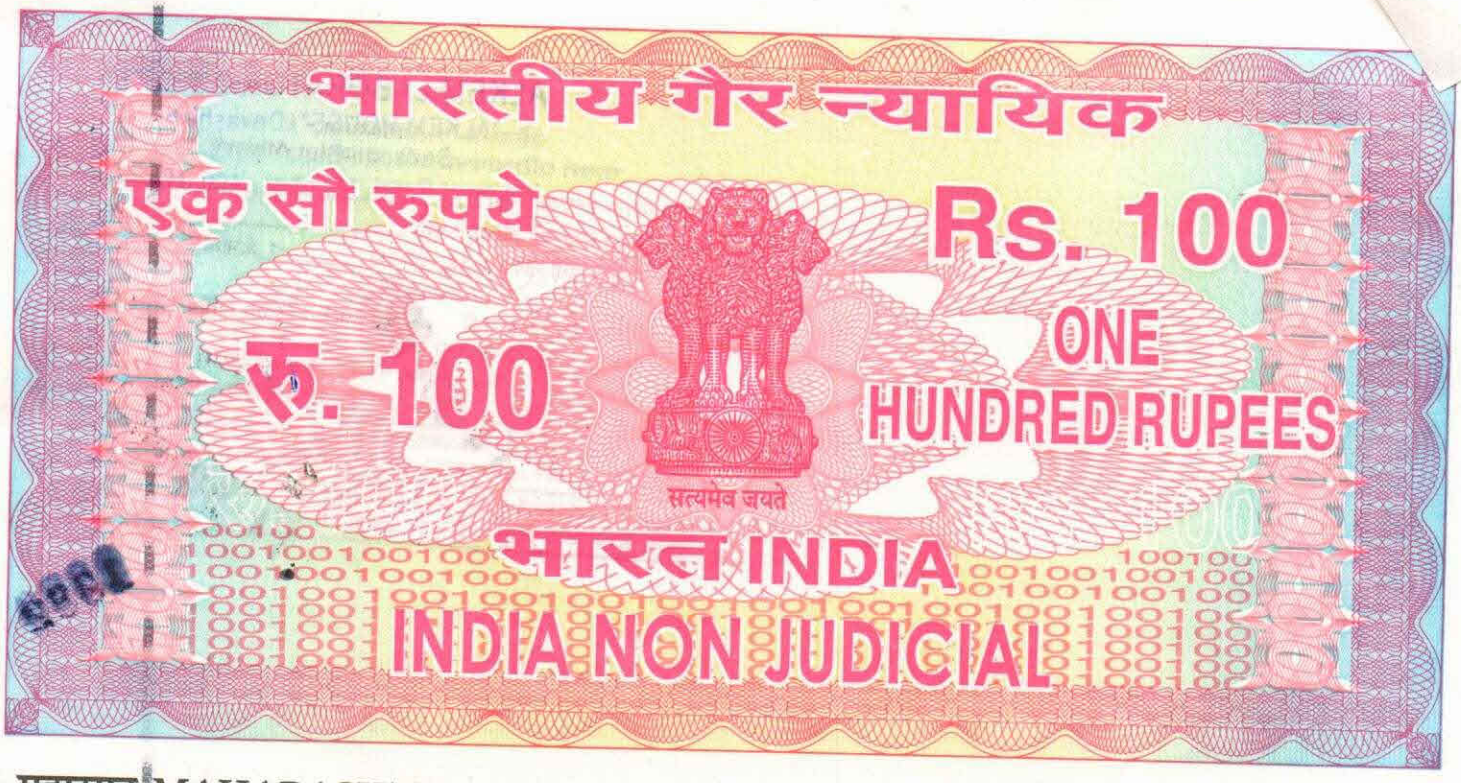

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ YS 617232

प्रधान मुद्रांक कार्यालय मुंबई
प.म वि क ८०००००६
13 JUL 2021
सक्षम अधिकारी

CLINICAL TRIAL AGREEMENT

This contract (hereinafter "the Contract") is made as of **25 -08- 2021**, by and among श्री. दि. क. गवडे

Dr. Venkate Gowda H T, Professor & HOD, Dept. of Ophthalmology Adichunchanagiri Hospital & Research Centre,B G Nagara-571 448,Nagamangala Taluk, Mandya District, Karnataka

Hereinafter "the **INVESTIGATOR**",

AND

Adichunchanagiri Hospital & Research Centre, B G Nagara-571 448,Nagamangala Taluk, Mandya District, Karnataka

Hereinafter "the **INSTITUTION**" study site

AND

Alkem Laboratories Limited, having its registered office at **Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai 400013, India.**

Hereinafter "the **SPONSOR**"

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Initials INVESTIGATOR Initials INSTITUTION Initials SPONSOR

ALKEM LABORATORIES LTD.
"ALKEM HOUSE", Devashish,
Senapati Bapat Marg,
Lower Parel, Mumbai - 400 013.

जोडपत्र - १ Annexure - I
फक्त प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव ____________

मुद्रांक विकत घेणाऱ्याचे रहिवासी पत्ता ____________

मुद्रांक विक्रियाबाबतची नोंद वही अनु. क्रमांक ________ दिनांक ________

मुद्रांक विकत घेणाऱ्याची सही   परवानाधारक मुद्रांक विक्रेत्याची सही

परवाना क्रमांक : ८००००[illegible]

[illegible] एल. चव्हाण

३/२०२, [illegible] एस.बी.एस. मार्ग, फोर्ट, मुंबई - ०१.

[illegible] प्रतिज्ञापत्र सादर करणेसाठी [illegible] (शासन आदेश दि. ०१/०४/२००४) [illegible]

[illegible]

14 JUL 2021

14 JUL 2021

1383

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

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial (hereinafter the "**Study**") to evaluate its product **[RANI1]** (hereafter the "Investigational Product") in accordance with a protocol of SPONSOR entitled 'A Comparative, Double-Blind, Randomized, Multicenter, Phase III study to compare the safety & efficacy of ENZ105 of Enzene Biosciences Ltd. with Innovator Ranibizumab in subjects with Neovascular (Wet) Age related Macular Degeneration (AMD)' **[ALK21/ENZ105-RANI1]** and its amendments (hereinafter collectively the "Protocol"),

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

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

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATOR, INSTITUTIONand SPONSOR, as such Protocol is submitted to the registered Institutional Ethic Committee ("**IEC/IRB**") for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB according to regulation & guidelines mentioned in section 3.1. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE

The Study shall be performed at the INSTITUTION (hereinafter the "**Study Site**"). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

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

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

ARTICLE 3. COMPLIANCE

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

3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure

that the content of the case report form (CRF)/electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/e-CRFs to the SPONSOR.

ARTICLE 4. TERM

This Contract is being entered into force from **25th August, 2021 ("Effective Date")** and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately Twenty months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR

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

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

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

For the purpose of the Contract, the term "Collaborator(s)" shall mean any person involved in the Study including but not limited to research associates, sub-investigators, biologists, assistants and nurses.
Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Product shall be returned or made available to the SPONSOR upon completion of the Study.

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

The Investigational Product will not be released until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB and DCGI for the study.

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

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

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

ARTICLE 6. SUBJECTS' RECRUITMENT

6.1 The INVESTIGATOR has estimated that he/she may require to recruit a maximum of 15 (Fifteen) Subjects (the "**Subjects**"), within Fifteen months of commencement of the Study. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g, x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of two patients must be enrolled within Two months of initiating the Study at the STUDY SITE. If no subjects are enrolled over a period of Fifteen months, the SPONSOR may decide at its discretion to discontinue the Study at the STUDY SITE.

6.3 The SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed informed consent. The INVESTIGATOR shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS

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

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

7.3 The INVESTIGATOR&/ INSTITUTION shall ensure that the entire informed consent process referred to in Article 7.2 above be video recorded if the same is applicable as per local regulations and/or made applicable by Institutional Ethics Committee. The INVESTIGATOR &/ INSTITUTION should ensure that the confidentiality of the recorded files is appropriately maintained.

ARTICLE 8. MONITORING OF THE STUDY

8.1 The SPONSOR shall appoint monitor(s) from their end or from Clinical Research Organization (CRO), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the "**Monitor(s)**"). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information

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

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR, Licensing Authority & Ethics Committeeof any serious adverse event ("**SAE**") or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS

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

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the "**Confidential Information**"), is confidential. The INVESTIGATOR and the INSTITUTION agree to keep confidential and not to disclose

the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.

11.2 Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

11.3 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION give the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.4 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination or expiry whichever is later.

ARTICLE 12. RECORD RETENTION

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) set only of all original data generated in the course of the Study for 5 years from the date of the last visit of SPONSOR to the Study Site after the Study is completed ("**Retention Period**").

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

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

ARTICLE 13. DATA PROTECTION

13.1 The Subject data, the INVESTIGATOR's data, the INSTITUTION's data and Collaborators' data, which may be included in the SPONSOR's databases, shall be treated by the Parties in compliance with all applicable laws and regulations.

13.2 The SPONSOR also collects specific data regarding the INVESTIGATOR and the Collaborators which may be included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations.

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

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

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

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

ARTICLE 15. PROPERTY RIGHTS

15.1 All Confidential Information, documents, materials, Investigational Product and equipment provided by the SPONSOR (hereinafter collectively "**Information**") are and shall remain the sole and exclusive property of the SPONSOR.

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

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

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

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE

16.1 The SPONSOR agrees that it has subscribed to a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance.

16.2 The insurance subscribed to by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policies.

16.3 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and the Collaborators ("**Indemnitees**") from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Product or the performance of any procedure required under the Protocol as per Indian laws, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Product or the performance of any required procedure;

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or wilful malfeasance of the Indemnitees.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnitees cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnitees without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and the INSTITUTION shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

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

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

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

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

17.6 The rights and obligations under this Article shall remain in effect for a period of five (5) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT

This Contract may be terminated: (1) by a mutual written consent of the SPONSOR, INVESTIGATOR and the INSTITUTION on immediate basis; or (2) by the SPONSOR upon serving thirty (30) days prior written notice to the INVESTIGATOR and the INSTITUTION.

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

The terms and conditions of Articles 11,13,14,15,19 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE

The INVESTIGATOR and the INSTITUTION represent and warrants that neither he/she nor any Collaborators /INSTITUTION involved in conducting the Study nor any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct.0.

The INVESTIGATOR shall immediately notify the SPONSOR should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the Twenty months following the expiration or termination of the Contract.

ARTICLE 20. CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE

The INVESTIGATOR shall ensure that he/she and the Collaborators involved in this Study at the INVESTIGATOR's Study Site provide the SPONSOR with the appropriate financial disclosures required for compliance with DCGI, on such forms as the SPONSOR may supply or approve.

ARTICLE 21. MISCELLANEOUS

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

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

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

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

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

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

21.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR and the INSTITUTION shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract.

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

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

21.10 No Party may assign or novate its rights, interests, liabilities or obligations under this Contract or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed.

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

ALKEM LABORATORIES LIMITED

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Name: Dr. Akhilesh Sharma
Designation: President & Chief Medical Officer

INVESTIGATOR

Professor & HOD
Department of Opthalmology
AIMS, B.G. Nagara -571 448

Name: Dr. Venkate Gowda H T
Designation:Principal Investigator
AH&RC, B G Nagara

INSTITUTION

Dr. RAJESH VENKATARAMAN
Head Clinical Trials
Adichunchanagiri Hospital & Research Centre
Adichunchanagiri University
B. G. Nagara - 571 448

Name: Dr. Rajesh Venkataraman
Designation: Head, Clinical Trials
AH&RC, B G Nagara

EXHIBIT 1

1. The SPONSOR will pay Investigator fees per visit, as per table below for subjects included in accordance with the Protocol and who has completed these visits as per protocol requirement, on monthly or quarterly basis against the invoice raised by INVESTIGATOR .

Visit. No	Particulars	PI grant	Clinical Trial Centre fees	Patient expense
1	Screening	4,500	1,000	1000
2	Baseline - W0	4,500	1,000	2000*
3	W1	4,500	1,000	1000
4	W4	4,500	1,000	2000*
5	W8	4,500	1,000	2000*
6	W12	4,500	1,000	2000*
Per Patient Grant (A)		**27000**	**6,000**	**10000**
RANIBIZUMAB STUDY Site Budget				
Additional Grant (B)				
1	Screen failure (20%)	5,500		
2	Lab Cost	**Actuals**		
3	Institutional Overheads (20%)	6600		
Total (A+B)		49600		

*Includes patient travel and meal expense for next day

The above fees is inclusive of Investigator, coordinator, Nurse, Phlebotomist, Social worker fees including assessment such as physical Examination (including assessment of signs and symptoms associated with COVID-19), vital signs, body weight, detailed ophthalmic examination (including Fundus examination, Visual acuity, OCT and Tonometry) and any other administrative cost such as OT, OPD fees/hospitalisation fees if required, patient expense (travel, snacks etc), Institutional overhead charges, etc.

2. Ethics Committee fees and local lab charges will be paid on actual basis.

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

4. Archival fees for 5 years will be Rs. 25,000/-

5. The institute will receive Rs. 50,000/- as a advance payment and the same will adjusted in the next payment of PI fees.

6. Laboratory tests including RT-PCR test should be done in an acredidated lab, while ECG and OCT with CSFT will be done in the hospital if available or can be performed in an external qualified facility, the expense towards the same shall be reimbursed by the sponsor as per the rate card approved by the sponsor.

7. In case, if the Site team conducts any specific unscheduled lab investigation for AE and SAE management, the same will be reimbursed by the sponsor, as per the rate card approved by the sponsor.

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

9. A sum of Rs 5500/- (Five thousand five hundred only) per subject will be paid as investigator fees for upto 20% of screen failure subjects at site, this sum includes investigator fees, patient travel and meals. The screen failure payment will be done at the end of recruitment.

10. The investigator fees towards the completed visits shall paid on prorata basis by the SPONSOR in event of drop out or withdrawal.

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

11. The payment for recruited Subjects will be made to the INSTITUTION upon presentation of the invoices within 45 days as per below payee account details.

NAME OF PAYEE	
Payment through Cheque :	
Name of Payee:	SACCP CLINICAL RESEARCH
Address of Payee:	Clinical Research Centre Hospital Block, B G Nagara-571 448.
PAN / TAN Number:	AAAJA2708B
GST No.	29AAAJA2708B1ZU
Payment through wire transfer:	
Beneficiary's Account Name:	SACCP CLINICAL RESEARCH
Beneficiary's Account Number:	8610101031980
Bank Name:	Canara Bank
Bank Address:	Adi-Chunchunagiri Instt of Medical Science branch Bellur, Karnataka-571 448
IFSC:	CNRB0008610

12. Goods and Service Tax shall be added to invoiced amount as per indian tax regulations.

13. All payments made shall be subject to tax deducted at source.

14. The final payment will occur only after:
- The delivery and review of the final data of the study, provided that they shall be ready for statistical analysis;
- The completion of all CRF, including resolution of all DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- Receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- The INVESTIGATOR has returned all remaining Investigational Product and applicable study material, if any.

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:13:24 GMT)

CTRI Number	CTRI/2021/11/038206 [Registered on: 23/11/2021] - **Trial Registered Prospectively**
Last Modified On	03/01/2023
Post Graduate Thesis	No
Type of Trial	PMS
Type of Study	Drug
Study Design	Single Arm Study
Public Title of Study	Postmarketing safety evaluation of recombinant anti-Rho (D) immunoglobulin
Scientific Title of Study	A Prospective, Multi-centre, Phase IV study for Post-Marketing Safety Evaluation of Recombinant Anti-Rho(D) immunoglobulin in the prevention of Maternal Rh-isoimmunization

Secondary IDs if Any

Secondary ID	Identifier
BSV_ANTID_21_03 Version 03/26-Aug-2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Pratik Shah
Designation	Vice President - Medical Affairs
Affiliation	Bharat serums and Vaccines LTd
Address	3rd Floor, Liberty Tower Airoli, Navi Mumbai, Thane MAHARASHTRA 400708 India
Phone	022-45043456
Fax	022-45043200
Email	pratik.shah@bsvgroup.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Anirban Roy Chowdhury
Designation	Vice President- Clinical Research and Pharmacovigilance
Affiliation	Bharat serums and Vaccines LTd
Address	3rd Floor, Liberty Tower Airoli, Navi Mumbai, Thane MAHARASHTRA 400708 India
Phone	022-45043456
Fax	022-45043200
Email	Anirban.roychowdhury@bsvgroup.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Anirban Roy Chowdhury
Designation	Vice President- Clinical Research and Pharmacovigilance
Affiliation	Bharat serums and Vaccines LTd
Address	3rd Floor, Liberty Tower Airoli, Navi Mumbai, Thane MAHARASHTRA 400708 India
Phone	022-45043456
Fax	022-45043200
Email	Anirban.roychowdhury@bsvgroup.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Bharat Serums and Vaccines LTd 3rd Floor, Liberty Tower Airoli, Navi Mumbai, Thane 400 708

Primary Sponsor

Primary Sponsor Details	
Name	Bharat Serums and Vaccines Ltd
Address	3rd Floor, Liberty Tower Airoli, Navi Mumbai, Thane 400 708
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rashmi MD	Apollo BGS Hospital	Adichunchangiri road Kuvempunagara Mysore Mysore KARNATAKA	0821-2568888 drrashmimd@gmail.com
Dr Prema DCunha	Father Muller Medical College Hospital	Department of OBG Father Muller Medical college Hospital Kankanady, Mangalore-575002 Dakshina Kannada KARNATAKA	9845342488 prema_dcunha@yahoo.com
Dr Swati Chitnis	Shalby Hospital	Department of Gynaecology, Opposite Karnavati Club SG highway 380015 Ahmadabad GUJARAT	7506193044 swatiprakash131@gmail.com
Dr Rani Kumari L	Gandhi Hospital	Department of OBG Musheerabad Secunderabad 500003 Hyderabad TELANGANA	9491657107 dr.ranikumari@gmail.com
Dr Lakshmikantha G	Cheluvamba Hospital	Department of OBG Mysore MEdical college and Research Institute Irwin Road 570001 Mysore KARNATAKA	9740810611 gdrlakshmikantha@gmail.com
Dr Rekha Sachan	King Georges Medical University	Department of Obsetrics and Gynaecology, King Georges Medical University, Shahmeena road, Chowk, -226003 Lucknow UTTAR PRADESH	8765000700 drrekhasachan@gmail.com
Dr Ashalata Mallapur	S Nijalingappa Medical College & HSK hospital	Womens and Childrens Health Research Unit,3rd Floor OBG Building, S Nijalingappa Medical College & HSK hospital, 587102	994569986 drashalatamallapur@gmail.com

		Bagalkot KARNATAKA	
Dr Sweety Saigal	Brij Medical Centre Private Ltd	94 E, Near Panki Police Station, Gangaganj Colony, Panki 208020 Kanpur Nagar UTTAR PRADESH	8176882317 sweetidr6@gmail.com
Dr Shilpa Naik	B.J. Govt Medical College and Sassoon General Hospital	Department of Obstetrics nad Gynecology, B.J. Govt Medical College and Sassoon General Hospital, Sassoon road Somwar Peth, 411001 Pune MAHARASHTRA	9850046747 shilunnaik@yahoo.co.in
DR Suchita Mundle	All India Institute of Medical Sciences	Department of Obstetrics and Gynaecology, Plot No. 2, Sector 20, Mihan, All India Institute of Medical Sciences, 441108 Nagpur MAHARASHTRA	9822706087 srmundle@gmail.com
Dr Kiran Kurkoti	MTES'S Sanjeevan Hospital	Plot No 23, Karve Road, Erandwane, 411004, Pune MAHARASHTRA	8208116533 drkurtkoti@gmail.com
Dr Shilpa Ghosh	Aakash HealthCare Private Limited	Hospital Plot, Road No. 201, Sector 3, Dwarka, 110075 New Delhi DELHI	9818924476 drshilpaghosh@gmail.com
Dr Hema Patil	KLES Dr. Prabhakar Kore Hospital & MRC	KLES Dr. Prabhakar Kore Hospital & MRC, Bauxite road, 590010 Belgaum KARNATAKA	9164342888 hemabanad@gmail.com
Dr Richa Vaishnav	Apex Hospital	Apex Hospital Mansarovar Pvt Ltd., Vidhyanchal Marg, Rajat Path, Mansarovar, 302020 Jaipur RAJASTHAN	9784837616 clinicalresearchapex@gmail.com
Dr Niti Kautish	Fortis Escorts Hospital	Fortis Escorts Hospital, Neelam Bata Road, 121001 Faridabad HARYANA	9871079134 drnitikautish@gmail.com
Dr Shery Angel	Chettinad Hospital and Research Institute	Chettinad Hospital and Research Institute, Rajiv Gandhi Salai, Kelambakkam- 603103, Chennai TAMIL NADU	044-47411000 drsheryangel08@gmail.com

Dr Ravindra Pukale	Adichunchanagiri Hospital & Research Centre	B.G. Nagara Nagamangala Taluk, Mandya, 571448 Mandya KARNATAKA	9449751733 ravindrapukale@yahoo.com
Dr Srinivas Gadappa	Government Medical College Aurangabad	Panchakki Road, 431001 Aurangabad MAHARASHTRA	9822441553 gadappashrinivas@gmail.com
Dr Vidya V Bhat	Radhakrishna Multispeciality Hospital &IVF Center	3/4 Sunrise Tower, JP Road, Girinagar, 560085, Bangalore KARNATAKA	8026422977 vidyabhat68@gmail.com
Dr Roopa N K	BGS Global Institute of Medical Sciences and Hospital	No. 67, BGS Health and Education City, Uttarahalli Road, Kengeri, 560060 Bangalore KARNATAKA	9880715085 srikanthroopa@yahoo.com
Dr Ritu Gupta	Shalby Hospital	Sector 03, Chitrakoot Marg, Vaishali Marg, 302021 Jaipur RAJASTHAN	9829245770 drguptarr@rediffmail.com
Dr Gourisankar Kamilya	Institute of Post Graduate Medical Education and Research & SSKM Hospital	244 Acharya Jagadish Chandra Bose Road, 700020 Kolkata WEST BENGAL	9833122643 drgkmilya@gmail.com
Dr Neema Acharya	Acharya Vinoba Bhave Rural Hospital	Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences (DU), Sawangi (M), 442004 Wardha MAHARASHTRA	9926692511 neemaacharya@gmail.com
Dr Nithya Ramamurthy	Fortis Malar Hospital	No. 52, 1st main road, Gandhinagar, 600020 Chennai TAMIL NADU	9841073626 nithys.ramamurthy@fortishealthcare.com
Dr Swati Kochar	S P Medical College & AG of Hospital	Department of Obsetrics and Gynecology, S P Medical College & AG of Hospitals, 334003 Bikaner RAJASTHAN	9983277180 sfalodia@yahoo.com
Dr Archana Bhosale	Lokmanya Tilak Municipal Medical College & General Hospital	Gynecology and Obstetric department LTMMC hospital Sion Mumbai (Suburban) MAHARASHTRA	9867168656 aabhosale2006@gmail.com
Dr Seema Parvekar	Daga Women and Child Government Hospital	Near Agrasen Sqaure, Gandhibagh, 440018 Nagpur MAHARASHTRA	9890987153 seemaparvekar@gmail.com
Dr Seema Upadhyay	GSVM Medical College	Deaprtment of	9455635389

		Obstetrics and Gynaecology, GSVM Medical College, Swaroop Nagar, 208002 Kanpur Nagar UTTAR PRADESH	seema993573@gmail.com
Dr Shital Kapadia	BJ Medical College & Civil Hospital	Deaprtment of Obstetrics and Gynaecology, B.J. Medical College & Civil Hospital, 380016 Ahmadabad GUJARAT	9924643700 sheetalobgy@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
10_Institutional Ethics Committee AIIMS Nagpur	Approved	24/01/2022	No
11_Ethics Committee, Sanjeevan Hospital	Approved	22/01/2022	No
12_Aakash Healthcare Institutional Ethics Committee	Approved	12/01/2022	No
15_Institutional Ethics Committee KLES Belgaum	Approved	14/12/2021	No
16_Institutional Ethics Committee, Apex Hospitals Pvt Ltd	Approved	13/01/2022	No
17_Ethics Committee Fortis Escorts Hospital	Approved	30/12/2021	No
18_Chettinad Academy of Research and Education, Institutional Human Ethics Committee	Approved	31/12/2021	No
19_Institutional Ethics Committee Adichunchanagiri Institute of Medical Sciences	Approved	17/12/2021	No
1_Institutional Ethics Committee, Apollo BGS Hospital	Approved	06/12/2021	No
20_Institutional Ethics Committee, Department of Pharmacology, Government Medical College Aurangabad	Approved	17/12/2021	No
21_Institutional Ethics Committee Radhakrishna Multispecialty hospital	Approved	07/03/2022	No
22_Institutional Ethics Committee BGS Global Institure	Submittted/Under Review	No Date Specified	No

23_Ethics Committee Shalby Limited Jaipur	Approved	21/12/2021	No
24_IPGME&R Oversight Committee Kolkata	Approved	28/02/2022	No
25_Institutional Ethics Committee Datta Meghe Institute of Medical Sciences Dr Neema	Approved	21/01/2022	No
26_Institutional Ethics Committee Fortis Malar Hospital	Approved	30/12/2021	No
27_Ethics Commitee S P Medical College & AG of Hospitals	Approved	29/12/2021	No
28_Institutional Ethics Committee Lokmanya Tilak Hospital	Approved	28/04/2022	No
28_Institutional Ethics Committee Rughwani Child Care center and Hospital Nagpur	Approved	26/03/2022	No
29_ Ethics Committee GSVM Medical College	Approved	05/05/2022	No
2_Father Muller Institutinal Ethics committee	Approved	18/12/2021	No
30_The Institutional Ethics committee BJ Medical College and Civil hospital Ahmedabad	Approved	01/04/2022	No
3_Ethics Committee -Shalby Limited	Approved	02/11/2021	No
4_Institutional Ethics Committe Gandhi Medical college and hospital	Approved	04/12/2021	No
5_Institutional Ethics Committee, Mysore Medical College and Research Institute,	Approved	06/12/2021	No
6_Institutional Ethics Committee King Georges Medical University	Approved	07/03/2022	No
7_Institutional Ethics Committee SNMC, Bagalkot	Approved	06/11/2021	No
8_Ethics Committee, Brij Medical Centre Pvt Ltd	Approved	22/11/2021	No
9_Institutional Ethics Committee BJ Medical College & Sassoon General Hospital	Approved	23/12/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	16/07/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Maternal care for rhesus isoimmunization

Intervention / Comparator Agent

Type	Name	Details
Intervention	AntiD (recombinant anti-Rho (D) immunoglobulin?	Dose - Single-dose of 300 mcg/ 150 mcg Route of administered-Intramuscular Duration of treatment is a single day within 72 hours of sensitizing event to Rh-negative female subjects.
Comparator Agent	Not applicable	Not applicable

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Female
Details	1. Rh negative female subjects ? 18 years of age with negative ICT (nonsensitized). 2. Rh negative female subjects who would receive AntiD™ as per approved indications. 3. Subjects able to adhere to the study visit schedule and other protocol requirements. 4. Subjects willing to participate in the study by giving written informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects suffering from any medical condition that in the investigator's opinion could compromise the subject's ability to participate in the trial. 2. Subjects participating in another clinical trial in the four weeks before the screening visit. 3. History of anaphylactic or other severe systemic reaction to immunoglobulins. 4. Subjects requiring blood transfusion.

Method of Generating Random Sequence

Not Applicable

Method of Concealment

Not Applicable

Blinding/Masking

Not Applicable

Primary Outcome

Outcome	Timepoints
Incidences of Serious adverse events (SAEs) and adverse events (AEs) throughout the study	Throughout the study Day 1, Day 3, Day 28

Secondary Outcome

Outcome	Timepoints
No secondary outcome.	No secondary outcome

Target Sample Size

Total Sample Size=300
Sample Size from India=300
Final Enrollment numbers achieved (Total)=300
Final Enrollment numbers achieved (India)=300

Phase of Trial

Phase 4

Date of First Enrollment (India)

01/12/2021

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of Trial

Years=1
Months=6

	Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This is a Prospective, Multi-centre, Phase IV study for Post-Marketing Safety Evaluation of Recombinant Anti-Rho(D) immunoglobulin in the prevention of Maternal Rh-isoimmunization, The subject who are eligible for receiving AntiD will be enrolled in the study. The subject will receive AntiD withing 72 hours of sensitizing event. The follow-up will last till day 28. All SAEs and AEs during this study duration will be captured and analyzed.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 50

e-Stamp

Certificate No.	:	IN-KA65749271161852U
Certificate Issued Date	:	14-Mar-2022 03:30 PM
Account Reference	:	NONACC/ kakscsa08/ HASSAN4/ KA-HS
Unique Doc. Reference	:	SUBIN-KAKAKSCSA0866138530995469U
Purchased by	:	Dr RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	H M FIROZ STAR HI HERBS PVT LTD
Second Party	:	Dr RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY
Stamp Duty Paid By	:	Dr RAJESH VENKATARAMAN ADICHUNCHANAGIRI UNIVERSITY
Stamp Duty Amount(Rs.)	:	50 (Fifty only)

PUSHPAGIRI ENTERPRISES
Court Premises, Hassan
Authorised Signatory

Please write or type below this line

CLINICAL TRAIL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day (16/03/2022) ("Effective Date ")

Star Hi Herbs Pvt Ltd, A Company Registered Under Companies Act, *Having Its Registered Office At* Plot N0 -50, First Phase, Third Main Road Jigani Industrial Complex, Anekal Taluk

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.

Bangalore Ka 562106, India, Represented By **H.M. Firoz Hussain Managing Director** Who Is An Authorised Person (Hereinafter Called "Sponsor")

AND

Clinical Trial Centre (PAN: AAAJA2708B) address at Adichunchanagiri Hospital & Research Centre, B.G Nagara, Mandya, Karnataka-571448 represented by **Dr. Rajesh Venkataraman, Head, Clinical Trials,** authorised **Dr. Ravi B, Department of Medicine** to conduct the clinical study **(herein after "Principal Investigator"/ "Investigator")**

Protocol: "" (Hereinafter referred to as "Study ").

WHEREAS the **SPONSOR, INSTITUTE** and **PRINCIPAL INVESTIGATOR** and/or investigator shall participate in the aforementioned clinical trial in accordance with this Agreement.

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

NOW THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants and Agreements as hereinafter set forth below, the parties hereto agree as follows:

I. DEFINITIONS

A. **Safety** is the state of being "safe", the condition of being protected from harm or other non-desirable outcomes.

B. **Site means** : The place whether clinical trial takes place

C. **Study :** Study means deemed to "Clinical Trial" as define in the rules of the Drugs and Cosmetics ACT (which includes amendments)

D. ***Adverse event***: means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

E. ***unexpected adverse event***: An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.

6. Review the clinical protocol and agree that it contains all the necessary information to conduct the study. The study should not begin until all necessary Ethics Committee and regulatory approvals have been obtained.

7. To conduct the study in accordance with the current protocol. The PRINCIPAL INVESTIGATOR should not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

8. To personally conduct and/or supervise the clinical trial at their site.

9. To inform all Subjects, that the drugs are being used for investigational purposes and ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.

10. To report to the Sponsor all adverse experiences that occurs in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

11. To read and understand the information in the Investigator's brochure, including the potential risks and side effects of the drug.

12. To ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

13. To maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or
their authorized representatives, in accordance with regulatory and GCP provisions. To fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

14. To promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

15. To inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurrence.

16. To maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

Id. Patient

F. ***An ethics committee*** is a body responsible for ensuring that medical experimentation and human research are carried out in an **ethical** manner in accordance with national and international law.

G. **Drug screening,** the evaluation or investigation of substance as part of a drug development, to assess suitability for a particular use

H. **Price** shall mean the sum total of the cost of the project including procuring the raw materials, investors fee, institution overhead as well as any other fee or cost associated with the services rendered herein, which are referenced and identified in a Project Agreement entered into between the parties pursuant to this research Agreement.

I. **Research Services** shall mean those services including drug screening and securing of lab notebook records, duplication of records from lab note books, authoring, reviewing, and delivery of project report.

J. **Project Agreement (or Project Agreement and Letter of Authorization)** shall mean any specific agreement, including Appendixs, authorized by this CLINICAL STUDY AGREEMENT and entered into between the parties to authorize and perform the services described in this CLINICAL SRUDY AGREEMENT and/or the terms of the Project Agreement

K. **Headings** and **References**: Section and other **headings are** for **reference only**, and shall not affect the interpretation or meaning of any provision of this Agreement. Unless otherwise provided, **references** to Sections and Exhibits shall be deemed **references** to Sections of, and Exhibits to, this Agreement.

II Investigator Responsibilities:

1. The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria
2. To be responsible for the conduct of the trial according to the protocol and the Good Clinical Practice (GCP) Guidelines and also for SOP compliance as per the undertaking as per given in Appendix VII of Schedule –Y of Rules.
3. Standard operating procedures are required to be documented by the investigators for the tasks performed by them.
4. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.
5. Investigator(s) shall report all serious and unexpected adverse events to the Sponsor within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence.

Id. Dwari

17. To comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials

III Responsibilities of the Institute:

1. Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.
2. Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.
3. Fulfilment of necessary obligations by Institutional Ethics Committee (IEC), The Principal Investigator (PI) and supporting staff
4. Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.
5. Adequate treatment for Serious Adverse Event (SAE) to trial participants.
6. Necessary infrastructure support to PI
7. Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related study documents
8. Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Report Forms (CRFs) and in all required reports.
9. Safety reporting as per schedule Y (Drug and Cosmetics Rules, 1945) and/or Sponsor policy. Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.
10. The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.
11. If Sponsor violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.
12. Approval of study within reasonable weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from sponsor.
13. Review of progress report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.
14. Review of SAE and necessary action within the time frame decided by regulatory agencies.
15. Review of final report.
16. Facilitate visit of sponsor's monitor or representative of regulatory agencies.
17. Providing alternate Principal Investigator (PI) if PI unable to continue.

IV PAYMENT:

1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure-A. Sponsor will not make further payments, towards Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

2 Sponsor shall pay on a Per Project Cost Satisfactorily Completed Project (as defined below) in accordance with Annexure-A as attached to this Agreement.

3 All payments will be paid by cheque /RTGS in the favour of

Payee Name	**SACCP CLINICAL RESEARCH**
Payee Address	**ADICHUNCHANAGIRI UNIVERSITY' ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE B.G.NAGAR,NAGAMANGALA TALUK MANDYA DISTRICT, KARNATAKA-571448**
Bank Name	**CANARA BANK**
Bank Account Number	**8610101031980**
IFSC Code	**CNRB0008610**
PAN No.	**AAAJA2708B**
GST Number	**29AAAJA2708B1ZU**

V CLINICAL TRIAL GOVERNANCE

The SPONSOR shall inform the Site, Contact Person and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The SPONSOR shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.

The Parties shall comply with all laws of the Schedule Y, Laid down by the Drugs Controller General of India, DCGI.

The Sponsor shall comply with all guidelines from time to time in force and published by The DCGI and other competent regulatory authorities in relation to clinical trials.

The Investigator shall be responsible for obtaining and maintaining all favourable opinions from the relevant research ethics committee for the conduct of the Clinical Trial and the Investigator shall keep the SPONSOR fully apprised of the progress of ethics committee submissions and shall upon request provide the Sponsor, the SPONSOR and the R&D Office with all correspondence relating to such submissions. The Investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the prior written consent of the Sponsor.

The SPONSOR shall perform such of the Sponsor's trial-related duties and functions in respect of the Clinical Trial under ICH GCP and Schedule Y.

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

The Parties shall conduct the Clinical Trial in accordance with:

- The approved Protocol,
- Clinical Trial Authorization granted by the relevant Licensing Authority; and
- The terms and conditions of the favourable opinion of the relevant Research Ethics Committee(s).

Until the Sponsor has obtained all required documentation from the Regulatory Authority and a favorable opinion from the Research Ethics Committee, it shall not supply, nor authorize the SPONSOR to supply, the Investigational Medicinal Product to the Site. The Site shall ensure that neither administration of the Investigational Medicinal 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 until it is satisfied that all relevant regulatory approvals and a favorable opinion from the research ethics committee have been obtained.

The SPONSOR shall make available to the Investigator a relevant copies of the documentation and evidence of the grant of authorizations and the Investigator shall include such documents together with the favorable opinion of the research ethics committee in the Site File for Sponsor benefits.

The Investigator shall make any necessary disclosures of financial interests and arrangements as specified by the Sponsor and for the purposes of these obligations the Sponsor shall advise the Investigator in writing of the completion date of the Clinical Trial.

Id. Amar

Neither the Site nor the Investigator shall permit the Investigational Medicinal 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 Investigational Medicinal Product shall, at the Sponsor's option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor's written instructions.

In the event that the Clinical Trial is part of a multi-centre clinical trial the Sponsor may amend the number of patients to be recruited.

The following provisions relate to access, research misconduct and Regulatory Authorities.

- The Site shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice.

- Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial.

- The SPONSOR will alert the Site promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial;

- In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Site and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Site. In the event that the Site reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Site, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor;

- The Site shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward to the Sponsor and SPONSOR copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Site will use all reasonable endeavours to procure that the Sponsor may have a representative present during any such visit;

- The Site will permit the Sponsor to examine the conduct of the Clinical Trial and the Trial Site upon reasonable advance notice during regular business hours to determine that the Clinical

Trial is being conducted in accordance with the Protocol, ICH GCP and the applicable regulatory requirements.

- The Site shall ensure that any clinical biological samples required to be tested by the Site during the course of the Clinical Trial are tested in accordance with the Protocol and at a laboratory approved by the Sponsor.

- Upon completion of the Clinical Trial (whether prematurely or otherwise) the Investigator shall cooperate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.

- Subject to the Site's and the Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the Site nor the Investigator nor Trial Site Team Members shall during the term of this Agreement conduct any other trial which might hinder the Site's or Investigator's ability to recruit and study the required cohort of Clinical Trial Subjects.

VI CONFIDENTIALITY:

Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto **(Confidential Information).** Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

(i) Is or becomes publically available through no fault of Investigator or Institution.

(ii) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

(iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

(iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

Id. Dr. [illegible]

Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

(ii) To protect any Trial subject's safety or provide appropriate medical care for any Trial subject or to prevent a public health emergency with prompt notice to Sponsor.

(iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

VII CONFIDENTIAL INFORMATION:

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute and PI will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement and the obligations of this section shall survive termination of this Agreement

VIII No joint Venture Etc.,

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

IX USE OF OTHER PARTIES' NAMES:

The Principal Investigator and Institute 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.

X LIABILITIES AND INDEMNITY

- Sponsor shall indemnify Principal Investigator and Site,(including PRINCIPAL INVESTIGATOR 's and Site's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnities") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees incurred by Investigator Indemnities arising directly out of the performance of the Study pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or wilful misconduct of an Investigator Indemnities or any Investigator Indemnities failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable central, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

- The Sponsor undertake that they will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an a Clinical trial Study Agreement not appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

XI EFFECT OF TERMINATION:

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails

to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

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

XII RECORD KEEPING

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

Institute 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 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's written approval shall be obtained.

XIII GOVERNING LAW

The validity, interpretation and performance of this Agreement shall be governed and constructed in accordance with the laws of INDIA as applicable & the place of jurisdiction for any dispute or claim before a court or an arbiter shall be Chennai , notwithstanding any other provision to the contrary in any law in this regard .

XIVARBITRATION

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 by the Chairman of the Institutional Ethics Committee of the Institute within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto

XV AMENDMENT

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 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, as two documents duly authorised to sign on behalf of parties

XVI PUBLICATION

Both the Parties herein accept to publish as per mutual consent, wherein all the parties hold the Publication rights.

Annexure-A

Fees Inclusive of all emoluments to Investigator,IOH, Hospital charges, Co-Investigator, Study coordinator, Study assistant and Investigation Charges.

Type of Visit	Visit	Day	PI Grant	Clinical Trial Centre Fee	Travel Grant	Lab charges
Screening & Treatment Initiation	1	Week 1	650	550	500	2050
Follow-up 1	2	Week 4	650	550	500	750
Follow-up 2	3	Week 8	650	550	500	750
Follow-up 3	4	Week 12	650	550	500	2050

Serious Adverse Event related cost: Cost relating to SAE that arise due to study Participation would be borne by the Sponsor on actual.

PROJECT GRANT:

Total Grant: 12400*60=7,44,000/-

Clinical Trial Coordinator Fees:20000*3=60000/-

25%IOH=2,01000/-

Total 10,05000/-

The Subject Grant exclude 10% TDS& 18% GST

The grant excludes EC Clearance, Statistical Analysis, Sample Packing

Any changes from above a Clinical trial Study Agreement will be ratified with the mutual agreement of the SPONSOR and the INVESTIGATOR.

24/3/2022

Archiving will take place at sponsor site after itself after termination of project.

Agreed and Approved

For Star Hi Herbs Pvt Ltd

STAR HI-HERBS PVT. LTD.

14/03/2022

(SPONSOR)

H.M. Firoz Hussain

Managing Director

Star Hi Herbs Pvt Ltd

50, 3rd St Rd, 1st Phase, KIADB Industrial Area,

Vaddarapalya, Jigani, Karnataka 562106

For,

Clinical Trial Centre

Adichunchanagiri Hospital& Research Centre

24/3/2022

Dr. RAJESH VENKATARAMAN
Head, Clinical Trials
Adichunchanagiri Hospital & Research Cer
Adichunchanagiri University
B. G. Nagara - 571 448

(Authorised Signatory)

Dr.Rajesh Venkataraman

Head, Clinical Trial

AH & RC,ACU

24/3/2022

Dr. Ravi B .N

Principal Investigator

AH&RC,ACU

Dr. RAVI. B. NAGARAJAIAH
Professor
Dept. of Medicine
Hospital Research Center
B.G. Nagara, KMC Reg. No. 47342