



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
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File No. CT/25/000007

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/2025/47473 dated 27-Jan-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled **“A Randomised, Double-blind, Placebo-controlled, Parallel Group, Multicentre, Phase III Study to Evaluate the Efficacy and Safety of Tezepelumab in Adult Participants with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (EMBARC)” Protocol no. D5241C00006 CSP version 1.0 dated 02 Dec 2024 and Local CSP Addendum IND-1 version 1.0 dated 03 Jan 2025 with a total of up-to 100 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, serum and plasma samples 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, 12th 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. D5241C00006 CSP version 1.0 dated 02 Dec 2024 and Local CSP Addendum IND-1 version 1.0 dated 03 Jan 2025** 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
Stamp

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:

Names of the new drug or investigational new drug	Tezepelumab or Placebo Solution for injection 110 mg/ mL
Therapeutic class:	human immunoglobulin monoclonal antibody
Dosage form:	Solution for injection
Composition:	Tezepelumab =210.0000 milligram (mg) In House Specification Active
Indications:	Adult Participants with Moderate to Very Severe Chronic Obstructive Pulmonary Disease

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Zydus Hospitals & Healthcare Research Pvt. Ltd., Zydus Hospital Road, S G Highway, Thaltej, Ahmedabad, Gujarat -380054	Zydus Hospital Ethics Committee, Zydus Hospitals & Healthcare Research Pvt Ltd. Zydus Hospital Road, Near Sola Bridge, S G Highway, Thaltej, Ahmedabad, Gujarat -380054 ECR/855/Inst/GJ/2016/RR-19	Dr Jitendra Girdharlal Kotadiya
2.	Hindusthan Hospital, 522/3, 523/3 Nava India Road, Udaiyampalayam, Coimbatore, Tamil Nadu - 641028	Institutional Human Ethics Committee, Hindusthan Hospital, 522/3, 523/3, Nava India Road, Udaiyampalayam, Coimbatore, Tamil Nadu -641028	Dr Srikanth Krishnamurthy
3.	All India Institute of Medical Sciences, Nagpur, Plot No.02, Sector 20, MIHAN, Nagpur, Maharashtra - 441108	Institutional Ethics Committee for Clinical Trial, All India Institute of Medical Sciences, Nagpur, Plot No 2, Sector 20, 1st floor, OPD Building, MIHAN, Nagpur, Maharashtra - 441108 ECR/1392/Inst/MH/2020	Dr Srikant Kashinath Malegaonkar
4.	Aster Medcity, South Chittoor P.O, Cheranelloor, Kochi, Kerala -682027	Institutional Ethics Committee, Aster DM Health Care Limited, Aster Medcity, Kochi, Kuttisahib Road, Cheranallor, South Chittoor P.O, Ernakulam, Kerala -682027 ECR/737/Inst/KL/2015/RR-21	Dr Praveen Valsalan
5.	Dhiraj Hospital, Smt. B.K Shah Medical Institute & Research Centre (affiliated to Sumandeep Vidyapeeth - Deemed to be University) At & PO. Piparia, Ta. Waghodia,	Institutional Ethics Committee, SV Sumandeep Vidyapeeth, At and Post Pipariya, Vadodara, Gujarat - 391760	Dr Arti Dhawal Shah

	Vadodadara, Gujarat, 391760	ECR/152/Inst/GJ/2013/RR-24	
6.	Charak Hospital and Research Centre, Hardoi Road, Dubagga, Lucknow, Uttar Pradesh -226003	IEC Charak Hospital and Research Centre, Hardoi Road, Dubagga Lucknow, Uttar Pradesh –226003 ECR/1255/Inst/UP/2019/RR-24	Dr Rahul Kumar Rathore
7.	Shri Guru Ram Rai Institute of Medical & Health Sciences and Shri Mahant IndiresH Hospital, Patel Nagar, Dehradun, Uttarakhand - 248001	Institutional Ethics Committee, SGRR Institute of Medical Health Sciences IEC, Administrative Building, Patel Nagar, Dehradun, Uttarakhand –248001 ECR/710/Inst/UK/2015/RR-21	Dr Jagdish Kumar Rawat
8.	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi -590010, Karnataka	Institutional Ethics Committee, KLE University, KLE Dr.PK Hospital and MRC, Nehru Nagar, Belagavi, Karnataka –590010 ECR/211/Inst/KA/2013/RR-24	Dr Jyothi Hattiholi
9.	Artemis Hospital, Sector -51, Gurugram, Haryana -122001	Artemis Health Sciences IEC, Artemis Hospital, Sector-51, Gurugram, Haryana, 122001 ECR/53/Inst/HR/2013/RR-24	Dr Arun Chowdary Kotaru
10.	Meenakshi Super Specialty Hospital, Lake Area, Melur Road, Madurai, Tamil Nadu - 625107	Institutional Ethics Committee Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai, Tamil Nadu, 625107 ECR/398/Inst/TN/2013/RR-24	Dr Velkumar Gopal
11.	Shalby Hospital, Naroda, Haridarshan Cross road, Naroda-Kathawada road, Naroda, Ahmedabad, Gujarat, 382330	Ethics Committe-Shalby Limited, Shalby Limited Ahmedabad, Opp. Karnavati Club, S.G. Highway, Ahmedabad, Gujarat, 380015 ECR/711/Inst/GJ/2015/RR-21	Dr Sujal Patel
12	B P Poddar Hospital and Medical Research Ltd, 71/1, Humayun Kabir Sarani, Block G, New Alipore, Kolkata, West Bengal -700053	BP Poddar and Parvati Devi Foundation For Education, 71/1, Humayun Kabir Sarani New Alipore, Block-G, Kolkata, West Bengal – 700053 ECR/1812/Inst/WB/2023	Dr Samadarshi Datta
13	Dr DY Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra - 411018	Ethics Committee, Dr DY Patil Vidyapeeth, Pimpri, Sant Tukaram Nagar, Pimpri Colony, Pimpri, Pune, Maharashtra –411018 ECR/361/Inst/MH/2013/RR-24	Dr Sachin kumar Dole

14	Princess Krishnammanni Tuberculosis and Chest Diseases Hospital (P.K.T B and C.D Hospital), Mysore Medical College and Research Institute, Mysore, KRS Road, Kumbarakoppal, Gokulam, Mysore, Karnataka, 570002	Institutional Ethics Committee, Mysore Medical College & Research Institute and Associated Hospitals, K. R Hospital, Irwin Road, Mysore, Karnataka –570021 ECR/134/Inst/KA/2013/RR-19	Dr C Prashanth
15.	Vardhman Mahavir Medical College & Safdarjung Hospital (VMMC & SJH), Near AIIMS Hospital, Ansari Nagar West, New Delhi, Delhi -110029	Institutional Ethics Committee VMMC and SJH, VMMC and Safdarjung Hospital, Ring Road, Ansari Nagar, New Delhi, South Delhi, Delhi –110029 ECR/593/Inst/DL/2014/RR-20	Dr Rohit Kumar
16.	All India Institute of Medical Sciences, Ansari Nagar, New Delhi -110029	Institute Ethics Committee All India Institute of Medical Sciences, Old OT Block, Room No.102, Ansari Nagar, New Delhi, Delhi –110029 ECR/538/Inst/DL/2014/RR-20	Dr Anant Mohan
17	ESIC Medical College and Hospital, Clinical Trial Unit, MRU (Multidisciplinary Research Unit), Basement, NH-3, NIT, Fariabad, Haryana-121001	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College And Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana –121001 ECR/1539/Inst/HR/2021	Dr Kamran Choudhary
