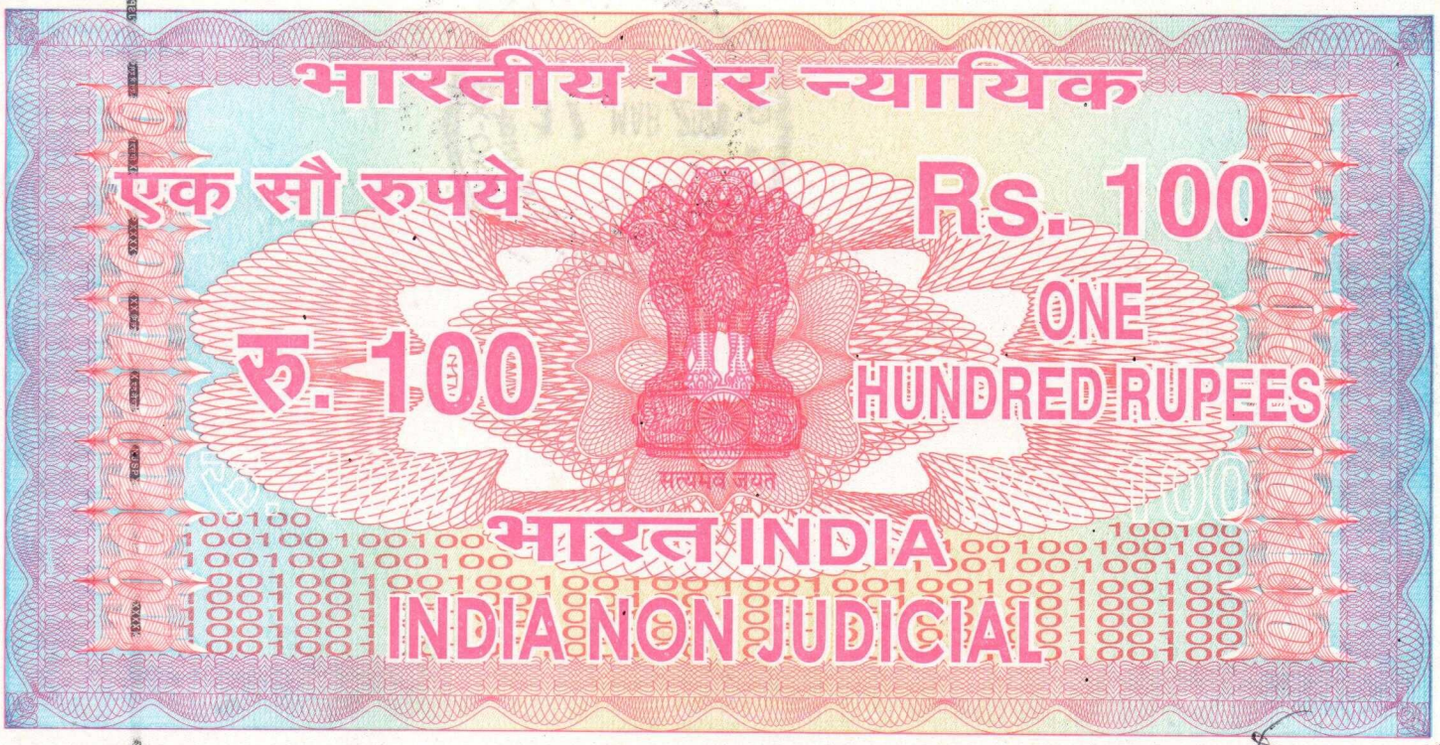

తెలంగాణ तेलंगाना TELANGANA

Sl.No 4371 Date **30-09-2020**
Sold To: Naga Raju S/o Bhaskar Raju R/o Hyd
For Whom: Unique Biotech Limited, Hyd

AA 953972
P.SRINIVAS
LICENCED STAMP VENDOR
L No: 16-11-074/1993
RL. No: 16-11- 039/2020
H.No.7-1-400/10, AMEERPET,
BALKAMPET ROAD,
HYDERABAD- 500 016,
Cell No: 9848495041

COLLABORATIVE RESEARCH
CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day (08/07/2021)("Effective Date ") between

Unique Biotech Limited, a company registered under companies Act,having its registered office at Plot No. 2, Phase-II, Alexandria Knowledge Park, Kolthur Village, Shameerpet Mandal, Ranga Reddy Dist, Hyderabad India, 500078, represented by **Dr. M. RatnaSudha,** Managing Director **(hereinafter called "Sponsor")**

AND

Clinical Research 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. Mahendrappa K B, Professor, Department of Peadiatrics** to conduct the clinical study **(herein after "Principal Investigator"/ "Investigator")**

Protocol : "A Prospective, Randomized Double Blind Placebo Controlled Study of L.reuteri UBLRu-87drops on Infantile Colic" **(Hereinafter referred to as "Study").**

For UNIQUE BIOTECH LIMITED

Dr. RATNASUDHA
Managing Director

ADICHUNCHANAGIRI HOSPITAL & RESEARCH CENTRE
Clinical Trial Centre
B. G. NAGARA - 571 448

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 here in after set forth below, the parties here to 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.

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 overheadas 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

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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 **headingsare** for **referenceonly**, 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 undertakingas 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.
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

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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.
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 supportingstaff
4. Protection ofconfidentiality, rights, safetyand well being of clinical trial participants.
5. Adequate treatment for Serious Adverse Event (SAE) totrial 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 Sponsorin the Case Report Forms (CRFs) and in all required reports.
9. Safety reporting as per schedule Y (Drugand 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&SeriousAdverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

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14. Reviewof 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 thisAgreement.

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

Payee Name	**SACCP CLINICAL RESEARCH**
Payee Address	**ADICHUNCHANA GIRI UNIVERSITY, ADICHUNCHANA GIRI 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 -NA (Collaborative Research)**

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.

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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.

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.

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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.

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- 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 the reto **(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.

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:

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(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 here to in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor.

X. INSURANCE

Sponsor will provide Insurance cover for treatment and compensation as per insurance company. Sponsor will also provide copy of Indian Insurance Company Policy to the institute.

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

XI. MONITORING; AUDIT; REGULATORY INSPECTIONS

The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

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

The Principal Investigator and Institute will permit the Sponsor to;
(a)Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
(b)Inspect and copy all Data, documents and records related to such work and the Study

XII. REPRESENTATION AND WARRANTIES:

Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his/her ability to complete the Trial in accordance with this Agreement and the Protocol. Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

XIII. TERMS & SEVERABILITY:

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

In case any provision in this Supplemental Indenture shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and such provision shall be ineffective only to the extent of such invalidity, illegality or unenforceability.

XIV. 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

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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

XV. 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, which ever 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.

XVI. 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.

XVII. 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.

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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 authorized to sign on behalf of parties

XVII. PUBLICATION

Both the Parties herein accept to publish as per mutual consent, wherein the Sponsor holds the Publication rights.

Agreed and Approved
For Unique Biotech Limited

UNIQUE BIOTECH LIMITED ★ HYDERABAD ★

(SPONSOR)
Dr. M. Ratna Sudha,
Managing Director
Unique Biotech Ltd

For,

Clinical Research Centre
Adichunchanagiri Hospital& Research Centre

(Authorised Signatory)

Dr. Rajesh Venkataraman
Head, Clinical Trial
AH & RC

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

Dr. Mahendrappa K B

Principal Investigator
AH&RC

Dr. K.B. MAHENDRAPPA
PROFESSOR
DEPT. OF PEDIATRICS
KMC. Reg. No. 26228

Payment Schedule- A

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

Type of Visit	Day	Visit	PI Grant	Clinical Research Centre Fees	Clinical Research Coordinator Fees	Travel Grant	Others	IOH 25%
Screening and baseline assessment & Treatment Initiation	0	1	650	550	300	200	100	2,250
Follow-up 1	07 ± 2	2	650	550	300	200	100	
Follow-up 2	14 ± 2	3	650	550	300	200	100	
Follow-up 3	21 ± 2	4	650	550	300	200	100	
End of study	28 ± 2	5	650	550	300	200	100	
Serial Total			3250	2750	1500	1000	500	2,250
Grant Total (Per Subject)			**₹11,250**					
*The Per Subject grant is Including 25% IOH: ₹ 2,250								
* The Per Subject grant is Excluding 10% TDS								
* Other charges it's including EC Clearance, Statistical analysis, Sample packing.								
*Screen failure payed by the Sponsor as actuals								

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: The amount is ₹9,00,000 **(₹11250 x 80).**
The number of patients expected to be enrolled is 80.
TDS 10%- ₹90,000/-
Total grant: ₹9,90,000/-

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

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

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Agreed and Approved
For Unique Biotech Limited

(SPONSOR)
Dr. M. Ratna Sudha, Managing Director, Unique Biotech Ltd

For,
Clinical Research Centre
Adichunchanagiri Hospital& Research Centre

(Authorised Signatory)

Dr.Rajesh Venkataraman
Head, Clinical Trial
AH & RC

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

Dr. Mahendrappa K B

Principal Investigator
AH&RC

Dr. K.B. MAHENDRAPPA
PROFESSOR
DEPT. OF PEDIATRICS
KMC. Reg. No. 26228

Executed by the parties
For Unique Biotech Limited

UNIQUE BIOTECH LIMITED HYDERABAD

Dr.M. Ratna Sudha

Managing Director, Unique Biotech Ltd

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub investigators and research staff are informed of their obligations under this Agreement.

Agreed and Approved

For Clinical Research Centre
Adichunchanagiri Hospital& Research Centre

(Authorised Signatory)

Dr.Rajesh Venkataraman
Head, Clinical Trial
AH & RC

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

Dr. Mahendrappa K B

Principal Investigator
AH&RC

Dr. K.B. MAHENDRAPPA
PROFESSOR
DEPT. OF PEDIATRICS
KMC. Reg. No. 26228

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:12:28 GMT)

CTRI Number	CTRI/2021/09/036977 [Registered on: 30/09/2021] - **Trial Registered Prospectively**
Last Modified On	05/04/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Medical Device
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	To evaluate the Safety and Hemostat Efficacy of Absorbable Hemostat Powder
Scientific Title of Study	A Prospective, Randomized, Active Controlled, Observer-blind Clinical Study Evaluating the Safety and Hemostat Efficacy of Absorbable Hemostat Powder of Lucktin (Hainan) Biotech Co., Ltd., in comparison with AristaTM AH (Absorbable Hemostat) of Davol, Inc., Subsidiary of C. R. Bard, Inc. in Mild or Moderate Parenchymal or Soft Tissue Bleeding During General Surgery

Secondary IDs if Any

Secondary ID	Identifier
HEMO-20-112 Ver 3.0, Dated 20 Jul 2021	Protocol Number

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

Details of Principal Investigator	
Name	Dr K Senthil Kumar
Designation	Head Clinical and Medical Monitor
Affiliation	Scitus Pharma Services Private Limited
Address	2 294 DRR Avenue 2nd Street AUDCO Nagar Kattupakkam Poonamallee Chennai 600056 Tamilnadu India Thiruvallur TAMIL NADU 600056 India
Phone	9994689336
Fax	
Email	senthilkumar.k@scitusbiolab.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr K Senthil Kumar
Designation	Head Clinical and Medical Monitor
Affiliation	Scitus Pharma Services Private Limited
Address	2 294 DRR Avenue 2nd Street AUDCO Nagar Kattupakkam Poonamallee Chennai 600056 Tamilnadu India Thiruvallur TAMIL NADU 600056 India
Phone	9994689336
Fax	
Email	senthilkumar.k@scitusbiolab.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr SD Rajendran
Designation	Director and Head Operations
Affiliation	Scitus Pharma Services Private Limited
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Lucktin (Hainan) Biotech Co., Ltd

Primary Sponsor

Primary Sponsor Details	
Name	Lucktin Hainan Biotech Co Ltd
Address	West Side of the Third Floor of No 1 Building No 16 Yaogu Yiheng Road Yaogu Industrial Park High tech Zone Haikou City Hainan China
Type of Sponsor	Other [Medical Device Industry]

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
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee Narayana Medical College Hospital	Approved	01/09/2021	No
Institutional Ethics Committee	Approved	06/10/2021	No
INSTITUTIONAL ETHICS COMMITTEE MAMC	Approved	30/11/2021	No
Institutional Ethics Committee of AH and RC	Approved	10/09/2021	No
Institutional Ethics Committee of DMIMS	Approved	28/10/2021	No
Dr Rela Institute & Medical Centre Institutional Ethics Committee	Approved	25/05/2022	No

Hycare super speciality hospital ethics committee	Approved	04/02/2022	No
Hycare super speciality hospital ethics committee - New Hope Medical Centre	Approved	05/08/2022	Yes
IEC Intervention Studies	Approved	22/11/2021	No
SRM Medical College Hospital and Research Centre	Approved	09/10/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	02/08/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Intervention / Comparator Agent

Type	Name	Details
Intervention	Absorbable hemostat powder	The product is modified plant starch, it has strong capability of water absorption. When in contact with the blood, it can quickly absorb the water molecules in the blood, it's capability of water absorption is equivalent to the function of hydrophilic molecular sieve. Moreover, it can gather the visible components (such as platelets, etc.) on the surface of the microspheres to accelerate the activation of endogenous coagulation molecules, and the "instant gel" is formed to form a dense fibrin net, which can instantly stop bleeding, and the coagulant block is firm and reliable
Comparator Agent	AristaTM AH (Absorbable Hemostat)	AristaTM AH is a medical device intended for application to surgical wound sites as an absorbable hemostat. This technology incorporates hydrophilic, flowable, microporous particles synthesized by cross-linking purified plant starch through a proprietary process; Arista AH is a 100% plant based polysaccharide Arista AH is a fine, dry, sterilized white powder that is biocompatible, non-pyrogenic, and is typically absorbed within 24 to 48 hours.

Inclusion Criteria

Inclusion Criteria

Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	I.Pre-operative 1.Male or female subjects aged from 18 to 60 years (both inclusive) requiring elective/non-emergent general surgical procedures (minimally invasive surgery or open surgery). 2.Subject or legally authorized representative has signed the Ethics Committee approved Informed Consent. 3.Subject whose International Normalized Ratio is <1.5 within 24 hours of surgery. 4.The subject is willing and able to comply with the requirements of the study protocol, including the predefined follow-up evaluations. II.Intra-operative 1.Presence of an appropriate target bleeding site (TBS) identified intra-operatively by the surgeon. 2.Subject(s) on anticoagulation undergoing surgery must have anticoagulation reversed prior to target bleeding site (TBS) identification and treatment.

Exclusion Criteria

Exclusion Criteria	
Details	I. Pre-operative 1. Female subjects who are pregnant or nursing; 2. Subject on anticoagulation medication (with the exception of aspirin) prior to surgery. Washout periods for respective medications must be observed. If information is not readily available within the Instructions for Use (IFU), a conservative approach should be taken and intravenous heparin stopped 12 hours prior to surgery and 2 days prior for oral medication; 3. Subject on antiplatelet/P2Y12 inhibitors medication prior to surgery. Platelet recovery times for respective medication must be observed. If information is not readily available within the IFU, a conservative approach should be taken and medication stopped 5 days prior to surgery. 4. Subject is currently participating or plans to participate in any other investigational device or drug trial without prior approval from the Sponsor; 5. Subjects who are known, current alcohol and/or drug abusers 6. Subjects with any pre-operative findings identified by the surgeon that may preclude conduct of the study procedure. 7. Subjects requiring neurological and ophthalmic procedures. 8. Subjects with post-partum bleeding or menorrhagia, uncontrolled hypertensive and diabetic patients. 9. History of blood dyscrasias or immunocompromised patients. 10. Known ongoing infection (local or systemic). 11. Subjects with known psychiatric disorder which would preclude him/her from completing the study. 12. Subjects with known congenital or acquired immunodeficiency. II. Intra-operative 1. Subjects with any intra-operative findings identified by the surgeon that may preclude the use of study device; 2. Subject with target bleeding site (TBS) in an actively infected field [Class III Contaminated or Class IV Dirty or Infected]; 3. Target bleeding site (TBS) is on arteries or veins where application of absorbable hemostat powder would present a risk of introducing the study device into an open blood vessel; 4. Major arterial or venous bleeding or major defects in arteries and veins; 5. Target bleeding site (TBS) where silver nitrate or any other escharotic chemicals have been applied, Target bleeding site (TBS) is in, around, or in proximity to foramina in bone, or areas of bony confine, the spinal cord, or optic nerve and chiasm;

	6. Target bleeding site (TBS) in urological procedures where plugging (blocking) of the urethra, ureter or a catheter is possible by the study device.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Proportion of subjects achieving hemostatic success at 5 minutes following the application of powder with no re-bleeding requiring additional treatment at the target bleeding site (TBS) in each group.	Intra-operatively

Secondary Outcome

Outcome	Timepoints
• Proportion of subjects achieving hemostatic success at 3 minutes following the application of powder with no re-bleeding that requires additional treatment at the TBS in each group. • Proportion of subjects achieving hemostatic success at 10 minutes following the application of powder with no re-bleeding that requires additional treatment at the TBS in each group.	Intra-operatively

Target Sample Size	**Total Sample Size=**360 **Sample Size from India=**360 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	30/09/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**9 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	Not Applicable
Brief Summary	This will be a prospective, parallel design, active controlled, observer-blind multicenter, clinical study comparatively evaluating absorbable hemostat powder in achieving hemostasis in mild or moderate parenchymal or soft tissue bleeding during surgery. The main objective of this study is to evaluate the efficacy (as the primary objective) and safety (as the secondary objective) of the Absorbable Hemostat powder of Lucktin (Hainan) Biotech Co., Ltd., (test device) in comparison with Arista™ AH (Absorbable Hemostat) of Davol, Inc., Subsidiary of C.R. Bard, Inc. (reference device; active control) in identified mild or moderate soft tissue/parenchymal bleeding for which conventional methods of control (e.g., suture, ligature, and cautery) are ineffective or impractical, and an adjunct device is required to achieve hemostasis. Approximately 360 subjects will be randomized to either test or reference device in a targeted 1:1 ratio. Subjects undergoing open

surgery and minimally invasive surgery will be selected in a targeted 2:1 ratio by stratified randomization technique. Thus, approximately 240 subjects will be selected from subjects undergoing open surgery, and approximately 120 subjects will be selected from subjects undergoing minimally invasive surgery. The test to reference ratio will be maintained at 1:1.

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:11:08 GMT)

CTRI Number	CTRI/2021/08/035907 [Registered on: 24/08/2021] - **Trial Registered Prospectively**
Last Modified On	17/02/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Biological
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to study the safety and efficacy of test Ranibizumab in patients with visual impairment
Scientific Title of Study	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).

Secondary IDs if Any

Secondary ID	Identifier
ALK21/ENZ105-RANI1 Version 2.0, 23/Nov/2020	Protocol Number

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

Details of Principal Investigator	
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Designation	President & CMO
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
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> Enzene Biosciences Limited, Plot No. 165/1/26, Block T, Bhosari MIDC Area, Pune-411057, Maharashtra

Primary Sponsor

Primary Sponsor Details	
Name	Enzene Biosciences Limited
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Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

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Countries of Recruitment

List of Countries
India

Sites of Study

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		Porur, Chennai- 600116 Chennai TAMIL NADU	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Aakash Healthcare Super Speciality Hospital Institutional Ethics Committee	Approved	21/06/2021	No
Aditya Jyot Eye Hospital Ethics Committee	Approved	01/12/2021	No
Centre for Sight Institutional Ethics Committee	Approved	08/03/2022	No
Ethics Committe, Dr B R Ambedkar Medical College and Hospital	Approved	26/07/2021	No
Ethics Committee Deoyani Multispeciality Hospital	Approved	10/06/2021	No
Ethics Committee Govt Medical College and hospital	Approved	18/02/2022	No
Ethics Committee of Care Institute of Medical Sciences	Approved	06/12/2021	No
Ethics Committee S.P Medical College	Approved	27/11/2021	No
Ethics Committee, N.R.S. Medical College	Approved	26/10/2021	No
Institute Ethics Committee, AIIMS, New Delhi	Approved	24/02/2022	No
Institutional Ethics Committee AIIMS Jodhpur	Approved	02/02/2022	No
Institutional Ethics Committee AMRITA Institute of Medical Sciences and research centre	Approved	28/11/2021	No
Institutional Ethics Committee GMERS medical college Sola	Approved	04/08/2021	No
Institutional Ethics Committee Great Easter medical school and hospital	Approved	04/08/2021	No
Institutional Ethics Committee JPM Rotary Club of Cuttack Eye Hospital and Research Institute	Approved	24/11/2021	No
Institutional Ethics Committee Lokmanya	Approved	22/03/2022	No

Tilak Municipal Medical College & General Hospital			
Institutional Ethics Committee, Adichunchanagiri Institute of Medical Sciences	Approved	07/05/2021	No
Institutional Ethics Committee, AIIMS Nagpur	Approved	02/02/2022	No
Institutional Ethics Committee, Heritage Institute of Medical Sciences	Approved	20/08/2021	No
Institutional Ethics Committee, Mysore Medical College and Research Institute and Associated Hospitals	Approved	17/01/2022	No
Institutional Ethics Committee, Seth G.S . Medical College and KEM Hospital	Approved	29/11/2021	No
Institutional Ethics Committee, Vision Research Foundation	Approved	06/10/2021	No
KIDS Ethics Committee	Approved	08/09/2021	No
LPR Ethics Committee	Approved	07/04/2021	No
Nirmal Hospital Ethics Committee	Approved	11/05/2021	No
Sangini Hospital Ethics Committee	Approved	13/01/2021	No
Sir Ganga Ram Ethics Committee	Approved	07/03/2022	No
The Institutional Ethics Committee, B. J. Medical College & Civil Hospital, Ahmedabad	Approved	19/01/2022	No
Veracity Independent Ethics Committee	Approved	01/03/2022	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	01/03/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Degeneration of macula and posterior pole

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Innovator Ranibizumab	It will be administered at the dose of 0.5 mg by intravitreal injection every 4 weeks for a total of 12 weeks (03 doses) under aseptic conditions.
Intervention	ENZ105	It will be administered at the dose of 0.5 mg by intravitreal injection every 4 weeks for a total of 12 weeks (03 doses)

		under aseptic conditions.

Inclusion Criteria

Inclusion Criteria	
Age From	50.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1.Willing to provide voluntary written informed consent.2.Male or female participant with age greater than or equal to 50 years at the time of screening.3.Subjects with treatment-naive CNV (choroidal neovascularization) secondary to AMD, involving the foveal center.4.Have a best corrected visual acuity of 20/40 to 20/320 using Early Treatment Diabetic Retinopathy Study chart- ETDRS (Snellen equivalent) in the study eye.5.Willing and able to comply with protocol.

Exclusion Criteria

Exclusion Criteria	
Details	1.Known hypersensitivity to Ranibizumab or any of the components of study medication. 2. Prior treatment with any intravitreal drug, verteporfin or photodynamic therapy in the study eye in the past (except for extrafoveal laser photocoagulation in the study eye) and/or non-study eye within past 3 months before enrollment in the study. 3. Laser photocoagulation in the study eye within 1 month before screening the subject. 4. Subject with vision only in one eye. 5. Prior treatment with any anti-VEGF therapy in last 6 months 6. Subfoveal fibrosis or Subfoveal atrophy in the study eye. 7. CNV in either of the two eyes due to causes other than AMD such as histoplasmosis or pathological myopia etc. 8. Retinal pigment epithelial tear involving the macula in the study eye. 9. Any concurrent intraocular condition in the study eye that could either require medical or surgical intervention during the study period or that could contribute to a loss of best corrected visual acuity over the study period (e.g. diabetic retinopathy, cataract, uncontrolled glaucoma, uveitis, previous corneal transplant, recent cataract surgery etc.). The decision regarding exclusion is to be based on the opinion of the investigator. 10. Presence of any uncontrolled systemic disease (e.g. cardiovascular disease, hypertension, diabetes mellitus etc.) 11. Known history of peripheral vasculopathy, peripheral arterial disease within 01 year of study participation 12. Subject with Polypoidal choroidal vasculopathy. 13.Active intraocular inflammation or active/suspected ocular or periocular infection in the study eye. 14. History of retinal or intraocular surgery in the study eye in the last three months. 15. Vitreous hemorrhage in the study eye or history of retinal detachment or macular hole (stage 3 or 4) in the study eye. 16. Any other retinal pathology i.e. Central retinal vein occlusion, Central retinal artery occlusion etc. 17. Pregnant or breastfeeding. 18. Subjects with suspected signs and symptoms of COVID-19/ confirmed novel coronavirus infection (COVID-19) or with history of travel / contact with any COVID-19 positive patient/isolation/quarantine.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
To compare the efficacy of ENZ105 (Enzene) with Innovator Ranibizumab in subjects with Neovascular (Wet) Age related Macular Degeneration (AMD) by Visual acuity test	Percentage of subjects who loose 15 letters in visual acuity in the study eye at week 12 compared to baseline

Secondary Outcome

Outcome	Timepoints
1.To assess the immunogenicity of ENZ105 (Enzene) versus Innovator Ranibizumab by assessment of anti-Ranibizumab antibody 2.Safety and tolerability of the investigational product.	1.Percentage of subjects who gain greater or equal to 15 letters in visual acuity in the study eye at week 12 compared to baseline 2.Mean change in best corrected visual acuity (BCVA) from baseline in the study eye at week 12

Target Sample Size	**Total Sample Size=**152 **Sample Size from India=**152 **Final Enrollment numbers achieved (Total)=**152 **Final Enrollment numbers achieved (India)=**152
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/09/2021
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 Comparative, Double-Blind, Randomized, Multicenter, Phase III study in subjects with Neovascular (Wet) Age related Macular Degeneration (AMD). A total of 152 subjects who meet the eligibility criteria will be randomized in a ratio of 3:1 to either of the treatment groups: Group A (N = 114) ENZ105 Group B (N = 38) Innovator Ranibizumab The study duration will be approximately 18 months considering 15 months of recruitment period and 3 months of study period (1 week screening period, 12 weeks of treatment period) Screening Period: It will last up to one week during which the subject will be assessed for eligibility in the study; Treatment Period: It will last for 12 weeks; all subjects will receive either ENZ105 or Innovator's Ranibizumab, 0.5 mg intravitreal injection once every 4 weeks for 12 weeks (3 doses); End of Study Assessment will be performed at week 12