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CLINICAL STUDY AGREEMENT

Swami Rama Himalayan University Director Research

CLINICAL STUDY AGREEMENT
Among
Parexel International Clinical Research Private Limited
And
Dr Sanjiv Verma
And
Swami Rama Himalayan University

Pfizer Protocol # C1071007

This Clinical Study Agreement ("**Agreement**") among

Parexel International Clinical Research Private Limited, with a place of business at CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World, Ground floor, Bay Area- Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bengaluru -560103, Karnataka, India ("**CRO**")
and

Dr Sanjiv Verma with a place of business at 'Himalayan Institute of Medical Sciences' a unit of Swami Rama Himalayan University, Jolly Grant- 248 016, Dehradun, Uttarakhand, India. ("**Principal Investigator**"),

and

Swami Rama Himalayan University, with a place of business at a University established under section 2(f) of the UGC Act, 1956 and enacted vide Uttarakhand Act no. 12 of 2013, having its registered office at Swami Ram Nagar, Jolly Grant- 248 016, Dehradun, Uttarakhand, India through its Registrar Dr. Susheela Sharma ("**Institution**"),

when signed by all parties, is effective as of 11 Apr 2023.

Pfizer Inc. ("**Pfizer**") wishes to sponsor a clinical study trial/entitled "MAGNETIS MM-7 / A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATAMAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION" ("**Study**") to be conducted by Principal Investigator at Institution under the Pfizer protocol identified above ("**Protocol**"). Pfizer has delegated responsibility for management of this Study, including contracting and Study monitoring, to CRO, and has authorized CRO to bind Pfizer to all commitments within this Agreement identified as belonging to Pfizer.

The parties agree as follows:

1. Responsibilities

1.1 Investigators and Research Staff. The Study will be conducted by Principal Investigator, namely Dr. Sanjiv Verma ("**Principal Investigator**") at a facility that is identified as a 'clinical trial site' under the Rules. Principal Investigator an employee of Institution and is authorized by Institution to conduct the Study at Institution under a separate agreement between Principal Investigator and Institution. Principal Investigator will ensure that only individuals who are appropriately trained, experienced and qualified assist in the conduct of the Study as investigators, sub-investigators or research staff. The Principal Investigator shall sign an undertaking in the form prescribed in **Table 4** of the **Third Schedule** of the Rules. Principal Investigator shall further ensure that the Study is subject to continuing oversight by the IRB/IEC throughout its conduct.

1.2 Compliance Obligations. Principal Investigator and Institution are responsible to CRO and Pfizer for compliance by all Study personnel with the terms of this Agreement, the Protocol, the applicable provisions of the Drugs and Cosmetics Act, 1940 ("**Act**"), the Rules, and International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research, as well as applicable law, regulations, and governmental guidance, including without limitation, the laws of the Republic of India. The Institution and CRO shall be jointly responsible for obtaining requisite permissions and approvals for the conduct of the Study in terms of applicable laws, including permission from the Central Licensing Authority. The Institution also undertakes to abide by and comply with any statutory modifications/ amendments to the Rules, as may be effective from time to time. Institution is responsible for compliance by all personnel who are employees or contractors of Institution, and Principal Investigator is responsible for compliance by any personnel not employed or contracted by Institution.

1.3 Pfizer GCP Training. Prior to enrollment of any Study Subjects (as defined in Section 4, Subject Enrollment), Principal Investigator and any sub-investigators will either complete or provide a valid certificate of the Pfizer-provided Good Clinical Practice training course ("**Pfizer GCP Training**"). Any investigators who later join the Study , in compliance with applicable laws including the Rules, will complete the Pfizer GCP Training or provide a valid certificate before performing Study-related duties.

1.4 Compliance with Global Trade Controls. The parties agree that activities under this Agreement may be subject to applicable import, export, and economic sanctions laws and regulations ("Global Trade Control Laws"). Institution and CRO will comply with all applicable Global Trade Control Laws.

a. The parties confirm that none of the activities under this Agreement will (i) take place in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; and (iii) involve companies, organizations, or Governmental Entities from a Restricted Market. "Restricted Market" shall mean the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria.

b. Each party represents and warrants that (i) it is not on any Restricted Party Lists (defined below); (ii) it is not owned or controlled by any individual or entity on any Restricted Party Lists; and (iii) that it will not involve any individual or entity on any Restricted Party Lists in the activities under this Agreement. In the event that an individual or entity on a Restricted Party List is included in activities under this Agreement, the party connected with such individual or entity will immediately notify the other party and suspend the relevant affected activities, including any and all affected payments, until the parties agree to go forward.

c. With respect to this Agreement, Restricted Party Lists include the Consolidated Screening List (https://www.export.gov/consolidated_screening_list); the Excluded Parties List System (https://www.sam.gov); and the Consolidated List of Persons, Groups, and Entities Subject to E.U. Financial Sanctions https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en

1.5 The Institution shall ensure that the Principal Investigator shall conduct Study/clinical trials only with the permission of the Institutional Review Board (IRB)/ Independent Ethical Committee (IEC) after the examination of the risk and complexity involved in the trials proposed to be conducted and shall not in any instance conduct any higher number of Study/clinical trial not permitted by the IRB/IEC. The Institution shall indemnify the CRO and Pfizer, their respective employees and agents against any and all claims and proceedings (to include any settlements or reasonable legal and expert cost and expenses) arising out of or in connection with the Principal Investigator's failure to adhere to provisions of this Clause.

2. Funding. CRO will provide funding in support of this Study to Institution as delineated in Attachment A, Study Budget and Payment Terms, and subject to the terms specified in that Attachment. Institution certifies that payments to the Institution comply with applicable law and any applicable policies and procedure of the Institution.

2.1 Payee. As indicated in Attachment A, Institution is the payee for all Study funding. CRO's only payment obligation under this Agreement is to Institution. Allocation of funds between Institution and Principal Investigator is governed by a separate

agreement between those parties. Principal Investigator releases CRO and Pfizer from any obligation or liability related to the disbursement of funds by Institution.

2.2 Investigator Meetings. If Principal Investigator or other Study personnel are required to attend investigator meetings for this Study, CRO will arrange and pay directly for travel and accommodation and will cover the reasonable costs of meals in connection with those meetings, but does not provide compensation for such attendance.

2.3 Disclosure by Pfizer. In the interest of transparency relating to its relationships with investigators and Study sites or to ensure compliance with applicable local laws, Pfizer may publicly disclose the support it provides under this Agreement. Such a disclosure by Pfizer may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals.

3. Protocol. Principal Investigator will conduct the Study and Study-related activities in accordance with the Protocol, including, but not limited to, the requirements relating to approval of the IRB / IEC (as laid out in Clause (B) of **Table 1** of **Third Schedule** under the Rules) and the Licensing Authority under the Rules as also related to reporting / adverse event reporting in terms of the applicable laws.

3.1 Amendments. The Protocol may be modified only by a written amendment, approved by Pfizer, the CRO, the responsible IRB/IEC and the Central Licensing Authority (**"Amendment"**) except, as described in the Protocol, for emergency changes necessary to eliminate immediate hazards and/or protect the safety of the Study Subjects (as defined in Section 4, Subject Enrollment). The Amendment(s) of the Protocol, if any, to eliminate immediate hazards and protect the safety of the Study Subject shall be immediately notified to the responsible IRB/IEC, provided that any administrative and/or logistic changes in the Protocol shall be notified to the Licensing Authority within 30 days in accordance with applicable laws.

3.2 No Additional Research. No additional research may be conducted on Study Subjects (as defined in Section 4, Subject Enrollment) during the conduct of the Study or on biological samples collected during the conduct of the Study unless it is approved by Pfizer and documented as an Amendment to the Protocol in compliance with applicable laws.

4. Subject Enrollment. Principal Investigator has agreed to enroll qualified Study participants during the Pfizer-specified enrollment period, unless CRO, upon Pfizer's prior instructions, modifies the enrollment period by written notice. A qualified participant is one who meets all Protocol criteria for inclusion in the Study (**"Study Subject"**).