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/24/000063

To
M/s. PPD Pharmaceutical Development (India) Pvt. Ltd.,
102, A Wing, Fulcrum, Hiranandani Business Park,
Sahar Road, Andheri East, Mumbai – 400099, India.

Sir,

With reference to your application no. GCT/CT04/FF/2024/43085 dated 30-Apr-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A PHASE III, OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY OF ASTEGOLIMAB IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE." Protocol No.: GB43374 Version No. 2 Protocol Date 03-APR-2023 with a total of up-to 80 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, specifically::-

(i) Any subject who received Investigational drug, found to be active tuberculosis should be excluded from the study and treated accordingly to National Tuberculosis Elimination Program (NTEP)

(ii) Protocol should include testing frequency for every 6 months for tuberculosis infection (Chest X- ray, Quantiferon and sputum test)

(iii) Human biological samples i.e. Blood sample related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(xix) 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;

(xx) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xxi) 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;

(xxii) 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,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(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. PPD Pharmaceutical Development (India) Pvt. Ltd., 102, A Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri East, Mumbai (India) – 400099** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: GB43374 Version No. 2 Protocol Date 03-APR-2023** 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 _____

RAJEEV SINGH RAGHUVANSHI

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(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:

Names of the new drug or investigational new drug	Astegolimab (RO7187807)
Therapeutic class:	IgG2 monoclonal antibody
Dosage form:	Injection
Composition:	Astegolimab =140.0000 mg/ml InHouse Specification Active
Indications:	Chronic Obstructive Pulmonary Disease (COPD)

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	S.M.S. Medical College and Attached Hospitals, Jaipur , First Floor, Dhanvantri OPD Block, S.M.S. Hospital, J.L.N. Marg Jaipur Rajasthan - 302004	Ethics Committee S.M.S Medical College & Attached Hospitals, JLN Marg, Jaipur, Rajasthan-302004, India ECR/26/Inst/RJ/2013/RR-19	Dr Ajit Singh
2.	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Rajasthan -302039	IEC, Maharaja Agrasen Hospital Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur, Rajasthan -302039 India ECR/1222/Inst/RJ/2019/RR-22	Dr Manish Kumar Jain
3.	MV Hospital And Research Centre, 314/30, Mirza Mandi Chowk Lucknow-Uttar Pradesh Lucknow Uttar Pradesh - 226003	Institutional Ethics Committee For M.V. Hospital And Research Centre, First Floor, 314/30 Mirza Mandi, Chowk Lucknow-226003, Uttar Pradesh, India ECR/13/Inst/UP/2013/RR-19	Dr Sandeep KumarGupta
4.	IPGME & R SSKM hospital, 244 Acharya J. C. Bose Road Kolkata West Bengal -700020	IPGME and R Research Oversight Committee, Office of the Dean, College Building, 5th Floor, Institute of Post Graduate of Medical Education and Research,244, A.J.C Bose Road, Kolkata – 700020, West Bengal, India ECR/35/Inst/WB/2013/RR-19	Dr Jotideb Mukhopadhyay
5.	Jawahar Lal Nehru Medical College, Jawahar Lal Nehru Medical College Kala Bagh,Kala Bagh Rajasthan - 305001	Institutional Ethics Committee Jawahar Lal Nehru Medical College, Kala Bagh , Ajmer-305001, Rajasthan, India ECR/1156/Inst/RJ/2018/RR-22	Dr Piyush Arora
6.	104, TB and Chest Department, GMERS Medical College and Civil Hospital, Sola Gram Road, Beside High Court Ahmedabad Gujarat - 380060	Institutional Ethics Committee GMERS Medical College, Sola, GMERS Medical College & Civil Hospital, Sola Highway, Beside Gujarat High Court,Ahmedabad-380061, Gujarat, India ECR/404/Inst/GJ/2013/RR-20	Dr Kirankumar Chandubhai Rami
7.	ESIC Medical College and Hospital, NH-3 NIT, Behind BK Hospital Faridabad Haryana - 121001	Institutional Ethics Committee for ESIC Faridabad ESIC Medical College & Hospital, NH3, NIT, Behind BK Hospital, Faridabad, Haryana -121001, India.	Dr Anil Kumar Pandey

		ECR/1539/Inst/HR/2021	
8.	Shree Hospital and Critical Care Centre, Shree Hospital and Critical Care Centre 799, Om Nagar, Opp Tajshree Building, Sakkardara Sq, Nagpur 440009 Maharashtra India Nagpur Maharashtra -440009	Shree Hospital Ethics Committee Shree Hospital Unit, Plot No.786 A, 3rd Floor Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umrer Road, Sakkardara, Sq, Nagpur-440009, Maharashtra, India ECR/553/Inst/MH/2014-RR-20	Dr Akash Lataru Balki
9.	Karnataka Institute of Medical Sciences, Karnataka Institute of Medical Sciences, Vidyanagar, Hubballi -580022 Hubballi Karnataka -580022	Institutional Ethics Committee, Karnataka institute of medical sciences, Hubballi-580022, Karnataka, India. ECR/486/Inst/KA/2013/RR-20	Dr Ram S Kaulgud
10.	Jawaharlal Nehru Medical College and Hospital, Department of Tuberculosis and Chest Disease, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh 202002, India Aligarh Uttar Pradesh -202002	Institutional Ethics Committee Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Civil Line Koil, Aligarh Uttar Pradesh -202002 India. ECR/1418/Inst/UP/2020	Dr Mohammad Shameem
11.	Paarthiv Lung Care Centre, Plot No. 2, Street No. 1, Czech Colony, Opp. Gokul Theatre, Sanath Nagar Hyderabad Telangana -500018	Institutional Ethics Committee, Neelima Hospitals Neelima Hospitals Private Limited,7-2-1735, Czech Colony, Sanathnagar, Hyderabad, Telangana –500018, India. ECR/807/Inst/TG/2016/RR-19	Dr Boyilla Nagaraju
12.	Government Medical College and Government General Hospital, Srikakulam Srikakulam Andhra Pradesh -532001	Institutional Ethics Committee Institutional Ethics Committee Government Medical College & Government General Hospital, Srikakulam Andhra Pradesh -532001 India ECR/492/Inst/AP/2013/RR-20	Dr Sunil Naik
13.	Aakash Healthcare Super Specialty Hospital, Hospital Plot, Plot No 201, Sector 3, Dwarka, New Delhi New Delhi Delhi -110075	Aakash Healthcare Super Specialty Hospital Institutional Ethics Committee Service Floor, Aakash Healthcare, Hospital Plot, Road No.-201, Sector-3, Dwarka, New Delhi-110075, India ECR/1265/Inst/DL/2019	Dr Prabhat Ranjan Sinha

14.	Apollo Spectra Hospital, ApolloSpecialty Hospital Pvt. Ltd., 14-138, Chunni Ganj Kanpur Uttar Pradesh -208001	Apollo Specialty HospitalsKanpur Ethics Committee, Apollo Specialty Hospital, 14/138, Chunni Ganj, Kanpur-208001, Uttar Pradesh, India ECR/1327/Inst/UP/2019	Dr Sandeep Katiyar
15.	Yashoda Hospital, Yashoda Healthcare Services Pvt. Ltd.Hitech City, Cyber Towers to JNTU Road, Hyderabad Telangana -500084	Institutional Ethics Committee - Yashoda Academy of Medical Education and Research Yashoda Hospitals, Behind Hari Hara Kala Bhavan, S P Road, Secunderabd-500003, Telangana State, India ECR/49/Inst/AP/2013/RR-22	Dr Venkata Nagarjuna Maturu
16.	Kothrud Hospital, Opp. HillView Park, Metro Car Depot, Beside NKGSB Bank, Kothrud Pune Maharashtra - 411038	Royal Pune Independent Ethics Committee Office No. 13, Srv. No. 81/A, Anupam Arcade, Opposite Snake Park, Katraj, Pune, Maharashtra –411046, India ECR/45/Indt/MH/2013/RR-19	Dr Himanshu Pophale

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