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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "**Agreement**") is made on 25th Day of February, 2025 ("**Effective Date**") by and between

Clinical Research Network India Pvt Ltd, a company incorporated under the laws of India having its registered office at B-806,807, Advant Navis Business Park Plot #7, Noida-Greater Noida Expressway, Sector 142, Noida, Delhi-NCR, Uttar Pradesh 201305, India ("**CRO**"), of the First Part; and

Dr. Renu Dhasmana, a registered medical practitioner holding MCI registration number: **2325** currently serving as HOD Ophthalmology and Vice Principal (Postgraduate) at Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India, hereinafter referred to as ("**Principal Investigator**"), of the Second Part; and

Swami Rama Himalayan University, a University established under section 2(f) of the UGC Act and enacted vide Uttarakhand State Act **(For its constituent academic unit *Himalayan Institute of Medical Sciences*)** having its registered office at Swami Ram Nagar, Jolly Grant,

Swami Rama Himalayan University Director Research

Dr. Renu Dhasmana
Professor & Head
Department of Ophthalmology
HIMS, Dehradun

Doiwala, Dehradun, Uttarakhand 248016, represented by Registrar **Commander ChallaVenkateswar** hereinafter referred to as**("Institution/Site")**of the Third Part; and

KV Clinical Research Pvt Ltd, having Registered address at Off. No. 616,617 Sixth Floor Golden Trade Centre New Rajendra Nagar Raipur-492001 (C.G), hereinafter referred to as ("**SMO**") of the Fourth Part.

CRO, Principal Investigator, Institution and SMO are collectively referred to as**"Parties"**.

WHEREAS,

The CRO is a Contract Research Organization is engaged in the business of undertaking clinical trials (Phase I-IV), data management, biostatistics, medical writer, regulatory consulting, and other research work for the pharmaceutical industry. The CRO has been outsourced by **Gennova Biopharmaceuticals Limited ("Sponsor")** to conduct the clinical trial/study. The CRO is authorized by the Sponsor to enter into the agreement on its behalf and has undertaken to abide by all the terms and condition of this agreement. Authority letter is attached as annexure with this agreement.

A. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

B. The CRO has already identified the Principal Investigator based on her experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

C. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed her willingness to the CRO to conduct the proposed Study;

D. The CRO shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the CRO; and

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. **Definitions**

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1.1. "**Study**" or "**Clinical Trial**" shall mean study entitled: A Phase III Prospective, Randomized, Open-labelled, Blinded endpoint (PROBE), Multi-centric, Parallel Group, Non-inferiority Study to compare the Efficacy and Safety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration **(PROMISES Study).**

1.2. **"Sponsor"** shall mean an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study or trial at study site. Sponsor shall be the owner of the Clinical Trial Protocol and is interested in carrying out the said Clinical Trial, through the CRO, SMO & PRINCIPAL INVESTIGATOR at study site.

1.3. "**Protocol**" shall mean the description of the Study contained in the Study protocol number: **GBL1204/2024/01** and all amendments thereto as the Parties may from time to time agree in writing.

1.4. "**Study drug**" or "**Investigational Drug**" shall mean

- Test Product: GBL1204 (Bevacizumab manufactured by Sponsor as ophthalmic grade).

- Comparator Product: Ranibizumab (Accentrix®, Novartis India Limited, India)

1.5. "**Ethics Committee**" shall mean an independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of New Drugs and Clinical Trial Rules- 2019 and rules amended thereof.

1.6. "Adverse **event"** means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given.

1.7. **Serious Adverse Event (SAE):-** Any untoward medical occurrence that, at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalization* or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is medically significant or requires intervention to prevent one of the outcomes listed above

1.8. **"Publication"** means a paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the

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form of a written summary), or other disclosure of Registry Results, in printed, electronic, oral or other form.

1.9. **"Results"** shall mean and include all the methods, data, analysis and conclusions of a Registry.

1.10. **"Contract Research Organization or Clinical Research Organization (CRO)"** is a service organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services (for both drugs and medical devices).

1.11. **"Site Management Organization (SMO)"** is a company that provides clinical trial management services to pharmaceutical, biotech, medical companies or Medical Institutions. SMOs help sponsors streamline their administrative processes while ensuring that all regulatory requirements are met. They also support Clinical Research Organisation (CRO) and clinical investigators at the site with startup, monitoring, and closeout responsibilities.

1.12. **"Study Site"** means and include Swami Rama Himalayan University (SRHU), Jolly Grant, Dehradun.

2. Responsibility of the Principal Investigator and the Institution/Site

2.1. The Institution agrees to provide full support to the Principal Investigator to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, investigators and other persons with prior consent of the CRO, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2. The Principal Investigator and SMO shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the CRO strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Good Clinical Practice, Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; New Drugs and Clinical Trials Rules-2019, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("Applicable Laws& Guidelines"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide CRO a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

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2.3. The SMO will provide all administrative support to Principal Investigator to conduct the study as per the study protocol.

2.4. The Principal Investigator along with any co-investigator employed in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) The case report form has been completed by the Principal Investigator/designee in accordance with Study requirements.
(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the CRO; and
(iii) It can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the CRO.

2.5. Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the CRO, Chairman of Ethics Committee, the Institution and licensing authority within twenty-four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.6. The Principal Investigator and CRO shall provide report of serious adverse events of death after due analysis to the Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority and to the Institution of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

2.7. The Principal Investigator and CRO shall provide report of serious adverse events other than death after due analysis to the Chairman of Ethics Committee, licensing authority and to the Institution within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

2.8. In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any later stage, the Principal Investigator shall provide notice to the Study subjects, the institution, Ethics Committee and CRO at least thirty (30) days before Principal Investigator intends to stop Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator from among the

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