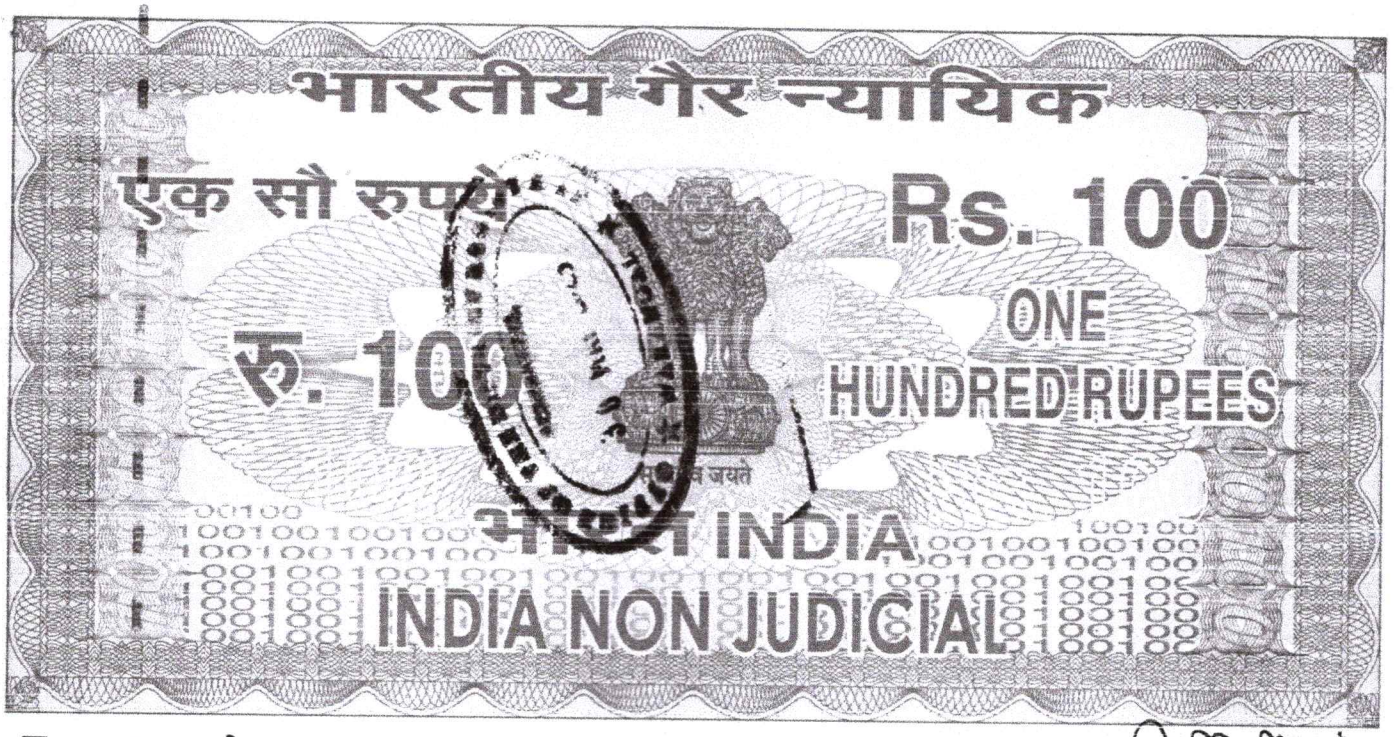

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter "Agreement) is made on 14th July 2023

by and between

NMC Clinical Services acts as a Clinical Research Consultancy having its registered office at #12-52, Road No. 2, P&T Colony, Medipally, Hyderabad -500 039 represented through its authorized signatory (hereinafter known as the "**NMC**", which expression shall unless be repugnant to the context include its successors and assigns) of the **FIRST PART**

And

DR. YOGESH PREET SINGH, working at Himalayan Institute of Medical Sciences, an academic unit of Swami Rama Himalayan University having its place of business at Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand-248016, India (hereinafter referred to as "**Principal Investigator**" (which expression unless repugnant to the context, shall mean and include his permitted assigns) of the **SECOND PART**

And

SWAMI RAMA HIMALAYAN UNIVERSITY, a University established under section 2(f) of UGC Act, 1956 and enacted vide Uttarakhand Act no. 12 of year 2013, having its registered office at Swami Ram Nagar, Jolly Grant 248 016, Dehradun, Uttarakhand, India through its Registrar Dr. Susheela Sharma (hereinafter referred to as "**Institution**" which expression shall unless repugnant to meaning or context mean and include its successors and permitted assigns) of the **THIRD PART**

NMC, Principal Investigator and Institution are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**".

WHEREAS:

A. Virchow Healthcare Pvt. Ltd. ("Virchow" or "Sponsor") wishes to sponsor a clinical trial study entitled "*Comparative pharmacokinetic, pharmacodynamic, safety, efficacy and immunogenicity study of VBRTXM01 (Virchow Rituximab) versus Ristova (Roche Rituximab) in patients with Rheumatoid Arthritis*" (hereinafter referred to as "Study") to be conducted by Principal Investigator at the Institution under the appended protocol carrying study code VBRTXM01/2020-CT1 ("Protocol") and all its subsequent amendments.

B. Virchow has delegated responsibility for the management of this Study, including contracting and Study monitoring, to NMC, and has authorized NMC to bind Virchow to all commitments within this Agreement identified as belonging to Virchow.

C. Principal Investigator is professionally equipped to undertake the Study and has agreed to perform the Study on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the parties agree as follows:

1. STUDY

The Principal Investigator will perform the project set forth in the appended protocol carrying the study code **VBRTXM01/2020-CT1.**

Any additional work not identified in the protocol, but indicated during the course of the study, will be separately agreed upon by Sponsor and Principal Investigator.

2. PERIOD OF PERFORMANCE AND TERMINATION

The Study will be conducted during the period starting from 14 July 2023 to 13 June 2024 and may be extended by mutual agreement in writing, duly signed by all the Parties to this Agreement. This Agreement shall be terminated by the Parties in writing with at least thirty days prior notice to the other Party.

3. PROVISION OF MATERIAL AND INFORMATION

NMC agrees to provide:

1. All trial materials necessary for the conduct of the study;
2. All relevant clinical pharmacology and toxicology information and advice to the Principal Investigator and the Institution for the proper planning and conduct of the study throughout the study period. Such information will include any serious adverse drug experience, all relevant clinical, pharmacological and toxicology data; and

NMC CLINICAL SERVICES HYDERABAD

Sikkim Manipal University Registrar

3. Supervision, training and monitoring support during the conduct of the Study.

4. CONDUCT OF THE STUDY

Principal Investigator and Institution shall conduct the Study in accordance with any and all applicable laws, regulations, guidelines and protocols, including but not limited to, the terms of the Study Protocol, the trial authorisation given by the Drug Control General of India, New Drugs and Clinical Trials Rules, 2019 Guidelines issued by the Central Drug Standard Control Organization, Ministry of Health, Government of India, Ethical Guidelines for Biomedical Research on Human subjects issued by the Indian Council for Medical Research and in accordance with the ethical principles that have their origin in the declaration of Helsinki and other ethical conditions imposed by the Institutional Ethics Committee.

4.1. IP to Be Used Only for Study

Principal Investigator shall not make any use of IP provided by Sponsor other than for the performance of the Study.

4.2. Valid Subjects' Recruitment

Principal Investigator shall use his best effort to recruit only valid subjects and shall not knowingly enrol any subjects, which in Principal Investigator's best professional judgment do not adequately meet the criteria for a valid subject.

4.2.1. Number of subjects

The study anticipates an average enrolment of 25 completed and evaluable patients from the Principal Investigator. Recruitment for this study will be through competitive enrolment and Principal Investigator may enrol more or less depending on the enrolment at other sites.

4.2.2. Timeline

Principal Investigator shall recruit the eligible patients in the stipulated time schedule of 3 months after site initiation of the study.

4.3. Case Report Forms

Principal Investigator shall complete the Case Report Form provided by Sponsor promptly and accurately. Principal Investigator shall give these forms and make available any source documents related to the Study to Sponsor and NMC at periodic monitoring visits or otherwise promptly upon request. Principal Investigator shall assist Sponsor and NMC to resolve any discrepancies, errors or missing information in the Case Report Forms. Principal Investigator shall assist Sponsor to conduct audits of original case records, laboratory reports, and/or raw data sources underlying data recorded in the Case Report Forms. Such audits shall be conducted with due regard to patient confidentiality.

4.4. No Ancillary Study

Principal Investigator agrees that no valid subject in this Study may participate concurrently in any ancillary study (technique, procedure, questionnaire, or observation other than those set forth in the Protocol) without prior approval in writing from Sponsor.

4.5 Ethics Committee's Approval

Principal Investigator shall be responsible for obtaining approval of the Protocol, Informed Consent and any alteration to or waiver of any valid subject authorization permitting the disclosure of confidential valid subject information in connection with the Study, from the appropriate Ethics Committee prior to commencement of the Study and notifying the same with sponsor and NMC.

4.6. Changes to Protocol or Informed Consent

In the event the Ethics Committee requires changes in the contents of the Protocol or the Informed Consent, such changes shall not be implemented until Sponsor is notified and gives its approval. The contents of the Protocol or the Informed Consent shall not be revised without the prior written agreement of Sponsor and the Ethics Committee.

4.7. Informed Consent to Be Signed

Principal Investigator shall be responsible for obtaining an Informed Consent document signed and dated by or on behalf of each valid subject, prior to the valid subject's participation in the Study. Principal Investigator shall also be responsible for audio visual recording of informed consent process while adhering to the principles of confidentiality.

5. Monitoring of the Study

5.1 Inspections/Audits

During the term of this agreement, and subject to prevailing patient confidentiality, Principal Investigator agrees to permit representatives of the Sponsor or other appropriate governmental authorities direct access to examine (a) the facilities where the Study is being conducted, (b) include Informed Consent Form (c) raw Study data including original valid subjects' records and (d) any other relevant information (and to make copies) necessary for Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with federal laws and state laws. Principal Investigator agrees to take any reasonable actions requested by the Sponsor to cover deficiencies noted pursuant to the Study during an audit or inspection.

5.2. Adverse Event

Principal Investigator shall promptly notify Sponsor and NMC in writing of any serious or unexpected adverse events or claim of illness or injury actually or allegedly due to the adverse reaction to the IP and allow Sponsor to handle such claim (including settlement negotiations) and shall co-operate fully with Sponsor in its handling of the claim.

Principal Investigator responsibilities in case of serious adverse events (SAE)

- Principal Investigator shall report all SAE to the Licensing Authority, Sponsor and Ethics committee, which accorded approval to the study protocol within 24 hrs of occurrence.
- In case of death, Principal Investigator shall forward his/her reports on SAE after due analysis to Chairman of the Expert committee and Chairman of Ethics Committee with a copy of the report to Licensing Authority and head of the Institution where the trial has been conducted, within 10 days of occurrence of death.
- In case of SAEs other than deaths, PI shall forward his/her report on SAE after due analysis to Chairman of Ethics Committee, Licensing Authority and head of the Institution where the trial has been conducted, within 10 days of occurrence of SAE.
- Ensure adequate follow-up.
- Report any Principal Investigator Notifications to respective EC.
- Sponsor agrees to reimburse the Institution or Principal Investigator for reasonable and necessary medical expenses incurred by the Institution or Principal Investigator as a direct result of diagnosing and treating of an SAE resulting from the use of the Trial drugs when administered in strict accordance with the Protocol and Sponsor's instructions, provided that the SAE did not occur as a direct result of the Institution's or Principal Investigator's negligence or misconduct. The Institution and Principal Investigator agree to treat any such illness or injury. Payments will be made following an invoice per treatment and confirmation by Sponsor that the treatment was performed as a result of an SAE. Institution or Principal Investigator will provide all information reasonably requested by Sponsor to confirm such treatment.
- If during the course of the Trial any injury occurs to a patient (**"Patient Injury"**), Sponsor agrees to pay financial compensation as well as reimbursement of reasonable and necessary medical expenses to the patient or his legal heirs. However, where the Patient Injury is due to (i) the failure of the Institution or Principal Investigator, or their officers, agents, or employees to follow the Protocol or administer the Trial drugs in strict accordance with the Protocol or Sponsor's instructions or (ii) their negligence, the Institution and Principal Investigator agree to pay any such compensation to the patient.

5.3. Change in Principal Investigator

In the event of a change of Principal Investigator, the Principal Investigator shall alert NMC within three (3) days. If NMC considers that Principal Investigator's non-affiliation with the Institution would adversely affect the Study, NMC may in its absolute discretion shall sign the agreement with the new Principal Investigator who shall be required to agree to the terms and conditions of this agreement.

6. Payments

In consideration for performance under terms of this AGREEMENT, NMC agrees to pay **PI per patient** per visit, in accordance with the appended BUDGET in Annexure through Cheque(s)/Online payable to the Principal Investigator.

If to PI
Payee Name: SRHU SCIENTIFIC AND INDUSTRIAL RESEARCH
Bank Name: STATE BANK OF INDIA
Bank Account No.: - 33082676422