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Description of Document	:	Article 5(J) Agreement (in any other cases)
Property Description	:	CLINICAL STUDY AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ASTRAZENECA PHARMA INDIA LIMITED
Second Party	:	SWAMI RAMA HIMALAYAN UNIVERSITY AND DR ANKIT BATRA
Stamp Duty Paid By	:	ASTRAZENECA PHARMA INDIA LIMITED
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CLINICAL STUDY AGREEMENT

between

ASTRAZENECA PHARMA INDIA LIMITED

and

SWAMI RAMA HIMALAYAN UNIVERSITY (A UNIT OF HIMALAYAN INSTITUTE OF MEDICAL SCIENCES)

and

Dr. ANKIT BATRA

Dr. Ankit Batra (M.D.,D.M.)
Associate Professor
Dept. of Medical Oncology
HIMS, Dehradun

Swami Rama Himalayan University
Director Research

Swami Rama Himalayan University
Registrar

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3. In case of any discrepancy please inform the Competent Authority.

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ASTRAZENECA PHARMA INDIA LIMITED

and

SWAMI RAMA HIMALAYAN UNIVERSITY (A UNIT OF HIMALAYAN INSTITUTE OF MEDICAL SCIENCES)

and

Dr. ANKIT BATRA

Study Code:	D8535C00001
Study Name:	CAMBRIA 2 "A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a Next Generation, Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease"
Study Site number:	3508

Dr. Ankit Batra (M.D., D.M.)
Associate Professor
Dept. of Medical Oncology
HIMS, Dehradun

Swami Rama Himalayan University
Registrar

CLINICAL STUDY AGREEMENT

PARTIES

1. AstraZeneca Pharma India Ltd. , a company incorporated in India, whose registered office is at Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore – 560045, Karnataka, India (the "**Company**") and
2. 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- 248016 for its constituent college "Himalayan Institute of Medical Sciences (hereinafter referred as the (the "**Institution**"); and
3. Dr.Ankit Batra, Assistant Professor, Medical Oncology, Himalayan institute of medical sciences (a constituent college of SRHU), Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, 248016, Uttarakhand India (the "**Principal Investigator**")

together the "**Parties**" and each a "**Party**".

BACKGROUND

(a) The Company intends to conduct the Study at Himalayan Institute of Medical Sciences, which is a constituent medical college of Institution i.e. of Swami Rama Himalalyan University, Dehradun.

(b) The Institution has the appropriate facilities and personnel to conduct the Study. The Institution has designated the Principal Investigator to take responsibility for the day-to-day conduct of the Study, and the Principal Investigator has the necessary qualifications, training, experience and expertise to carry out such tasks.

(c) The Company wishes to engage the Institution and the Principal Investigator to conduct the Study on its behalf.

EFFECTIVE DATE

The effective date of this Agreement shall be the date on which the last of the Parties signs this Agreement.

AGREED TERMS

1. DEFINITIONS

Unless otherwise specifically provided in this Agreement, capitalised terms shall have the meanings set forth in Appendix A

2. CONDUCT OF THE STUDY

2.1. The Company hereby engages the Institution and the Principal Investigator to conduct the Study.

2.2. The Institution and the Principal Investigator shall conduct the Study at the Study Site in accordance with this Agreement, the Protocol, Study associated documents, ICH GCP Guidelines and all Applicable Laws.

2.3. The Institution and/or the Principal Investigator will not deviate from the Protocol unless in order to eliminate an immediate hazard to Participants. The Institution and/or Principal Investigator shall

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promptly notify the Company upon becoming aware of the deviation. The Company and/or Principal Investigator will notify the Ethics Committee of deviations in accordance with Applicable Laws.

3. RESPONSIBILITIES OF THE COMPANY

3.1. AstraZeneca AB, a company incorporated in Sweden whose registered office is at 151 85 Södertälje, Sweden , has assumed the role of sponsor of the Study, and has engaged the Company to conduct and manage the Study in accordance with this Agreement, the Protocol, Study associated documents, ICH GCP Guidelines and all Applicable Laws. AstraZeneca AB has also appointed Fortrea Development India Private Limited, a company registered in India with its registered offices at Building No. 1, Unit No. 601, Raheja Mindspace Plot Nos. Gen/2/1/D, Gen/2/1/E & Gen2/1/F at MIDC Trans Thane Creek Industrial Area within the village limits of Bonsari, Kukshet, Shiravane, Taluka and Registration Sub-District of Thane, Navi Mumbai, Maharashtra 400706, India to act as the Local Clinical Trial Applicant and provide legal representation of the sponsor for the study in addition to responsibility for all regulatory requirements.

4. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

4.1. The Principal Investigator shall be responsible for oversight and overall Study conduct including day-to-day conduct of the Study, training, leading and supervising Study Site Staff.

4.2. The Principal Investigator shall:

4.2.1 ensure that he/she is appropriately qualified by training and expertise, and obtain and maintain all contractual, regulatory and ethical approvals, notifications and authorisations required (including approvals from entities by which he/she is employed or to which he/she is affiliated), to enter into this Agreement and conduct the Study in accordance with Applicable Laws (and provide evidence of the same to the Company on request);

4.2.2 provide appropriately qualified Study Site Staff, and ensure that they are supervised and are made aware of, and comply with the terms of this Agreement, and, as appropriate, with all versions of the Protocol, Study associated documents, informed consent forms and Applicable Laws;

4.2.3 obtain and maintain all Ethics Committee approvals (if applicable) required for the conduct of the Study, keep the company informed of the progress of all applications for the same and provide company with copies of such approval(s) on request;

4.2.4 ensure that any amendments to the Protocol are approved by the Ethics Committee and/or the Regulatory Authority prior to implementation in accordance with Applicable Laws, and ensure to maintain all approvals from the relevant Regulatory Authority, if not instructed otherwise by Company;

4.2.5 once all necessary regulatory and ethical authorisations, notifications and approvals have been obtained, use his/her reasonable endeavours to enrol the target number of Participants into the Study. However, the Participant enrolment period may be extended or shortened and the number of Participants that Principal Investigator may enrol in the Study may be changed, at the Company's sole discretion;

4.2.6 ensure that informed consent is obtained from each Participant, and maintained, in accordance with the Protocol and Applicable Laws, such consent to include authorisation for the use and disclosure of the Participant's protected health information in accordance with Applicable Laws;

4.2.7 report to the Sponsor all Adverse Events and Other Safety Reportings in the form and within the time frame set out in the Protocol and in accordance with all Applicable Laws;

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4.2.8 provide such other assistance in connection with the Study as the Company may reasonably request from time to time;

4.2.9 ensure that each Participant: a) receives Participant engagement communications and ongoing/Post Study communications promptly upon obtain approval by the Ethics Committee and/or the Regulatory Authority, as applicable, prior to Study Closure; b) receives the post Study communications provided by the Company or its Designee no later than 12 months after Study Closure.

4.2.10 ensure that computerized system used at Study Sites fulfil GCP requirements. In the event that the electronic Medical Records (eMR) system is not appropriately validated, paper copies will be printed, dated and signed by the Principal Investigator;

4.2.11 report to the Sponsor all non-compliance with the Protocol and other applicable regulations and laws, e.g. Serious Breach, enabling the Sponsor to meet requirements for the expedited reporting when and where required.

4.3. Principal Investigator and/or Study Site Staff may be invited to attend and participate in meetings relating to the Study. The Parties agree that there will be no additional compensation for attendance or participation at such meetings by the Principal Investigator or any Study Site Staff. If the Principal Investigator and/or Study Site Staff are required to perform any additional tasks, over and above those required for the conduct of the Study, the terms and obligations for the provision of such services shall be subject to a separate agreement.

5. RESPONSIBILITIES OF THE INSTITUTION

5.1. The Institution shall:

5.1.1 provide appropriate premises, facilities and equipment for the Study, including the Study Site, and provide such assistance, resources and cooperation as the Company may reasonably request in connection with the Study;

5.1.2 provide, or ensure that the Principal Investigator provides, appropriately qualified Study Site Staff and ensure that they are made aware of, and comply with, the terms of this Agreement, all versions of the Protocol, and Applicable Laws;

5.1.3 notify the Company immediately if the Principal Investigator ceases to be employed by or associated with the Institution,or is otherwise unable to act or continue to act as the Principal Investigator.

6. STUDY DRUG AND MATERIALS

6.1. The Company shall use commercially reasonable efforts to supply (or procure the supply), at no cost to Institution or Principal Investigator, the quantities of Study Drug required to conduct the Study in accordance with the Protocol, Study associated documents and Applicable Laws.

6.2. The Institution and the Principal Investigator shall ensure that the Study Drug is stored, dispensed and administered under proper conditions and in accordance with the Protocol, the Applicable Laws and, where relevant, the Company's instructions.

6.3. The Institution and/or Principal Investigator shall promptly report to the Company any adverse findings in relation to any Study Drug delivered to it, and the Company shall take such steps as are reasonably practicable in the circumstances to provide replacement Study Drug or otherwise to minimise the impact on the Study. If the Company and/or any Regulatory Authority deem that a recall of Study Drug is required, the recall strategy shall be developed by the Company and followed by the Institution and the Principal Investigator with strict regard to the requirements in terms of timing and/or any other conditions imposed.

Swami Rama Himalayan University Director Research

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