



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/24/000101

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/2024/44776 dated 06-Aug-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Barzolvolimab in Patients with Chronic Spontaneous Urticaria Who Remain Symptomatic Despite H1 Antihistamine Treatment (EMBARQ – CSU2)” Protocol No.: CDX0159-13 Version No. 1 Protocol Date 29-MAR-2024 with a total of up-to 125 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) **Human biological samples i.e. Human blood (Whole), Plasma, Serum and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (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. 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.: CDX0159-13 Version No. 1 Protocol Date 29-MAR-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
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	Barzolvolimab (CDX-0159)
Therapeutic class:	IgG1k monoclonal antibody
Dosage form:	Injection
Composition:	Barzolvolimab (CDX-0159)=150.0000 mg/ml In House Specification Active
Indications:	Chronic Spontaneous Urticaria

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Shree Hospital and Critical Care Centre, 799, Om Nagar, Opp. Tajshree Building, Sakkardara Sq. 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 Shyamal Balki
2.	Dhiraj Hospital, Sumandeep Vidyapeeth Deemed to be University, At and Po. Piraia, Ta, Waghodia Vadodara, Gujarat -391760	Institutional Ethics Committee, SV Sumandeep Vidyapeeth Sumandeep Vidyapeeth At and Post Pipariya Pipariya Vadodara Gujarat -391760 India ECR/152/Inst/GJ/2013/RR-19	Dr Rashmi Mahajan
3.	KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar Belagavi Karnataka - 590010	Institutional Ethics Committee, KLE University KLE Dr PK Hospital and MRC, Nehru Nagar, Belagavi (Belgaum) Karnataka –590010, India ECR/211/Inst/KA/2013/RR-19	Dr Shivakumar Patil
4.	Oyster and Pearl Hospitals, Phadnis Clinic Pvt Ltd, 1671-75, Ganeshkhind Road, Shivajinagar, Pune Maharashtra –411005	O AND P ETHICS COMMITTEE Oyster and Pearl Hospitals, 1671-75, Ganeshkhind Road, Shivaji Nagar, Pune-411005, Maharashtra, India ECR/71/Inst/MH/2013/RR-19	Dr Hemant Kumar Talnikar
5.	Excelcare Hospital, 103, Sanjay Nagar-A, Joshi Marg, Kalwar Road, Jhotwara, Rajasthan -302012	Institutional Ethics Committee Sardarmal Khandaka Memorial Hospital, Kalwar Road, Hathoj, Jaipur-302012, Rajasthan ECR/1032/Inst/RJ/2018/RR-21	Dr Sakshi Midha
6.	K R Hospital attached to Mysore Medical College and Research Institute, Department of Dermatology, Irwin Road, Mysuru Karnataka -570001	Institutional Ethics Committee- Mysore Medical College and Research Institute and Associated Hospitals, K R Hospital attached to Mysore Medical College and Research Institute, Irwin Road, Mysore 570001, Karnataka, India. ECR/134/Inst/KA/2013/RR-19	Dr Nanjundaswamy B L
7.	Deenanath Mangeshkar Hospital and Research Centre, Madhubhau Chaudhari, Department of Dermatology and Research Center, Main Building, 3rd Floor D wing, Erendwane, Pune,	Institutional Ethics Committee, Deenanath Mangeshkar Hospital and Research Centre, Karve Road, Erendwane, Pune-411004, Maharashtra, India ECR/15/Inst/Maha/2013/RR-22	Dr Vinay Kulkarni

	Maharashtra -411004		
8.	GSVM Medical College, Department of Dermatology, GSVM Medical College, Swaroop Nagar, Kanpur Uttar Pradesh -208002	ETHICS COMMITTEEGSVM MEDICAL COLLEGE GSVM Medical College, Swaroop Nagar, Kanpur, Uttar Pradesh -208002 India ECR/680/Inst/UP/2014/RR-20	Dr Dev Prakash Shivhare
9.	Sheth Vadilal Sarabhai General Hospital, Madalpur Gam, Paldi, Road, Ellisbridge, Ahmedabad Gujarat -380006	Sangini Hospital Ethics Committee, Sangini Hospital Santorini Square, B/H Abhishree Complex Opp. Star Bazar, Nr Jodhpur Cross Roads Satellite, Ahmedabad Gujarat - 380015 India ECR/147/Inst/GJ/2013/RR-24	Dr Rajvee Shah
10.	Nirmal Hospital Pvt Ltd, Ring Road, Surat Gujarat -395002	NIRMAL HOSPITALETHICS COMMITTEE Nirmal Hospital Pvt Ltd, 2/1423-8-6 SAGRAMPURA, Ring Road Near Centre Point, Surat-395002, Gujarat, India ECR/390/Inst/GJ/2013/RR-19	Dr Dipak Patel
11.	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar Orissa -751019	Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar, Odisha-751019, India ECR/534/Inst/OD/2014/RR-20	Dr Chandra Sirka
12.	Assured Care Plus Hospital, 4th and 5th Floor, Star Plus Complex, Lam Road, Near Muktidham Temple, Opp. NMC Divisional office, Nashik Road, Nashik Maharashtra -422101	Institutional Ethics Committee Assured Care Plus Hospital, 4th & 5th Floor, Star Plus Complex, Lam Road, Near Muktidham Temple, Opp. NMC Divisional office, Nashik 1 Road, Nashik 422101, Maharashtra, India ECR/1756/Inst/MH/2022Dr	Dr Suneel Vartak
13.	Medical College Baroda and SSG Hospital, Jail Road, Indira Avenue, Vadodara Gujarat - 390001	Institutional Ethics Committee for Human Research (IECHR) Medical College Baroda & S.S.G. Hospital, Medical College and SSG Hospital Jail Road, Indira Avenue, Vadodara-390001, Gujarat, India ECR/85/Inst/GJ/2013/RR-19	Dr Nipul Vara
14.	B. J. Medical College and Civil Hospital, Department of Skin and VD, Asarwa, Ahmedabad Gujarat -380016	INSTITUTIONAL ETHICS COMMITTEE, B. J. Medical College and Civil Hospital, Office of Medical Superintendent Civil Hospital, Ahmedabad, Gujarat - 380016, India	Dr Rima Joshi

		ECR/72/Inst/GJ/2013/RR-19	
15.	RUHS College of Medical Sciences and, OPD Block, Sector-11. Kumbha Marg, Pratap Nagar, Jaipur Rajasthan -302033	RUHS CMS-Ethics Committee RUHS College of Medical Science, Sector-11, Kumbha Marg, Pratap Nagar, Tonk Road, Jaipur-302033, Rajasthan, India ECR/762/Inst/RJ/2015/RR-22	Dr Ajit Singh
