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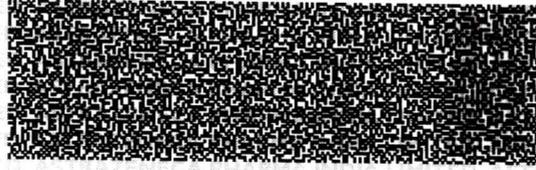
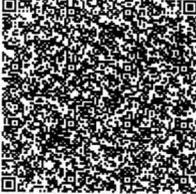
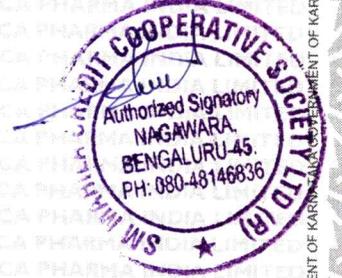
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Rs. 500

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Certificate Issued Date : 08-May-2024 07:19 PM  
Account Reference : NONACC (FI)/ kacrsf08/ NAGAWARA/ KA-GN  
Unique Doc. Reference : SUBIN-KAKACRSFL0858270755609581W  
Purchased by : ASTRAZENECA PHARMA INDIA LIMITED  
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  
Stamp Duty Amount(Rs.) : 500  
(Five Hundred only)

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Please write or type below this line

**CLINICAL STUDY AGREEMENT**

between

**ASTRAZENECA PHARMA INDIA LIMITED**

and

**SWAMI RAMA HIMALAYAN UNIVERSITY**

and

**Dr. ANKIT BATRA**

**Statutory Alert:**

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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**CLINICAL STUDY AGREEMENT**

**between**

**ASTRAZENECA PHARMA INDIA LIMITED**

**and**

**SWAMI RAMA HIMALAYAN UNIVERSITY**

**and**

**Dr. ANKIT BATRA**

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**STUDY NAME: A Phase III, Open-label, Randomised Study of Neoadjuvant DatopotamabDeruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)**

**STUDY CODE: D926QC00001**

**STUDY SITE NUMBER: 3505**

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## 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 (hereinafter referred to as the “**Company**”);
- (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 office at Swami Ram Nagar, Jolly Grant, Dehradun- 248016, Uttarakhand, INDIA (hereinafter referred to as the “**Institution**”); and
- (3) Dr. Ankit Batra, Assistant Professor, Medical Oncology, who is employed by Himalayan institute of medical sciences (a constituent college of SRHU), Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, 248016, Uttarakhand India, who is employed by Institution (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 Himalayan University, Dehradun.
- (b) The Institution has the appropriate facilities and personnel, and the Principal Investigator has the necessary qualifications, training, experience and expertise, to conduct the Study.
- (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 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 Subjects. The Institution and/or Principal Investigator shall 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**

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 and Applicable Laws, and has authorised it to enter into this Agreement.

Company shall not interfere in any Ethics Committee procedures. If Ethics Committee need any assistance from company, then company shall promptly give its assistance to Ethics Committee. Further, the company shall timely fulfil all its obligations undertaken in this agreement.

## **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, Informed Consent Forms and Applicable Laws;

- 4.2.3. obtain and maintain all Ethics Committee approvals 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 Subjects into the Study. However, the Subject enrolment period may be extended or shortened and the number of Subjects that Institution and 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 Subject, and maintained, in accordance with the Protocol and Applicable Laws, such consent to include authorisation for the use and disclosure of the Subject's protected health information in accordance with Applicable Laws;
- 4.2.7. report to the Sponsor all Adverse Events in the form and within the time frame set out in the Protocol and in accordance with all Applicable Laws;
- 4.2.8. ensure that surgical specimens, including primary tumours, lymph nodes and margins should first be locally assessed prior to sending them along with the local pathology report for central assessment of pathological response (please refer to the Pathology Manual). The surgical specimen should be mapped and sampled as outlined in the Pathology Manual. Local assessment should include the result of the pathology re-staging margin and lymph node assessment (plus cytology if applicable).
- 4.2.9. provide such other assistance in connection with the Study as the Company may reasonably request from time to time; and
- 4.2.10. ensure that each subject: a) receives patient engagement communications and ongoing study communications promptly upon receipt by the Company or its Designee prior to Study Closure; b) receives the post study communications provided by the Company or its Designee no later than 2 months after Study Closure.
- 4.2.11. ensure that computerized system used at 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 investigator.
- 4.2.12. 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 and
  - 5.1.4. ensure that the Principal Investigator shall 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.

## **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 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.

- 6.4 The Study Drug must be used only for the purposes outlined in the Protocol and, neither the Institution nor the Principal Investigator shall use, supply or otherwise make available any Study Drug for any other purposes, nor engage in any promotion or commercialisation of Study Drug for any unauthorised indication.
- 6.5 The Principal Investigator shall maintain complete and accurate records relating to the Study Drug consistent with the Protocol and as required by Applicable Laws. At the completion or termination of the Study or earlier termination of this Agreement all remaining Study Drug shall, at the Company's option, be returned to the Company (at Company's expense) or disposed of in accordance with Applicable Laws.
- 6.6 The Company will timely provide the Institution and the Principal Investigator with the Study Drug and Materials required for the conduct of the Study. The Company shall retain all rights, title and interest in and to the Materials unless otherwise agreed by the Company in writing. The Materials may only be used by the Institution, the Principal Investigator and the Study Site Staff to the extent required for the conduct of the Study.
- 6.7 The Institution and the Principal Investigator shall be responsible for keeping any Materials in good repair and in such condition as they were on the date of delivery (fair wear and tear excepted). The Materials shall be kept and operated in a suitable environment and used only for the purpose for which they are intended, by trained staff in accordance with any instructions provided by the Company.
- 6.8 At Study Site Closure or at Company's earlier request, Institution and Principal Investigator shall promptly return all Materials to the Company, unless the Parties agree that Institution or Principal Investigator shall acquire the Materials for their fair market value. Any such acquisition of Materials shall be subject to a separate agreement between the relevant parties.

## **7. STUDY DOCUMENTATION**

- 7.1 The Institution and the Principal Investigator shall compile and maintain all Study Documentation, the investigator study file (including but not limited to copies of CRFs, data queries and Adverse Event reports (if applicable)) and all other documents required under this Agreement, in accordance with this Agreement, the Protocol and Applicable Laws.
- 7.2 The Institution and the Principal Investigator shall make the Study Documentation available for the Company and the Regulatory Authorities in accordance with Applicable Laws. The Study Documentation shall be retained for a minimum of twenty-five (25) years, or longer in accordance with the Applicable Laws, after the Study closure unless the local regulations differ.

## **8. MONITORING AND AUDIT BY THE COMPANY**

- 8.1 The Institution and the Principal Investigator shall permit the Company or its Designee to access the Study Site during normal business hours and on reasonable notice in order for



the Company to monitor that the Study has been and is being conducted in accordance with the Protocol and Applicable Laws.

- 8.2 The Institution and the Principal Investigator agree to cooperate fully with the Company during monitoring and audits, including making all Study Documentation available for review by the Company or its Designee (subject to reasonable safeguards for the protection of personal data and medical confidentiality as set out in Clause 13).
- 8.3 The Institution and the Principal Investigator shall ensure that all questions and action items arising from monitoring and audit pursuant to this Clause 8 are resolved within such reasonable period as the Parties may agree.

## **9. INSPECTION BY THE REGULATORY AUTHORITIES**

- 9.1 A Party shall notify all other Parties as soon as reasonably possible (and in any event within two working days) following:
  - 9.1.1. receipt of any request from a Regulatory Authority for an inspection of the Study Site (or the conduct of any inspection if without notice); or
  - 9.1.2. receipt of any written or oral enquiries from a Regulatory Authority, regarding any aspect of the activities pursuant to this Agreement or the conduct of the Study, and shall provide copies of all associated correspondence with the Regulatory Authority.
- 9.2 To the extent reasonably practicable, the Institution and the Principal Investigator shall allow the Company or its Designee to attend any inspection by a Regulatory Authority. If the Company or its Designee are not allowed to attend any such inspection, the Institution and/or Principal Investigator shall provide the Company with a detailed summary of the Inspection as soon as reasonably practicable thereafter.
- 9.3 The Institution and Principal Investigator shall notify the Company of any violation or deficiency noted by a Regulatory Authority. The Parties shall cooperate with each other in relation to the preparation of any response.

## **10. PAYMENTS**

- 10.1 In consideration of the services rendered under this Agreement, the Company shall pay the Institution and/or the Principal Investigator in accordance with Appendix B.
- 10.2 Payment will not be made until the Company has received an invoice or such any other documentation as set out in Appendix B evidencing that the relevant services have been completed. The Company shall pay any invoices within sixty (60) days of the date of receipt by the Company, PROVIDED THAT if any amount included in the invoice is disputed, the Company shall not be required to pay the disputed amount until the dispute is resolved in accordance with this Agreement.
- 10.3 The Parties acknowledge that the amounts to be paid by the Company under this Agreement are reasonable, represent fair market value and are for services actually performed by the

Institution, the Principal Investigator and/or Study Site Staff for the work under this Agreement and that neither the Institution, the Principal Investigator nor the Study Site Staff have received any other compensation or inducement from the Company in connection with the Agreement or their participation in the Study.

- 10.4 The Company shall deduct or withhold from the amounts payable any taxes that it is required by Applicable Laws to deduct or withhold. All payments made by the Company under this Agreement are inclusive of value added taxes, sales taxes or similar taxes. The Institution will be responsible for all such taxes with respect payments under this Agreement.
- 10.5 The Institution and the Principal Investigator shall keep and maintain accurate and reasonably detailed financial records in connection with the activities performed under this Agreement. Upon request, the Company shall have the right to audit such financial records to test compliance with this Agreement.

## 11. INTELLECTUAL PROPERTY

- 11.1 Except as expressly set out in this Agreement, no Party shall acquire any right, title or interest in or to the Intellectual Property of any of the other Parties or their licensors.
- 11.2 The Company shall own all rights and title in any Intellectual Property arising from the Study or relating to the Study Drug, any Developed Technology and the Study Documentation, except to the extent that the Institution and Principal Investigator are required to retain any Study Documentation in accordance with GCP and the Applicable Laws. The Institution and the Principal Investigator shall promptly disclose any such Intellectual Property to the Company in writing or in such other format as the parties may agree.
- 11.3 To the extent capable of prospective assignment, the Institution and the Principal Investigator hereby assign to the Company (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 11.2 above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution and the Principal Investigator shall assign, and shall procure that the Study Site Staff shall assign, such Intellectual Property to the Company (or its Designee) on creation.
- 11.4 The Institution and the Principal Investigator shall, and shall ensure that the Study Site Staff take all steps as the Company may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 11.
- 11.5 The Company hereby grants to the Institution a perpetual, royalty-free non-exclusive licence to use the Intellectual Property arising only from the Study for internal research and educational purposes only, and with no right to grant sub-licences. The provisions of Clauses 12 and 14 of this Agreement shall continue to apply in relation to any such licence.

## 12. CONFIDENTIAL INFORMATION

- 12.1 Subject to Clauses 12.2 and 12.3, each Party shall at all times keep confidential the Confidential Information. Each Party shall safeguard the other Party's Confidential Information with at least the same level of care as it affords to its own Confidential Information, and shall not use any other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement. All Study Site Staff shall be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement.
- 12.2 The obligations on each Party set out in Clause 12.1 shall survive for ten (10) years after the expiry or termination of this Agreement, but shall not apply to any information which:
- 12.2.1. was in that Party's possession (with full right to disclose) prior to receiving it from another Party, as demonstrated by written records;
  - 12.2.2. is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or
  - 12.2.3. it can demonstrate was developed independently without reference to the Confidential Information, or was received from a third party who had the right to disclose such information in a non-confidential manner.
- 12.3 A Party may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the disclosing Party gives the affected Party as much notice of such disclosure as possible; and (ii) the disclosing Party complies with the affected Party's reasonable directions for taking legally available steps to resist or narrow such requirement (at the affected Party's reasonable expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.
- 12.4 The Parties acknowledge that damages alone would not be an adequate remedy for the breach of any of the terms of Clause 12, and that in the event of a breach or threatened breach the Party that initially disclosed the Confidential Information shall be entitled to seek equitable relief and/or injunctive relief concerning any threatened or actual breach (in addition to any other rights and remedies it may have under this Agreement or otherwise).

## 13. PERSONAL DATA AND BIOLOGICAL MATERIALS

- 13.1 The Parties agree to adhere to the principles of medical confidentiality in relation to Subjects involved in each Study and to comply at all times with their respective obligations under all data protection Applicable Laws in relation to this and the protection of the Personal Data of Subjects and Study Site Staff, where both the Company and the Institution shall act as Data Controllers with regard to the processing and protection of this Personal Data each of them undertakes



- 13.2 Both the Company and the Institution shall maintain appropriate technical and organisational security measures to protect the Subjects' and the Study Site Staff's Personal Data they process in relation to this Agreement.
- 13.3 The Institution shall appoint a person that shall act as a primary point of contact and shall respond to all Data Subjects' rights exercised by the Subjects and/or the Study Site Staff in respect to the processing of their Personal Data in relation to this Agreement ('**Data Subject's Request**'). The Institution shall inform the Company and request its assistance in responding to a Data Subject's Request only to the extent the Institution is unable to manage and respond to the Data Subject's Request without information which could only be provided by the Company. To the extent, the Company needs to provide information to the Institution, the Institution shall inform the Company within 3 days upon receiving the Data Subject's Request. Under such circumstances, the Company shall cooperate with the Institution and shall provide the Institution is with, subject to Applicable Law, the requested information and undertake any reasonable actions to enable the Institution to respond to the Data Subject's Request. The Institution shall, upon the reasonable request by Company, provide Company with any information, undertake any actions or provide assistance to the Company as may be required by the Company to respond to a Data Subject's Request
- 13.4 If a Personal Data Breach occurs in relation to any Subjects' or Study Site Staff's Personal Data processed in relation to this Agreement and it is likely that such breach poses a risk to an individual's rights and freedoms (a "**Reportable Breach**"), the Institution must notify the relevant supervisory authority without undue delay and at the latest within 72 hours after having become aware of such breach. If such Reportable Breach poses a high risk to the affected individuals, then the Institution shall also inform them, unless the Institution has put in place effective technical and organisational protection measures that ensure that the risk is no longer likely to materialise. The Institution shall notify the Company of any Reportable Breach no later than 24 hours after having become aware of such Reportable Breach.
- 13.5 The Parties shall indemnify, defend, and hold each other harmless from and against any and all liabilities, claims, losses, suits, judgments, and reasonable legal fees arising from any breach, negligent act, error or omission of relevant data protection obligations under this Agreement or each Schedule by the other Party, its staff or Subcontractors
- 13.6 The Parties agree to comply with all Applicable Laws in relation to the protection of the personal data of Subjects, the Principal Investigator and Study Site Staff. The Institution and the Principal Investigator shall maintain appropriate technical and organisational security measures to protect the confidentiality and security of Subjects' personal data.
- 13.7 The Institution and Principal Investigator shall ensure that any collection, handling, transportation and retention of Biological Materials in connection with the Study is carried out in accordance with the Protocol, the informed consents of Subjects, and all Applicable Laws and in such a way as to ensure that the security, integrity, quality and identity of the Biological Materials is maintained at all times.
- 13.8 Company will require that any party to whom company discloses Health Information ("Recipient") agrees, to use and disclose the Health Information only as permitted in the Informed Consent form and Authorization documents (collectively, the "Authorization Documents") and in accordance with all applicable laws and regulations. The



Authorization Documents will not authorize the company or any Recipient to use Health Information to recruit research subjects to additional studies, to advertise additional studies or products or to perform marketing or marketing research.

#### **14. RIGHTS TO PUBLICATION 8010480821**

- 14.1 The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study, as indicated in this Section 14. If this Study is part of a multi-centre clinical trial, Institution and Investigator agree not to independently publish the results of the Study until first occurrence of one of the following: (i) multi-centre primary Publication is published; (ii) no multi-centre primary publication is submitted within two years after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-centre primary Publication. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors (ICMJE) guidelines, (ii) not be false or misleading, (iii) comply with all Applicable Laws, (iv) not be made for any commercial purpose.
- 14.2 The Institution and/or the Principal Investigator shall provide the Company with copies of any materials relating to the Study, or the Developed Technologies that either intends to publish (or submit for publication) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.
- 14.3 At the request of the Company, the Institution and/or the Principal Investigator:
- 14.3.1. shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and
- 14.3.2. shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Company receives the material to allow the Company to take such measures as the Company considers necessary to preserve its proprietary rights and/or protect its Confidential Information.
- 14.4 The Institution and the Principal Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or the Developed Technologies, as well as in any financial disclosure information relating to the Study: AstraZeneca Pharma India Ltd sponsored this clinical trial.” A copy of any publications and presentations relating to the Study, the Study Documentation and/or the Developed Technologies shall be provided to the Company on publication or presentation, and the Company shall be entitled to make copies of and distribute the publication or presentation as it considers necessary.
- 14.5 Subject to Clause 14.4, no Party shall mention or otherwise use the name, trade mark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party; provided, however, that the Company shall have the right to identify the Institution, the Principal Investigator and the responsible Study Site Staff in any Study recruitment activities or other Study-related meetings.

- 14.6 The Company has a long-standing commitment to transparency, and the Institution and the Principal Investigator acknowledge that the Sponsor shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format (including [www.astrazenecaclinicaltrials.com](http://www.astrazenecaclinicaltrials.com)), and/or provide such results to the Regulatory Authorities and in accordance with Applicable Law.
- 14.7 If the Company invites the Principal Investigator to be an author of a Company-managed publication, the Principal Investigator shall agree to comply with ICMJE authorship criteria. The Principal Investigator shall direct, draft and/or review the proposed publication, approve the final version of the publication to be published and retain full responsibility for its content. Company financial support for this research, any other financial relationship with Company, as well as any other relevant financial relationships as required by the journal or congress shall be disclosed in the publication. Any authorship, medical writing, editorial or logistical support provided to the Principal Investigator or the Institution by the Company in respect of publication shall be subject to the Company's publications policy, details of which are available at [www.astrazeneca.com](http://www.astrazeneca.com). No compensation shall be provided in respect of any such authorship.

## 15. INSURANCE AND INDEMNITY

- 15.1 Each of the Parties shall ensure that adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws, in particular towards Subjects for personal injury arising as a result of participation in the Study.
- 15.2 The Company agrees to indemnify the Institution and the Principal Investigator against all direct costs, claims, liabilities, penalties or expenses (including reasonable legal fees and disbursements), (collectively "**Losses**") arising out of or relating to the conduct of the Study.
- 15.3 The Company's indemnity under Clause 15.2 will not apply to the extent that such Losses arise from or relate to (a) any breach of this Agreement or Applicable Laws by the Institution and the Principal Investigator, or (b) any negligence, recklessness or willful act or omission by the Institution, the Principal Investigator or the Study Site Staff in the performance of their obligations under this Agreement.
- 15.4 If any third party makes a claim, or notifies an intention to make a claim, against the Institution or the Principal Investigator which may reasonably be considered likely to give rise to a liability under this indemnity (a "**Claim**"), the Institution and/or the Principal Investigator shall:
- 15.4.1. as soon as reasonably practicable, give written notice of the Claim to the Company, specifying the nature of the Claim in reasonable detail;
- 15.4.2. not make any admission of liability, agreement or compromise in relation to the Claim without the prior written consent of the Company, such consent not to be unreasonably withheld; and

15.4.3. take such action as the Company may reasonably request to avoid, dispute, compromise or defend the Claim (including granting the Company full conduct and control of the claim).

15.5 Subject Injury. Company agrees that the Subjects or the subject's nominee(s) shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Company in case of Subject injury or death, during the conduct of Study, as a direct result of the clinical study in accordance with laws in force, including New Drugs and Clinical Trials Rules, 2019 & its amendments as may be amended from time to time.

## **16. COMPLIANCE, TRANSPARENCY, ANTI-BRIBERY, ANTI-CORRUPTION AND CONFLICTS OF INTEREST**

16.1 The Parties will ensure that neither they, nor any of their officers or employees, directly or indirectly offer, make, accept or request any Payments or Transfers of Value to or from any official or other person, that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation, including but not limited to inducements, bribes, kickbacks and facilitation payments.

16.2 The Institution and the Principal Investigator warrant that neither they nor any of their Study Site Staff have engaged in any conduct that has resulted or may result in a criminal conviction, nor are currently excluded, debarred, suspended, or otherwise ineligible to participate in the Study and/or government health care programs in any country. The Institution and the Principal Investigator agree to notify the Company immediately in the event they become aware that they or any of their Study Site Staff are being investigated by any Regulatory Authority.

16.3 The Institution and the Principal Investigator acknowledge and agree (and shall be responsible for obtaining consent from the Study Site Staff) that the Company and/or its Affiliates may store, use and publicly disclose information (including personal data) about the Institution, the Principal Investigator and the Study Site Staff and certain Payments or Transfers of Value provided to them in relation to the Study as required by Applicable Laws. Certain Payments or Transfers of Value may also be disclosed on public websites.

16.4 The Institution and the Principal Investigator declare that neither the Principal Investigator, nor any member of the Study Site Staff, is subject to any conflicting obligations or legal impediments and/or has any financial, contractual or other interests in the outcome of the Study that might interfere with the performance of the Study or that is likely to affect the reliability and robustness of the data generated in the Study. The Principal Investigator shall inform the Company immediately upon learning of the existence of any financial arrangement or interest between the Principal Investigator and the Company.

16.5 If during the term of this Agreement or within 2 years of its termination the Principal Investigator (i) joins or participates in any committee that sets formularies or develops clinical guidelines, or (ii) is involved in any decision or recommendation relating to the adoption of any products of the Company or its Affiliates for clinical use in any local or

national health care service, the Principal Investigator will disclose to such committee the existence and nature of this Agreement and will follow the disclosure obligations and procedures set forth by the committee.

## 17. TERM AND TERMINATION

- 17.1 This Agreement will remain in effect until (a) termination or completion of the Study, close-out of the Study Site, receipt of all Study Documentation by the Company, and completion of the obligations of the Parties under the Protocol, or (b) earlier termination in accordance with this Agreement.
- 17.2 Any Party may terminate this Agreement with immediate effect at any time upon written notice to all other Parties if:
- 17.2.1. on reasonable grounds it believes the Study should cease in the interest of the health, safety or well-being of Subjects;
  - 17.2.2. any Party or any of their employees, agents, or sub-contractors commits any of the acts referred to in Clause 16.1 or any offence under the applicable transparency or anti-corruption laws in relation to this Agreement or the Study, or any breach of the warranty given in Clause 16.2;
  - 17.2.3. any other Party commits a material breach of any of its obligations under the Agreement and fails to remedy such breach (where possible) within thirty (30) days of written notice from a non-defaulting Party; or
  - 17.2.4. any step, application, order, proceeding or appointment is taken or made by or with respect to any other Party for distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, if that Party is unable to pay its debts or if any event occurs which, under the applicable law of any jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Clause 17.2.4.
- 17.3 The Company may terminate or suspend the Study and/or terminate this Agreement immediately for any reason whatsoever upon written notice to Institution and Principal Investigator.
- 17.4 The Company shall have no liability to the Institution or the Principal Investigator for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination. For the avoidance of doubt, (except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution or Principal Investigator) the Company shall, upon receipt of invoices and other supporting documentation, pay to the Institution and/or Principal Investigator all costs incurred and falling due for payment up to the date of termination and all non-cancellable costs committed before receipt of notice of termination, provided that such commitments are reasonable and necessarily incurred by the Institution or Principal Investigator for the performance of the Study prior to the date of termination and agreed with the Company.

17.5 Upon notice of termination of this Agreement:

17.5.1. the Parties shall take all reasonable steps to minimise any inconvenience or harm to the Subjects; and

17.5.2. the Institution and the Principal Investigator shall:

17.5.2.1 immediately -cease enrolment of Subjects into the Study; and

17.5.2.2 promptly provide to the Company all Study Documentation (except where required to be retained pursuant to Applicable Laws), the Company's Confidential Information and any Materials provided by the Company in connection with the Study.

17.6 The following Clauses shall survive the termination or expiry of this Agreement to the extent necessary to preserve such rights and obligations: Clause 4.2.10(Study Communication); Clause 6 (Study Drug and Materials); Clause 7 (Study Documentation); Clause 8 (Monitoring and Audit by Company); Clause 9 (Inspection by the Regulatory Authorities); Clause 10 (Payments), in respect of any rights to payment arising prior to termination; Clause 11 (Intellectual Property); Clause 12 (Confidential Information); Clause 13 (Personal Data and Biological Samples); Clause 14 (Rights to Publication); Clause 15 (Insurance and Indemnity); Clause 16 (Compliance, Transparency, Anti-Bribery, Anti-corruption and Conflicts of Interest); Clause 17.3 (Term and Termination); and Clause 18 (General).

## 18. GENERAL

### 18.1 Representation & warranties

- a) Each Party represents to the other that it has the necessary right and authority to enter into this Agreement and to the best of its knowledge, it is not party to any agreement which would prevent it from fulfilling its obligations under this Agreement.
- b) Company has at all times complied with and will continue to comply with all the rules, regulations, requirements and guidelines regarding administration, manufacture, and production of drugs under regulatory control of the applicable governmental agencies in connection with any Study Drug administered or used pursuant to the Protocol; and
- c) Company warrants to Institution that it shall have and maintain appropriate/applicable licences, approvals, permits, certifications and the like necessary to lawfully perform its obligations under this Agreement. In particular, the company shall comply with all reporting rules, as per the applicable regulatory agency, that require it to inform Institution and/or Principal Investigator of any serious and adverse experience associated with the Study Drug or device.

18.2 **Force Majeure** - No Party shall be liable to any other for any delay or non-performance of its obligations under this Agreement arising from any Force Majeure Event. In the event of a Party being so delayed or prevented from performing its obligations, such Party shall: (i) give notice in writing of such delay or prevention to the other Parties as soon as reasonably

possible, stating the commencement date and extent of such delay or prevention, the cause of such delay or prevention and its estimated duration; (ii) use commercially reasonable efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement; and (iii) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

- 18.3 **Assignment, Subcontracting** - The Principal Investigator and the Institution may not assign, delegate, subcontract, sublicense or otherwise transfer any or all of their rights and obligations under this Agreement without the prior written consent of the other Parties. Company shall be entitled to assign, delegate, sublicense or otherwise transfer its rights and obligations under this Agreement to any Affiliate, any external service providers such as contract research organisations retained to assist the Company in managing and monitoring the Study, and to any successor in interest to all or substantially all of the business to which this Agreement relates. The Company shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates. Any assignment in violation of this Agreement shall be null and void.
- 18.4 **No Partnership** - Nothing in this Agreement shall create, or be deemed to create a partnership, joint venture, employer/employee, contractor/contractee, or other relationship between the Parties other than the contractual relationship expressly provided for in this Agreement.
- 18.5 **Waiver** - No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that (or any other) right or remedy, nor shall it preclude or restrict its further exercise. In addition, no single or partial exercise of any such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.
- 18.6 **Construction** - The Parties acknowledge and agree that they have reviewed, negotiated and jointly drafted this Agreement and that it should be construed without regard to the Party or Parties responsible for its preparation.
- 18.7 **Invalidity** - If any provision of this Agreement is held by any court or other competent authority to be illegal, invalid or unenforceable in whole or in part, this Agreement shall continue to be valid as to its other provisions, and if possible the affected provision should be modified to the minimum extent necessary to make it valid, legal and enforceable.
- 18.8 **Inconsistency** - In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.
- 18.9 **Notices** - Any notice to be given by any Party under or in connection with this Agreement must be in writing and shall be: (a) delivered by hand or by courier; (b) sent by pre-paid recorded (i.e. signed for) post; or (c) sent by fax, to the addresses set out at the start of this Agreement or such addresses or numbers as may be notified to the other Parties from time to time. Notices sent in accordance with this Clause are to be deemed to have been received (i) if delivered by hand or by courier, when left at the address referred to above; (ii) if sent by post, three business days after posting; (iii) if sent by fax, when transmitted.



- 18.10 **Entire agreement** - This Agreement together with the Appendices (all of which are incorporated by reference) constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior agreements, whether written or oral, with respect to that subject matter.
- 18.11 **Amendments** - Any amendment or modification to this Agreement must be in writing and signed by authorised representatives of each Party.
- 18.12 **Counterparts** - This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same agreement.
- 18.13 **Governing law** - This Agreement and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of India without regard to the conflicts of law principles thereof. The Parties irrevocably agree that the courts of Dehradun, Uttarakhand shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter (including non-contractual disputes or claims).

**AGREED** by the Parties on the dates indicated below.

SIGNED for and on behalf of  
**AstraZeneca Pharma India Ltd.**

SIGNED for and on behalf of  
**Swami Rama Himalayan University,  
Swami Ram Nagar, Jolly Grant,  
Dehradun, Uttarakhand**

  
-----  
Signature

-----  
Signature

Name: Mr. Sandeep AV  
Title: Senior Director, Oncology Country  
Head, Oncology Site Management &  
Monitoring India  
Date: 09 May 2024

Name:  
Title:  
Date:

SIGNED by  
**Principal Investigator**

-----  
Signature  
Name: Dr. Ankit Batra  
Title: Assistant Professor, Medical  
Oncology  
Date:

## **APPENDIX A - DEFINITIONS**

**“Adverse Event”** shall have the meaning set out in the Protocol.

**“Affiliate”** means any business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party, with “control” meaning in the case of a company, direct or indirect ownership of 50% or more of the voting interest in such company, and in the case of a partnership the right to a share of more than half the assets, or of more than half the income of the partnership.

**“Applicable Laws”** means all applicable international, national, regional and local laws, rules, regulations and guidance including without limitation Regulatory Authority rules and regulations, decisions and industry codes (including any modification or re-enactment thereto) applicable to the Study and the activities or interactions under this Agreement, including Good Clinical Practice, and all generally accepted standards of good laboratory practice, good clinical practice and good medical practice.

**“Biological Materials”** means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells.

**“Confidential Information”** means (i) the terms of this Agreement; and (ii) any business, employee, patient or customer information or data in any form which is disclosed or otherwise comes into possession of a Party, directly or indirectly, as a result of this Agreement and which is of a confidential or proprietary nature (including, without limitation, the Study Documentation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications

systems, costs and prices, wage rates, records, finances and personnel).

**“Case Report Form”** or **“CRF”** means a printed document (“pCRF”), optical or electronic document (“eCRF”) or database designed to record all of the information to be reported to the Company on each Subject, as required by the Protocol.

**“Designee”** means any person designated by the Company in writing who undertakes activities on behalf of the Company in relation to the Study, which may include an Affiliate.

**“Developed Technology”** means any inventions, discoveries, improvements or developments made by the Institution, the Principal Investigator or any Study Site Staff (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to the Study Drug, or the use thereof.

**“Ethics Committee”** means the independent institutional, regional, national or supranational committee or review board responsible for ensuring the protection of rights, safety and well-being of human subjects in a clinical study, and for reviewing and approving/providing an opinion on the Protocol, the suitability of the investigator(s), the Study Site(s), the Subject recruitment materials and methods, and informed consent forms.

**“Force Majeure Event”** means any circumstance beyond a Party’s reasonable control, including acts of war or other action of military forces, terrorism, riot, civil commotion, sabotage, vandalism, accident, fire, flood, acts of God, strike, lock-out or other industrial disputes (whether or not involving employees of the relevant party) or legislative or administrative interference and which could not have been avoided or mitigated by the exercise of reasonable care by that Party.

“**Good Clinical Practice**” or “**GCP**” means the International Conference on Harmonisation Guideline for good clinical practice (including any modification or re-enactment thereto).

“**Intellectual Property**” means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

“**Materials**” means any equipment, materials (excluding Study Drug), documents, data, software and information supplied by or on behalf of, or purchased at the expense of, the Company, in connection with the Study, as described and set out in the Protocol and this Agreement.

“**Payment or Transfer of Value**” means a direct or indirect transfer of *anything* of value, whether cash or in kind in connection with the development or sale of medical products. “**Value**” shall mean the discernible economic value on the open market. A direct Payment or Transfer of Value is one made directly by a company for the benefit of a recipient. An indirect Payment or Transfer of Value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

“**Personal Data**” means any information relating to an identified or identifiable natural person (‘Data Subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical,

physiological, genetic, mental, economic, cultural or social identity of that natural person.

“**Protocol**” means the clinical study protocol that has been approved by the relevant Ethics Committee, which describes the Study, including all amendments thereto as the Parties may from time to time agree in writing.

“**Regulatory Authority**” means any international, national, regional or local agency, authority, department, inspectorate, minister, ministry official, parliament, public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement, the Study, or the Parties.

“**Serious breach**” means any deviation of the approved protocol version or the clinical trial regulation that is likely to affect the safety, rights of trial participants and/or data reliability and robustness to a significant degree in a clinical trial.

“**Site Closure**” means the date of receipt by the Principal Investigator of the site closure visit report from the Company.

“**Study Closure**” the date of publishing the Clinical Study Report as communicated by the Company.

“**Sponsor**” means the company, as identified in Clause 3, which takes responsibility for the initiation, management or conduct of the Study in accordance with Applicable Laws.

“**Study Documentation**” means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study and/or Study Drug, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

Study Code: D926QC00001  
Study Site Number: 3505

“**Study**” means the clinical study stated on the front page of this Agreement, as further described in the Protocol.

“**Study Drug**” means the investigational medicinal product(s), any placebo and any comparator drug(s) being studied or tested in the Study as set out in the Protocol.

“**Study Site(s)**” means the premises where Study related activities are conducted, as identified in the Protocol.

“**Study Site Staff**” means all those investigators, sub-investigators, employees, agents, students, sub-contractors and others who are engaged by the Institution and/or the Principal Investigator in the conduct of the Study, including any such persons at Study Site.

“**Subject**” means a person recruited to participate in the Study in accordance with the Protocol and Applicable Laws.



**APPENDIX B - PAYMENT**

The Company shall compensate the Institution for each Subject that completes the Study in accordance with the table below.

**Table 1:**

| Study period        | Activity              | Investigator Grant per subject |             | CRC* |
|---------------------|-----------------------|--------------------------------|-------------|------|
|                     |                       | Experimental Arm               | Control Arm |      |
| NeoAdjuvant setting | Screening             | 15000                          | 15000       | 1500 |
|                     | C1D1                  | 12000                          | 12000       | 1500 |
|                     | C1D18                 | NA                             | 10000       | 1500 |
|                     | C1D15                 | NA                             | 10000       | 1500 |
|                     | C2D1                  | 10000                          | 10000       | 1500 |
|                     | C2D8                  | NA                             | 7000        | 1500 |
|                     | C2D15                 | NA                             | 7000        | 1500 |
|                     | C3D1                  | 10000                          | 10000       | 1500 |
|                     | C3D8                  | NA                             | 7000        | 1500 |
|                     | C3D15                 | NA                             | 7000        | 1500 |
|                     | C4D1                  | 10000                          | 10000       | 1500 |
|                     | C4D8                  | NA                             | 7000        | 1500 |
|                     | C4D15                 | NA                             | 7000        | 1500 |
|                     | C5D1                  | 10000                          | 10000       | 1500 |
|                     | C6D1                  | 10000                          | 7000        | 1500 |
|                     | C7D1                  | 10000                          | 7000        | 1500 |
|                     | C8D1                  | 8000                           | 8000        | 1500 |
|                     | Pre surgery Safety FU | 8000                           | 8000        | 1500 |
|                     | Definitive Surgery    | 6000                           | 6000        | 1500 |
|                     | Adjuvant setting      | Pre-C1 Safety Follow-up        | 7000        | 7000 |
| C1D1                |                       | 11000                          | 11000       | 1500 |
| C2D1                |                       | 10000                          | 10000       | 1500 |
| C3D1                |                       | 10000                          | 10000       | 1500 |
| C4D1                |                       | 10000                          | 10000       | 1500 |
| C5D1                |                       | 10000                          | 10000       | 1500 |
| C5D8                |                       | 7000                           | NA          | 1500 |
| C5D15               |                       | 7000                           | NA          | 1500 |
| C6D1                |                       | 10000                          | 10000       | 1500 |
| C6D8                |                       | 7000                           | NA          | 1500 |
| C6D15               |                       | 7000                           | NA          | 1500 |
| C7D1                |                       | 10000                          | 10000       | 1500 |
| C7D8                |                       | 7000                           | NA          | 1500 |
| C7D15               |                       | 7000                           | NA          | 1500 |
| C8D1                |                       | 10000                          | 10000       | 1500 |
| C8D8                |                       | 7000                           | NA          | 1500 |
| C8D15               |                       | 7000                           | NA          | 1500 |
| C9D1                |                       | 8000                           | 8000        | 1500 |
| EOT                 |                       | 10000                          | 10000       | 1500 |

Study Code: D926QC00001  
 Study Site Number: 3505

|   |             |        |        |       |
|---|-------------|--------|--------|-------|
| Safety Follow Up  | Safety FU   | 8000   | 8000   | 500   |
|   | Safety FU   | 8000   | 8000   | 500   |
|   | Safety FU   | 8000   | 8000   | 500   |
| Survival follow up                                      | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
|   | Survival-FU | 5000   | 5000   | 500   |
| Total compensation per subject who completes the Study: |             | 360000 | 360000 | 65000 |

**Table 2:**

| Procedure  | Screening | Intervention period [Cycles, Visits, Days] (Cycles are 21 days)   |       |       |         |                              |                    |   |                         |       |       |         |        | Post-intervention period |        |   |      | Total quantity               |    |
|--|-----------|---|-------|-------|---------|------------------------------|--------------------|---|-------------------------|-------|-------|---------|--------|--------------------------|--------|---|------|------------------------------|----|
|  |           | Neoadjuvant setting   |       |       |         |                              |                    | Adjuvant setting  |                         |       |       |         |        | EoT                      | Safety | Disease recurrence/Progression/Survival follow-up |      |                              |    |
|  |           | C1 D1   | C2 D1 | C3 D1 | C4-8 D1 | Pre-surgery safety follow-up | Definitive surgery | Pre-C1 safety follow-up   | C1 D1                   | C2 D1 | C3 D1 | C4-9 D1 |        |                          |        |   |      |                              |    |
| [Visit] (includes virtual visits)  | 1         | 2   | 3     | 4     | 05-09   | 10                           | 11                 | 12  | 13                      | 14    | 15    | 16-21   | 22     |                          |        |   |      |                              |    |
| Visit window (± days)  | -28 to -1 | ±3  | ±3    | ±3    | ±3      | 28 (-3, +7)                  | 25 days to 6 weeks | 30 ± 7  | ±3                      | ±3    | ±3    | ±3      | -3, +7 | 30 ± 3                   | 60 ± 7 | 90 ± 7  | ± 14 |                              |    |
| 12-lead ECG  | X         | As clinically indicated   |       |       |         |                              |                    | X   | As clinically indicated |       |       |         |        |                          | X      |   |      |                              | 3  |
| ECHO/MUGA (LVEF)   | X         | As clinically indicated   |       |       |         |                              |                    | As clinically indicated   |                         |       |       |         |        | X                        |        |   |      |                              | 2  |
| Pulse oximetry (SpO2)  | X         | X   | X     | X     | X       | X                            | X                  | X   | 50                      | 1200  | X     | X       | X      | X                        | X      |   |      |                              | 24 |
| Chest CT   | X         | As clinically indicated or if ILD/pneumonitis is suspected  |       |       |         |                              |                    | As clinically indicated or if ILD/pneumonitis is suspected  |                         |       |       |         |        |                          |        |   |      | 1                            |    |
| Pulmonary function tests   | X         | As clinically indicated or if ILD/pneumonitis is suspected  |       |       |         |                              |                    | As clinically indicated or if ILD/pneumonitis is suspected  |                         |       |       |         |        |                          |        |   |      | 1                            |    |
| Ophthalmologic assessments   | X         | C4 and C7 only: within 14 days prior to the scheduled D1 visit for participants randomised to Dato-DXd and as clinically indicated for all participants |       |       |         |                              |                    | X   |                         |       |       |         |        |                          |        |   |      |                              | 2  |
| OCP  |           | Daily before dosing, throughout treatment, and up to the pre-surgery safety follow-up visit   |       |       |         |                              |                    |   |                         |       |       |         |        |                          |        |   |      | 9                            |    |
| Highly sensitive serum OR urine pregnancy test (FOCBP only)                            | X         | X   | X     | X     | X       | X                            | X                  | X   | 1000                    | 2400  | X     | X       | X      | X                        | X      |   |      |                              | 24 |
| Menopausal status assessments (including FSH, LH, and oestradiol); menstruation status | X         |   |       |       |         |                              |                    | X   |                         |       |       |         |        |                          | X      |   |      | Annually during Years 1 to 3 | 7  |
| Hepatitis B and C and HIV screening  | X         |   |       |       |         |                              |                    |   |                         |       |       |         |        |                          |        |   |      | 1                            |    |
| Clinical safety laboratory assessments (clinical chemistry)                            | X         | X   | X     | X     | X       | X                            | X                  | X   | 9000                    | 21600 | X     | X       | X      | X                        | X      |   |      |                              | 24 |
| Thyroid profile  | X         | X   | X     | X     | X       | X                            | X                  | X   | 750                     | 1875  | X     | X       | X      | X                        | X      |   |      |                              | 25 |
| Haematology  | X         | X   | X     | X     | X       | X                            | X                  | X   | 1000                    | 2500  | X     | X       | X      | X                        | X      |   |      |                              | 25 |
| Coagulation  | X         | As clinically indicated   |       |       |         |                              |                    | As clinically indicated   |                         |       |       |         |        |                          |        |   |      | 2                            |    |
| Urinalysis   | X         | As clinically indicated   |       |       |         |                              |                    | As clinically indicated   |                         |       |       |         |        |                          |        |   |      | 1                            |    |
| pCR assessment (surgical specimens at definitive surgery)                              |           |   |       |       |         |                              |                    | X   |                         |       |       |         |        |                          |        |   |      |                              | 1  |
| Bilateral mammogram or MRI scan of remaining breast tissue                             | X         |   |       |       |         |                              |                    | Every 12 months (± 1 month) (52 weeks [± 4 weeks]), timed from last scan prior to randomisation until recurrence/progression ff |                         |       |       |         |        |                          |        |   |      | 6                            |    |
| Day care   |           |   |       |       |         |                              |                    | Neoadjuvant and adjuvant period   |                         |       |       |         |        |                          |        |   |      | 17                           |    |

- For participants who complete planned study intervention, post-intervention follow-up visits (pre-surgery safety follow-up and safety follow-up following completion of adjuvant therapy) will be timed from the date of last study intervention administration. The pre-surgery safety follow-up will be performed 28 (-3, + 7) days after the last neoadjuvant study intervention administration and must be performed prior to surgery. Surgery will occur 25 days to 6 weeks after conclusion of neoadjuvant treatment or following early discontinuation. The pre-C1 safety follow-up visit will be performed 30 ( $\pm$ 7) days after definitive surgery. The adjuvant treatment phase is expected to start at least 30 days after definitive surgery. If initiated less than 30 days after definitive surgery, sponsor consultation is required. If the adjuvant treatment phase starts less than 23 days (30 – 7 days) after definitive surgery, the pre-C1 safety follow-up visit may be skipped. Following completion of adjuvant therapy, the first safety follow-up visit will be performed 30 ( $\pm$ 3) days after the last study intervention administration. For participants who complete planned study intervention, the EoT visit can occur at the same time as this first safety follow-up visit. The final safety follow-up visit can take place at the same time as the first disease recurrence/progression/survival follow-up visit.
- For participants receiving adjuvant olaparib, safety assessments after completion of adjuvant durvalumab or pembrolizumab (ie, after C9) will include (at a minimum): AEs and concomitant medications. Clinical chemistry/haematology laboratory assessments and vital signs may be performed as clinically indicated.
- If screening assessments have been performed within 3 days prior to starting study intervention, they do not have to be repeated at C1 Day 1 if the participant's condition has not changed.
- On C1 Day 1, participants in the Dato-DXd in combination with durvalumab group will be monitored, and vital signs collected/recorded in the eCRF prior to and after each infusion of Dato-DXd and durvalumab. On C1 Day 1, vital signs will be collected from participants in the Dato-DXd in combination with durvalumab group prior to the beginning of each infusion (measured once from approximately 30 minutes before up to 0 minutes) and at the end of each infusion of Dato-DXd and durvalumab (approximately 90 [ $\pm$  10] minutes after the start of infusion with Dato-DXd and approximately 60 [ $\pm$  10] minutes after the start of infusion with durvalumab) (see Section **Error!** **Reference source not found.**). Therefore, for participants receiving both Dato-DXd and durvalumab, assessments should be conducted prior to infusion of Dato-DXd, at the end of Dato-DXd infusion/prior to durvalumab infusion, and at the end of durvalumab infusion. Participants receiving IMPs other than Dato-DXd and durvalumab should have vital signs performed prior to the start of each dosing visit, as clinically indicated, and according to local practice.
- For participants receiving Dato-DXd and/or durvalumab, assessment should be conducted prior to the start of the infusion with Dato-DXd and at the end of the infusion with Dato-DXd/prior to the start of infusion with durvalumab. Participants receiving IMPs other than Dato-DXd and durvalumab should have vital signs performed prior to the start of each dosing visit, as clinically indicated, and according to local practice.
- Ophthalmologic assessments including but not limited to visual acuity testing, slit lamp examination, intraocular pressure measurement, funduscopy, and fluorescein staining will be performed by an ophthalmologist, or if unavailable, another licensed eye care provider. Please refer to the Dato-DXd Site Ophthalmologic Assessment Manual for further details.
- Participants will be provided an OCP prior to and during neoadjuvant study treatment. Daily before dosing, throughout neoadjuvant treatment, and up to the pre-surgery safety follow-up visit.
- Subsequent anticancer drug treatment may commence following discontinuation of study intervention, including at disease progression/recurrence.

- A negative serum pregnancy test must be documented during screening for all FOCBP. If a serum pregnancy test is collected greater than 72 hours prior to randomisation, perform a repeat pregnancy test (urine or serum per institutional guideline) within 72 hours before randomisation. Perform repeat pregnancy tests (urine or serum per institutional guideline) within 72 hours before treatment at each cycle. A positive urine pregnancy test result must immediately be confirmed using a serum test.
- For post-menopausal participants, menopausal status will be assessed at screening only.
- Prior HIV serology (anti-HIV with or without HIV RNA, as appropriate), hepatitis B serology (HBsAg, anti-HBs, and anti-HBc with or without HBV DNA, as appropriate), and hepatitis C serology (anti-HCV antibody with or without HCV RNA, as appropriate) testing results can be used if performed within 120 days before enrolment. In this case, there is no need for a repeat test during the 28-day screening period. If an HIV infection meets the criteria outlined in Section **Error! Reference source not found.**, monitoring of viral RNA load and CD4+ cell count is recommended and should be performed per local SoC (eg, every 3 months). Participants must be tested for HIV if acceptable by local regulations or an IRB/EC.
- Serum or plasma clinical chemistry (including liver function test monitoring) and haematology may be performed more frequently if clinically indicated. If TSH is measured within 14 days prior to Day 1 (first infusion day), it does not need to be repeated on C1 Day 1. Free T3 or free T4 will only be measured if TSH is abnormal or if there is clinical suspicion of an AE related to the endocrine system.
- Clinical safety laboratory assessments (clinical chemistry and haematology) are required within 7 days prior to randomisation.
- Clinical laboratory assessment parameters are to be assessed at baseline on Day 1 (unless all screening laboratory assessments are performed within 3 days prior to Day 1), and as clinically indicated.
- During study participation for participants with any remaining intact breast tissue (including male participants). The preferred tests are mammogram or MRI (MRI preferred for participants below 50 years of age). For participants who underwent a bilateral mastectomy, with no remaining breast tissue, a physical examination is sufficient and radiological tests are not mandatory. For participants who underwent a bilateral mastectomy, as well as for male participants, clinical exam may be supplemented by ultrasound exams at investigator's discretion.
- Adjuvant chemotherapy options to be used at the discretion of the investigator are: doxorubicin/epirubicin + cyclophosphamide, followed by paclitaxel + carboplatin; doxorubicin/epirubicin + cyclophosphamide, followed by paclitaxel; and carboplatin + paclitaxel. Capecitabine treatment may be provided at the discretion of the investigator.

#### **Terms and Conditions:**

1. Only the tests and assessments that are performed as per approved protocol will be paid for as mentioned above upon receipt of original invoice/bills on pro-rata basis. Eg: biopsy charge will be reimbursed only if a patient doesn't have tumour block or slides in quantity needed for eligibility assessment.
2. Tests which are not required as per approved protocol during the treatment and follow-up period will be paid for only in case of study **related injuries** as per regulatory requirement.
3. Institution will not be reimbursed for any additional testing, procedure or treatment not required by the approved clinical study protocol or specified in the agreement unless such additional testing, procedure or treatment is required to manage the **trial related** AEs/SAEs or same are pre-approved by AstraZeneca in writing.

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4. Investigator Professional fees mentioned in all the tables in Appendix B covers activities as per schedule of the assessments for respective visits as per clinical study protocol.
5. Cost for tests and assessments performed for all screen failure patients as per approved protocol will be paid on pro-rata basis. Investigator's Professional fees for applicable visits would be paid as per Tables on pro-rata basis.
6. If the onsite visit is changed to a telephonic visit, an INR **3900 (including IOH)** fee will be paid for that visit. No study nurse and phlebotomist charge are applicable.
7. Day care charges mentioned in table are inclusive of admission charges, pre or post medication, disposables for infusion, and other professional fees or any other ancillary costs.
8. Per subject payment shall be made for eligible subjects only on the basis of number of protocols specified visits completed for the subject on pro-rata basis.
9. All the visits and procedure included in the invoice must be entered into the electronic case report form for the payment to be processed.
10. All payments under this agreement are exclusive of GST. GST will be paid as applicable based on the invoice received.

The Company shall be entitled to withhold compensation in respect of Subjects whose visit data is incomplete or 'lost to follow-up' as a result of any failure by the Institution or the Principal Investigator to comply with their obligations under this Agreement.

Reimbursement will not be given for Subjects enrolled who do not meet all inclusion and exclusion criteria, unless otherwise approved by the Company, and the Institution will not be compensated for any Protocol violations, unless otherwise approved by the Company.

The Company shall additionally compensate the Institution and the Principal Investigator for the activities set out in the table below.

**Table: 3**

| Activity  | Compensation  |
|---|---|
| Institutional Overhead  | 20% of the Investigator Grant as specified in table 1   |
| Pre-Initiation activities Fees (Infrastructure cost for Cupboards, AV Setup)              | INR 25,000/- (Non-refundable, to be paid only after the site is initiated)  |
| Ethics Committee Fee  | As per EC SOP inclusive of applicable taxes.  |
| Drugs for Standard of Care (Neoadjuvant and adjuvant chemotherapy)                        | As per bills submitted in original inclusive of applicable taxes.   |
| Involvement in audits or inspections  | No financial compensation will be made towards the involvement in audits and/or inspection during the study conduct and post study conduct.   |
| Fee for archival of study documents   | Institution will retain and store all study related documents till 25 years after site closure at AstraZeneca's expense.<br><br>AstraZeneca agrees to pay fee for such storage for 25 years amounting to a lump-sum of INR 120,000.<br><br>At least one (1) patient must have been randomized at this site. |
| Protocol defined Investigation and procedural charges                                     | Payment towards protocol-specific assessments (table 2) and investigations, including blood investigation and radiology assessment, would be paid based on the actual cost on submission of bills.  |
| Subject travelling reimbursement amount per site visit completed as per study requirement | INR 2000 per visit upon submission of Invoice. If the site fails to submit the original bill for reimbursement, AstraZeneca will deduct TDS unless the original bill or a tax exemption certificate is provided.  |
| Additional travel arrangements for subjects   | INR 2,000 per visit upon submission of receipt/invoice.<br><br>Any travel arrangement for study subjects (either by site or subject) resulting in additional cost (>INR 2000) has to be discussed with  |

|  |  |
|--|--|
|  | and approved in advance by AstraZeneca Representative for the study. The same shall also be notified to Ethics Committee   |
| AEs/SAEs related payments:   | <p>1. In the event of an injury occurring to the clinical trial subject, site will provide free medical management to him/her as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. AstraZeneca Pharma India Limited will reimburse this cost to site on actuals.</p> <p>2. In the event of clinical trial related injury or death, AstraZeneca will pay compensation to the clinical trial subject or his/her nominee in case the clinical trial subject suffers from a study related injury or death, per the directive of the health authority of India. AstraZeneca has taken out an insurance to cover the clinical study-related injuries or death. In order for AstraZeneca to obtain the proceeds from the insurance for the study related injury or death, Investigator and Institute should provide the medical records and/or signed informed consent form of the clinical trial subject if requested by the Insurance company.</p> |
| Reimbursement of Local Transport for Clinical Research Staff during the COVID19/ pandemic related lockdown           | Reimbursement of the cost of Local Transport for the Clinical Research Staff on actuals to conduct the study related activities per protocol during the patient's on-site visit. This clause is valid for the period COVID 19 related local travel restrictions are in place and public transport is not available. This clause will cease to exist once public transport is restored in your city/area. Sponsor approval must be taken prior to making such travel and all such invoices must be sent to AstraZeneca along with sponsor's approval email and supporting bills in original.  |
| Biopsy/ FNAC   | Breast/ Lymph node biopsy or LN cytology charges, if performed, in case subject is unable to provide archival biopsy tissue block, will be paid as per actual.   |
| Additional investigations  | If some additional test/s or procedures needs to be performed beyond protocol requirement the cost of such test should be pre-approved by sponsor prior to reimbursement   |
| Breast conservative Surgery (BCS) or Modified radical mastectomy (MRM) after neoadjuvant chemotherapy procedure cost | As per Hospital charges for all clinical trials patients BCS or Modified radical mastectomy (MRM) surgery cost is Rs. 70,000/- per procedure   |

Payments will be made against invoices issued by the Institution or the Principal Investigator (or receipt of such other documentation evidencing that the relevant activity has been completed) to the following accounts:

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|                        | <b>Institution</b><br><b>(Overhead Charges &amp; Study Investigations, study Coordinator fees, Subject travel Allowance, and other investigations, if any, per actual bills)</b> | <b>Principal Investigator</b><br><b>(Principal Investigator Fees)</b> |
|------------------------|--|---|
| Bank Name:             | State Bank of India  | State Bank Of India   |
| Sorting Code/IFS Code: | SBIN0010580  | SBIN001580  |
| Account No.:           | 33082676422  | 10022449071   |
| Account Name:          | Swami Rama Himalayan University  | Ankit Batra   |
| PAN:                   | AAAJH0463L   |   |
| Bank Address:          | HIHT, Jolly Grant P.O Doiwala , Dehradun<br>0135 2412967   | HIHT Jolly Grant,<br>Dehradun UK                                      |

All invoices should be clearly marked with the "D" code for the Study and the subject "Ecode" wherever applicable.

Invoices to be sent :

AstraZeneca Pharma India Ltd.  
Block N1, 12th Floor,  
Manyata Embassy Business Park,  
Rachenahalli, Outer Ring Road,  
Bangalore -560045,  
Karnataka, INDIA

**APPENDIXC- FACILITIES, RECORDS and RESOURCES**

**1. PLANNED SUBJECT ENROLMENT**

**Number of enrolled subjects:** 15

**Number of randomised subjects:** 10

**First Subject enrolled by:** First Subject to be enrolled within 90 days from Investigator's receipt of written approval by Sponsor

**Last Subject completed before:** 28 Feb 2031

**2. MATERIALS PROVIDED BY COMPANY**

**Equipment:**

- Equipment required for collection and shipment of blood and tumour samples will be provided by the Central Laboratory
- 1 handheld device for Patient Reporting Outcomes per subject can be provided by the ePRO vendor or patient can choose to use their own personal device. Provisioned devices to be returned to AstraZeneca or its designee at the end of the study
- Electronic Start Up Kit or hard copy Start Up Kit for central imaging (as applicable) provided by eImaging vendor

**Other materials:**

- Investigational Product Dato-DXd; Durvalumab
- *Pembrolizumab*
- Oral care kit
- Study Protocol and associated documents (Investigator Brochure, Informed Consent Forms, Patient Participation Card, Patient Guides, Laboratory Manual, etc.)

**Insurance / Indemnity:** NA as no material is provided by Company which requires insurance or Indemnity.

### 3. MATERIALS PROVIDED BY STUDY SITE

#### Equipment:

- 12-lead ECG machine;
- Appropriate drugs and medical equipment to treat acute anaphylactic reactions;
- Appropriate drugs and medical equipment for pre-medication prior to any dose of Dato-DXd;
- A computer with high speed internet connection; scanner and printer;
- Centrifuge (Refrigerated preferably) as specified in the Central Laboratory Manual;
- Local lab supplies for laboratory assessments and pregnancy testing such as dipsticks for urinalysis, tubes, (including materials for Hepatitis B and C serology tests, HIV antibody tests, COVID-19 real-time PCR testing, Hy's law test panel etc.);
- IP should be kept in a secure place under appropriate storage condition according to the IP labels;
- 2°C to 8°C (36°F to 46°F) refrigerator with valid calibration and electronic temperature monitoring system or at least daily monitoring of min/max temperature control for IP storage;
- -20°C [-4°F] Freezer and/or -70°C [-94°F] Freezer as specified in the Central Laboratory Manual with valid calibration. Both equipped with electronic temperature monitoring system; or at least daily monitoring of min/max temperature control for biological samples storage;
- IV bag containing 0.9% (w/v) saline or 5% (w/v) dextrose, syringes, needles and infusion lines for intravenous administration of IP. IV lines with 0.2 or 0.22 µm filter with light protection covers;
- Scales for weight and height measurements;
- Standard pulse and blood pressure measurement device;
- Thermometer;
- CT\MRI\bone scanner;
- MUGA Scan\ECHO;
- Spirometry equipment; Equipment for ophthalmology assessments: , visual acuity testing, slit lamp examination, intraocular

pressure measurement, fundoscopy, and fluorescein staining;

**Other materials:**

- Crash cart (incl. Adrenaline shot, antihistamines, medical equipment, etc.) near where IP is administered to subjects/study assessments performed, to manage acute anaphylactic reactions
- Defibrillator. The site must have access to emergency care for patients who experience an AE/SAE during treatment, including imaging, ICU beds, etc

#### **4. SOURCE DATA, RECORDS AND STORAGE**

##### **4.1. Web-based Data Capture ('WBDC') and Electronic Patient Reported Outcome ('ePRO') System**

Data for each Subject should be entered into the electronic Case Report Form within 5 business days of each completed visit. Data queries shall be responded to within 5 business days of being issued. Expedited turn-around-time of query resolution within 24 hours when coming closer to data cut-off or for safety query.

The investigator will review patient's study visit data recorded in eCRF, including all associated modules (e.g. Concomitant Medication, AEs) preferably directly after the data has been recorded, but no later than 60 days after the visits date. Investigator will record review in the eCRF, as per the CRF instructions.

##### **4.1.1 WBDC, ePRO and/or other system access controls**

Access to electronic systems used in the study will be strictly restricted to these (Study Site Staff, Company employees, Company data management centre staff, Subjects depending on the system) who have been appropriately trained. Each user will be allocated access to the system for their sole use only. Principal Investigator and/or his Study Site Staff understand that access codes/tokens and passwords are for personal use only and not to be shared with others, and that an electronic signature, when used, is the legally binding equivalent of a traditional handwritten signature.

##### **4.1.2 ePRO training of Subjects**

Principal Investigator and/or Study Site Staff are responsible for training Subjects in the use of the ePRO system. The training shall be documented on device

It is essential that Principal Investigator and Study Site Staff comply with the subject training, compliance checks and data review requirements

such as Subject training should be performed by following the step by step instructions provided by the ePRO vendor. Compliance checks should be performed approximately weekly by monitoring the web-based compliance reports. Site personnel must notify the vendor of any errors they made in the assignment or end of device use, by submitting a data correction form provided by the vendor. Subject entered data cannot be viewed or changed.

#### **4.1.3 Back-up procedures for system unavailability**

In case of issues with PRO app and/or devices, site should create Customer Care ticket to inform the ePRO vendor about non-working device.

In case of technical (or other) problems with WBDC (Rave) application, data should be entered in the medical records. The eCRF must be completed as soon as the system is available again.

If the Rave system is not available, the Investigator/study site personnel reports an SAE to the appropriate AstraZeneca representatives by sending Clinical Study Serious Adverse Event Report Form via e-mail or fax or phone immediately no later than 24 hours of becoming aware of it.

When the Clinical Study Serious Adverse Event Report Form is used, the completed form and only relevant supporting documentation are faxed/e-mailed to the AstraZeneca representative immediately or no later than within 24 hours. Please site is still responsible for personal data protection.

If the system is expected to be available within the reporting timeframes, the Clinical Study Serious Adverse Event Report Form found in the ISF must be used. This is a back-up procedure only, and the Investigator still enters the data into Rave as soon as the system becomes available.

In case the IWRS (Interactive Web Response System; IRT) is not available, Investigator is asked to create Customer Care ticket and contact the responsible monitor.

## **4.2. Records and Documents**

### **4.2.1 Medical Records**

The medical (hospital/practice) records for each Subject should contain information which is important for the Subject's safety and continued care and to fulfil the requirement that critical Study data should be verifiable. To achieve this, the medical records of each Subject should clearly describe at least:

- that the Subject is participating in the Study, eg, by including the enrolment and/or the randomisation code and the Study code or other Study identification
- the Subject's general practitioner/family doctor was informed of the Subject's Study participation/was not informed and why
- date when Informed Consent was obtained
- diseases (past and current; both the disease studied and others, as relevant)

- treatments withdrawn/withheld due to participation in the Study
- treatments given, including Investigational Product, changes in treatments during the Study, and the time points for the changes
- visits to the clinic during the Study, including those for Study purposes only
- Serious Adverse Events (if any) including causality assessments
- date of and reason for discontinuation; and
- additional information according to local regulations and practice.

Company will have the right to assess the validity of the electronic system used for medical records in order to ensure proper Source Data Verification ('SDV'). If the electronic systems are not assessed/validated as requested by ICH GCP, paper copies will be printed, dated and signed by the investigator.

#### **4.2.2 Case Report Form as source document**

The following variables may be directly recorded in the CRF and need not be present in Subject medical records (electronic/paper CRF = source document), provided that the data is recorded in the CRF at once:

- Ethnic group and race
- AstraZeneca aware of SAE
- Electronic signature of investigator

#### **4.2.3 Source Data Location**

Source Data Location will be recorded on 'Source Data Agreement' and Source Data should comply with ALCOAc requirements.

#### **4.2.4 Electronic Patient Reported Outcome Source Data**

The ePRO source data are recorded electronically in a central database hosted by the ePRO service provider and are available for review and maintenance during the Study. Principal Investigator maintains control of the data and must authorise all ePRO data changes.

### **4.3. Storage of Study Documents**

The Study Documentation shall be retained and stored during the Study and for 25 years after Study Closure in accordance with this Agreement unless the local regulations differ.

When a WBDC system is used for the Study, Company will provide Principal Investigator with copies of the Study Site's electronic Case Report Forms and associated data (End of Study data). Principal investigator is responsible for retaining the End of Study data in accordance with ICH Guidelines, local regulation and internal site process for archiving of electronic documents, periodically checking for

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viability and retrievability. As with other study documents, the data should be stored in a safe and secure location to prevent accidental or premature destruction. The data should be regarded as part of the Investigator's study file, but may be stored separately.

For the ePRO, the external service provider will supply the Principal Investigator with copies of the final locked data on an optical media e.g., Compact Disc ('CD') or digital versatile disc ('DVD'). These are to be stored in the Investigator's study file (ISF).

Digital Copies of all the medical imaging scans (baseline and follow up) collected within the study should be kept within the ISF until the site closure

#### **4.4. Emergency Unblinding Tools**

N/A because of open label study design.



Date: 09 May 2024

To:

**Dr. Ankit Batra**

Himalayan Institute of Medical Sciences

Swami Ram Nagar, Beside Jolly Grant Airport Jolly Grant,

Doiwala, Uttarakhand 248016

**Study Code:** D926QC00001

**Study Title:** A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

**Subject: Clinical Study Agreement for Signatures**

**Dear Dr. Ankit Batra**

Kindly find enclosed the Clinical Study Agreement – Tripartite (3 in number) for the above referenced study. I request you to have the signatory part signed by yourself (Principal Investigator) and by the Faculty in Charge on behalf of **Himalayan Institute of Medical Sciences, Uttarakhand**. Please note that the agreements have been signed and dated by the Senior Director – Oncology Site Management and Monitoring India.

Please send one original signed CSA to us, retain one original document in the ISF and provide one original document to the institute. Please notify a copy of the signed CSA to your Ethics committee at the earliest and share its acknowledgment with the monitor for our records.

If you have any questions or concerns, please do not hesitate to contact me or your site monitor.

Sincerely,



Bharat Bhushan

Senior Local Study Associate Director - Oncology Site Management & Monitoring India

AstraZeneca, Manyata Embassy Tech Park,

Rachenahalli, Outer Ring Road, Bangalore 560045.

E: - [Bharat.bhushan2@astrazeneca.com](mailto:Bharat.bhushan2@astrazeneca.com)

P- 9717211556

| PI Acknowledgement receipt |                     |
|----------------------------|---------------------|
| Name of the PI:            | Signature and Date: |
| <hr/>                      | <hr/>               |

# TB-04\_ CSA cover letter 3505

Final Audit Report

2024-05-09

|                 |  |
|-----------------|--|
| Created:        | 2024-05-09 (Greenwich Mean Time)             |
| By:             | Rhea Roy (rhea.roy@astrazeneca.com)          |
| Status:         | Signed                                       |
| Transaction ID: | CBJCHBCAABAAGxiqiFOZpp1ymx_LjPAQixXbjjIGceVa |

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-  Document created by Rhea Roy (rhea.roy@astrazeneca.com)  
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-  Document e-signed by Bharat Bhushan (bharat.bhushan2@astrazeneca.com)  
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