File No. CT/63/22-DCG (I)

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

सत्यमेव जयते

File No. CT/22/000063

To

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

Sir,

With reference to your application no. GCT/CT04/FF/2022/33026 (GCT/63/22) dated 19-07-2022, please find enclosed herewith the permission in Form CT-06 for conduct of phase IIIA clinical trial titled," **A multi-center, randomized, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment in participants with COPD experiencing frequent exacerbations and characterized by eosinophil levels" Protocol Number: 208657/Amendment 6-STD dated 06-12-2021, in up-to 45 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 SAE including death irrespective of its causality assessment i.e. due to progression of disease should be considered as SAE and to be reported to CLA as per provision of NDCTR 2019;

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

(xx) 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;

(xxi) 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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
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Date: 2022.10.28 16:40:00 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

File No. CT/63/22-DCG (I)

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., 101, 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 Number: 208657/ Amendment 6-STD dated 06-12-2021** 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 ________________

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)

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	Mepolizumab (SB-240563)
Therapeutic class:	Monoclonal Antibody
Dosage form:	Injection
Composition:	Mepolizumab = 100.0000 mg/ml In House Specification Active
Indications:	Chronic obstructive pulmonary disease (COPD)

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Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	ClMS Hospital Pvt Ltd. Plot No 6711, Near Shukan Mall, Opp. Panchamrut Bungalows, off. Science City Road, Sola, Ahmedabad-380060, Gujarat, India	Ethics Committee of CIMS Hospital, CIMS Hospital Pvt Ltd. Plot No 67/1, Near Shukan Mall, Opp. Pancharnrut Bungalows, off. Science City Road, Sola, Ahmedabad-380060, Gujarat, India ECR/206/Inst/GJ/2013/RR-20	Dr. Amit Patel
2.	Yashoda Hospitals, Raj Bhavan Road Somajiguda, Hyderabad-500082, Telangana State, India	Institutional Ethics Committee, Yashoda Academy of Medical Education & Research, Yashoda Hospital, Behind Hari Hara kala Bhavan, S.P. Road, Secunderabad-500003, Telangana State, India ECR/49/Inst/AP/2013/RR-22	Dr. Venkata Nagarjuna Maturu
3.	Apollo Spectra Hospital (Apollo Speciality Hospital Pvt. Ltd.), 14/138, Chunni Ganj, Kanpur-208002, Uttar Pradesh, India	Apollo Specialty Hospital Kanpur Ethics Committee Apollo Spectra Hospital (Apollo Speciality Hospital Pvt. Ltd.), 14/138, Chunni Ganj, Kanpur-208002, Uttar Pradesh, India ECR/1327/Inst/UP/2019	Dr. Sandeep Katiyar
4.	Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai-625107, Tamil Nadu, India	Institutional Ethics Committee, Room No. 6701, 6th Floor Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai-625107, Tamil Nadu, India ECR/398/Inst/TN/203/RR-19	Dr. Velkumar Gopal
5.	M.V. Hospital & Research Centre, 314/30, Mirza Mandi, Chowk, Lucknow-226003, Uttar Pradesh, India	Institutional Ethics Committee for M.V. Hospital & Research Centre, ist Floor of M.V. Hospital & Research Centre, 314/30, Mirza Mandi, Chowk, Lucknow-226003, Uttar Pradesh, India ECR/13/Inst/UP/2013/RR-19	Dr. Sandeep Kumar Gupta

6.	Maharaja Agrasen Super speciality Hospital, central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur-302039, Rajasthan India	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Super speciality Hospital, central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur-302039, Rajasthan India ECR/1222/Inst/RJ/2019/RR-22	Dr. Manish Kumar Jain
7.	Aster Prime Hospitals, Opp. Passport Seva Kendra, Ameerpet, Hyderabad-500038, Telangana State, India	Ethics Committee-Prime Hospitals, Aster Prime Hospitals, Beside Bluefox Hotel, Behind Mythrivanam, Ameerpet, Hyderabad-500038, Telangana State, India ECR/381/Inst/AP/2013/RR-21	Dr. Boyilla Nagaraju
8.	Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh-202001, Uttar Pradesh, India	Institutional Ethics Committee Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh-202001, Uttar Pradesh, India ECR/1418/Inst/UP/2020	Dr. Zuber Ahmad
9.	Jaydeep Hospital, Near St. Xavier's Loyola School, Opposite Kamnath Mahadev, Near Darpan six Road, Navarangpura, Ahmedabad, 380013, Gujarat, India	KAIZEN Ethics Committee, 132 Ft. Ring Road, helmet Circle, Memnagar, Ahmedabad-380052 Gujarat, India ECR/447/Inst/GJ/2013/RR-19	Dr. Deepali Kamdar
10.	BLK-Max Super Specialty Hospital, Pusa-Road, New Delhi-110005	The Chairman/Member Secretary, Ethics Committee, Dr. B.L Kapur Memorial Hospital, Pusa-Road, New Delhi-110005 ECR/3/BLK/Inst/DL/2013/RR-19	Dr. Sandeep Nayar
11.	Sir Ganga Ram Hospital SGRH Marg Rajinder Nagar New Delhi-110060-India	Ethics Committee, Sir Ganga Ram Hospital Sir Ganga Ram Hospital SGRH Marg Rajinder Nagar New Delhi-110060, India ECR/20/Inst/DL/2013/RR-2019	Dr. Amit Dhamija
12.	Criticare Hospital & Research Institute, 4th Floor, Dhanshree Complex, Near Hotel Hardeo, Sitabuldi, Nagpur-440012, Maharashtra, India	Criticare Hospital & Research Hospital Ethics Committee, Crticare Hospital & Research Institute, 4th Floor, Dhanshree Complex, Near Hotel Hardeo, Sitabuldi, Nagpur-440012, Maharashtra, India	Dr. Vivek Gupta

		ECR/1011/Inst/MH/2017/RR-20	
13.	Shree Hospital &Critical care Centre /799, Om Nagar, Opp Tajshree Building, Sakkardara Sq. Nagpur-440009/ Maharashtra, India	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
14.	5th floor, Clinical Research Division, Getwell Hospital & Research Institute, 20/1, Dr. Khare Marg, Dhantoli, Nagpur-440012, Maharashtra, India	Getwell Institution Ethic Committee, 5th floor, Clinical Research Division, Getwell Hospital & Research Institute, 20/1, Dr. Khare Marg, Dhantoli, Nagpur-440012, Maharashtra, India ECr/109/Inst/Maha2013/RR-19	Dr. Rajesh Swarnakar

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