



सत्यमेव जयते

**GOVERNMENT OF INDIA**  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION (Headquarter)  
(Directorate General of Health Services)  
Ministry of Health & Family Welfare  
FDA Bhavan  
ITO, Kotla Road  
New Delhi - 110002 (Delhi)  
Phone No.: 91-11-23216367  
Fax No.: 91-11-23236973  
E-Mail : dci@nic.in

**File No. CT/24/000136**

To,

M/s. AstraZeneca Pharma India Limited,  
Block N1, 12th Floor Manyata Embassy,  
Business Park, Rachenahalli Outer Ring Road,  
Bangalore, Karnataka (India) – 560045.

Sir,

With reference to your application No. GCT/CT04/FF/2024/46426 dated 18-Nov-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase III, Open-label, Randomised Study of Osimertinib With or Without Datopotamab Deruxtecan (Dato-DXd), as First-line Treatment in Participants With Epidermal Growth Factor Receptor (EGFR) Mutation-positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer (TROPION-Lung14)” Protocol no. D516NC00001, Version 1.0 dated 04 Dec 2023 and Local CSP - Addendum IND1, version 1.0 dated 24 Oct 2024 with a total of up-to 30 subjects from India under the provisions of New Drugs and Clinical Trial Rules, 2019**

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

- (i) **Human biological samples i.e. Whole blood, plasma and tumor tissue block/slide related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
- (ii) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
- (iii) where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

- (iv) in case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking

- approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- (v) the Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
  - (vi) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
  - (vii) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
  - (viii) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
  - (ix) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;
  - (x) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
  - (xi) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
  - (xii) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
  - (xiii) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
  - (xiv) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
  - (xv) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
  - (xvi) the laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
  - (xvii) the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
  - (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
  - (xix) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will

automatically be granted to you;

(xx) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licencing Authority  
Stamp

**FORM CT-06**

(See rules 22,25,26,29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR  
INVESTIGATIONAL NEW DRUG**

1. The Central Licensing Authority hereby permits **M/s. AstraZeneca Pharma India Limited, Block N1, 12<sup>th</sup> Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore, Karnataka (India) - 560045** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. D516NC00001, Version 1.0 dated 04 Dec 2023 and Local CSP - Addendum IND1, version 1.0 dated 24 Oct 2024** in the below mentioned clinical trial sites [As per Annexure].
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date \_\_\_\_\_

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licencing Authority  
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**Note:** The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

**Annexure:**

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug</b>	Datopotamab Deruxtecan	
	Osimertinib	
<b>Therapeutic class:</b>	Anticancer	
	Anticancer	
<b>Dosage form:</b>	Powder concentrate for solution for infusion	
	Tablets	
<b>Composition:</b>	Datopotamab Deruxtecan(DS-1062a) =100.00 mg/vial In House Specification Active	
	Osimertinib=80.00milligram (mg) In House Specification Active	Osimertinib=40.00milligram (mg) In House Specification Active
<b>Indications:</b>	Participants with locally-advanced or metastatic EGFRm (Ex19del and/or L858R) NSCLC who have not received any prior anti-cancer therapy for advanced disease	

**Annexure:**

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Health Care Global Enterprises Limited, No 8, HCG Towers, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore, Karnataka 560027, India	HCG Central Ethics Committee HCG-Bangalore institute of Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India  ECR/386/Inst/KA/2013/RR-24	Dr. Satheesh C T
2.	CARE Hospitals, Hi-Tech City, Old Mumbai Highway, Jayabheri Pine Valley, Hyderabad, Telangana -500032,	CARE Hospitals, Institutional Ethics Committee, 6-3-248/2, Care Hospital, In-Patient building, 4th Floor Room No. 401, Road No-1, Banjara Hills	Dr. Deepak Koppaka

	INDIA	Hyderabad Telangana 500034 India ECR/94/Inst/AP/2013/RR-21	
3.	Bharat Hospital and Institute of Oncology, #438, 1st Stage, Outer Ring Road, Hebbal, Mysuru -570017 Karnataka, India	Institutional Ethics Committee, Bharath Hospital and Institute of Oncology NO. 438, 1st Stage, Outer ring road Hebbal Industrial Area Lakshmikanth Nagar Mysuru (Mysore) Karnataka-570017 India  ECR/994/Inst/KA/2017/RR-21	Dr. Srinivas KG
4.	Rajiv Gandhi Cancer Institute and Research Centre, Sir Chotu Ram Marg, Rohini Institutional Area, Sector 5, Rohini, New Delhi, Delhi 110085	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Rohini Sector V Rohini west Metro station Delhi South West Delhi Delhi - 110085 India  ECR/10/Inst/DC/2013/RR-19	Dr. Mansi Sharma
5.	Mahamana Pandit Madan Mohan Malaviya Cancer Centre, A unit of Department of Atomic Energy, Govt. of India, Sundar Bagiya colony, Near Nariya Gate, Varanasi, Uttar Pradesh, 221005, India	IEC MPMCC and HBCH Varanasi, Mohan Malaviya Cancer Centre, Sundar Bagiya colony, Near Nariya Gate, Varanasi, Uttar Pradesh, 221005, India  ECR/1501/Inst/UP/2021	Dr. Akhil Kapoor
6.	HCG Manavata Cancer Centre Behind Shivang Auto, Mumbai Naka, Nashik 422002, Maharashtra, India	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik 422002, Maharashtra, India  ECR/500/Inst/MH/2013/RR-20	Dr. Raj Vasantryo Nagarkar
7.	Apollo Multispeciality Hospitals Limited, 58, Canal Circular Road, Kolkata, West Bengal - 700054, India	Institutional Ethics Committee, Apollo Multispeciality Hospital, 58 Canal Circular Road, Kolkata-700054, India  ECR/373/Inst/WB/2013/RR-19	Dr Bivas Biswas
8.	Kailash Cancer Hospital and Research Center, Muni Seva Ashram, Goraj Waghodia Vadodara, Gujarat -391760, India	IEC-KCHRC, Kailash Cancer Hospital And Research Center, Muni Seva Ashram, Goraj Waghodia 391760 India  ECR/49/Inst/GJ/2013/RR-24	Dr. Ameya Anil Koranne

9.	Vardhman Mahavir Medical College and Safdarjung Hospital, Department of Medical Oncology Ansari Nagar West, New Delhi – 110029, Delhi, India	Institutional Ethics Committee VMMC and SJHVMMC And SAFDARJUNG HOSPITAL Ring Road Ansari Nagar New Delhi South Delhi Delhi -110029 India  ECR/593/Inst/DL/2014/RR-20	Dr.Kaushal Kalra
10.	All India Institute of Medical Sciences (AIIMS) Dr. B. R. Ambedkar Institute of Rotary Cancer Hospital, AIIMS, Ansari Nagar, New Delhi, Delhi – 110029, India	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi Delhi -110029 India  ECR/538/Inst/DL/2014/RR-20	Dr. Sachin Khurana

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