CLINICAL TRIAL AGREEMENT

PROTOCOL NO.: NIVO.22.001 (C2A02831)

This Clinical Trial Agreement (the **"Agreement"**) is entered into on the 21st day of February 2023 (the **"Effective Date"**) by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Cliantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad - 382 210 (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its assignees and successors-in-interest)

AND

DR. SANJIV KUMAR VERMA, whose principal place of work is at Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand, 248016 (hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his/ her successors and permitted assigns)

AND

SWAMI RAMA HIMALAYAN UNIVERSITY (SRHU), 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, Dehradun, Uttarakhand, India-248016 for its teaching hospital i.e. "Himalayan Institute of Medical Sciences" (hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest).

CRO, Institution and Principal Investigator are referred to herein individually as a "Party" and collectively as "Parties".

WHEREAS, CRO has been contracted by Zydus Lifesciences Limited (Formerly known as a Cadila Healthcare Limited ("Sponsor"), having its principal business address, Zydus Corporate Park, Scheme No. 63, Khoraj (Gandhinagar), 536, Sarkhej - Gandhinagar Hwy, Near Vaishnodevi Circle, Ahmedabad, Gujarat 382481., to perform one or more of Sponsor study related duties and functions for the clinical trial entitled as "A Phase III, Prospective, Randomized, Multicenter, Comparative, Double blind, Parallel-group Study to Investigate the Efficacy, Safety, and Pharmacokinetics of ZRC-3276 Versus Opdivo® (Nivolumab) in Subjects with locally advanced or Metastatic Non-Small Cell Lung Cancer." ("Study") according to Protocol Number "NIVO.22.001" "C2A02831", ("Protocol") including any subsequent duly authorized amendments and which is hereby incorporated by reference; and

WHEREAS, the Study is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

Swami Rama Himalayan University Director Research

Dr. Sanjiv Kumar Verma, Swami Rama Himalayan University, Dehradun, Uttarakhand

WHEREAS the Institution represents that it has the qualified personnel and facilities equipped according to Good Clinical Practices (GCP) to undertake the Study;

WHEREAS Principal Investigator represents that he/she is appropriately qualified and experienced and has the authority and willingness to conduct the Study at the Institution;

Now, therefore, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. **THE STUDY AND THE PROTOCOL**

A. The Study of Nivolumab (the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. NIVO.22.001 and entitled "A Phase III, Prospective, Randomized, Multicenter, Comparative, Double blind, Parallel-group Study to Investigate the Efficacy, Safety, and Pharmacokinetics of ZRC-3276 Versus Opdivo® (Nivolumab) in Subjects with locally advanced or Metastatic Non-Small Cell Lung Cancer" (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of Sponsor by the CRO.

B. The Principal Investigator represents and warrants that he/she is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of his/ her curriculum vitae and other relevant documents as and when requested by the Sponsor, the Ethics Committee, CRO and the regulatory authorities. Principal Investigator clearly understands that time is of the essence of this Agreement and will ensure that other resource demands of the Study will be fulfilled throughout the duration of the Study. The Principal Investigator should also ensure that he/ she does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

C. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study.

D. Conditions Precedent. The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the reference-listed product with full prescribing information and other information sources

relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Institution under the supervision and direction of the Principal Investigator, who will conduct the Study according to the Protocol which may be amended from time to time in writing by the Sponsor.

E. Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an Ethics Committee / Institutional Review Board ("IRB") that complies with the requirements of Drug Controller General of India and GSR 227 (E) and applicable regulatory requirements. Principal Investigator will further ensure that the Study is subject to continued oversight by the IRB throughout its conduct. Sponsor shall not interfere in any IRB procedures. If IRB need any assistance from Sponsor, then Sponsor shall promptly give its assistance to IRB. If the Study is disapproved by the IRB, this Agreement will immediately terminate.

F. **No Additional Research.** No additional research may be conducted on Subjects during the conduct of the Study by Institution and/or Principal Investigator unless it is approved and documented as a sub-study Protocol or an amendment to the original Protocol, after approval by the responsible Ethics Committee or IRB and DCGI or any other applicable regulatory authorities. Such prohibited research activities include, but are not limited to, analyses of biological samples from Subjects for any non-therapeutic purpose.

2. **THE STUDY SCHEDULE**

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / Ethics Committee / IRB approvals.

B. **Enrollment.** Principal Investigator shall be responsible for enrolling eligible subjects for the Study. Principal Investigator shall use the best efforts to recruit the Subjects and ensure unbiased selection of suitable Subject in accordance with the terms of Protocol. Principal Investigator will enroll Subjects (as per the randomization schedule provided) for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject shall require prior written consent of the Sponsor either directly or through the CRO. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Sponsor has informed the Principal Investigator and/or Institution to stop the enrollment;

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iv. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

Notwithstanding anything contained herein, Institution and Principal Investigator shall adhere to the strict principles of confidentiality under applicable laws and requirements and protect such personal data of Subjects including privacy laws as may be applicable thereon.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed within the time period, as mutually agreed by & between the Parties hereto, **three (3) days** from each Subject's visit. If any tests are to be performed after the Subject's visit, CRF shall be completed maximum within **three (3) days** from receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Institution, CRF for such Subject must be completed within **three (3) days** from such Subject's last visit to the Institution. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed/emailed to Sponsor and CRO within **twenty four (24) hours** of i) such event's occurrence; or ii) such event's occurrence was noted; or iii) such event's occurrence was recognized, whichever event occurs earlier. Principal Investigator and Institution shall ensure that the Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared, processed, stored and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit.

3. PAYMENT

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Payee (defined below) all direct and indirect costs incurred by the Payee in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque/electronic transfer to the Payee as per the details mentioned under Exhibit A, attached hereto. Payment shall be made within forty five (45) days after CRO has received invoice from the Payee.

For the purpose of this Agreement, "Payee" shall mean the person/ entity, details whereof, are more specifically mentioned under Exhibit A of this Agreement.

The Parties agree as follows:

- In case of changes in the Payee's address, the Institution shall inform the same to CRO in writing. However, in case of changes in address of Payee which do not involve a change of Payee or Payee's registrations numbers, no further amendments of this Agreement are required.
- The designated Payee is authorized to receive all of the payments for the services performed under this Agreement.
- If the Principal Investigator is not the Payee, then the Payee's obligation to reimburse the Principal Investigator, if any, is determined by a separate agreement between Principal Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by CRO to the Payee under this Agreement; and
- If the Principal Investigator is not the Payee, CRO shall not be obliged to pay him/ her even if the Payee fails to reimburse the Principal Investigator.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the Sponsor or by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any Subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a Subject's eligibility shall be addressed to and resolved by the Sponsor's clinical and/or medical monitor identified in the Protocol prior to entry of any such Subject into the Study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested and to the extent not already paid by CRO, CRO will, on behalf of the Sponsor, pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at the time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the Payee as per the details mentioned in Exhibit A of this Agreement.

Swami Rama Himalayan University Director Research