



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/25/000029

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/2025/48494 dated 25-Mar-2025, 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 of Felzartamab in Adults With IgA Nephropathy (PREVAIL)” Protocol No. 299IG301 Version No. 2.1 dated 13 Feb 2025 with a total of up-to 25 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. Whole blood, 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. 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 Licensing 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 Licensing 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 Licensing 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. 299IG301 Version No. 2.1 dated 13 Feb 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	Felzartamab
Therapeutic class:	Human monoclonal antibody
Dosage form:	Lyophilizate for reconstitution for IV infusion
Composition:	Felzartamab =65.0000 mg/ml Active
Indications:	Immunoglobulin A Nephropathy (IgAN)

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	SMS Superspeciality Hospital, Attached to SMS Medical College, Room No 507, 5 th Floor, Department of Nephrology, Vivekanand Marg, C-Scheme Jaipur Rajasthan - 302001	Institutional Ethics Committee, SMS Medical College & Attached Hospital, Office of Ethics Committee, Second Floor, New Academic Block, SMS Medical College, Jaipur-302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-24	Dr Dhananjai Agrawal
2.	Sir Ganga Ram Hospital, Department of Nephrology, Sir Ganga Ram Hospital Marg, Rajinder Nagar New Delhi Delhi - 110060	Sir Ganga Ram Hospital Ethics Committee, Room No 1643, 6th Floor Casualty Building Sir Ganga Ram Hospital Rajinder Nagar New Delhi-110060 ECR/22/DL/2013/RR-2024	Dr Anurag Gupta
3.	Muljibhai Patel Society for Research in Nephro and Urology, care of Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad, Gujarat - 387001	Muljibhai Patel Society for Research in Nephro-Urology Ethics Committee, Jayaramdas Patel Academic Centre, Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad, Gujarat 387001, India ECR/276/Muljibhai/Inst/GJ/2013/RR-24	Dr Sishir Dashrathmal Gang
4.	Noble Hospital Pvt. Ltd., 153, Magarpatta City Road Pune Maharashtra - 411013	Noble Hospital Institutional Ethics Committee, Room No. 5, Noble Annex Building, Noble Hospital Pvt. Ltd., 153, Magarpatta City Road, Hadapsar, Pune- 411013, Maharashtra, India ECR/259/Inst/MH/2013/RR-24	Dr Avinash Ignatius
5.	Seth GSMC and KEM Hospital, Ward 34 A, Third Floor, Old building, Department of Nephrology Mumbai Maharashtra - 400012	Institutional Ethics Committee I, New UG/PG Hostel, 20 Storey Hostel Building, Ground Floor, KEM Hospital Campus, Near Main Boys Hostel, Dr. S.S Rao Marg, Parel, Mumbai - 400012, Maharashtra, India ECR/229/Inst/MH/2013/RR-24	Dr Tukaram Jamale
6.	Nizams Institute of Medical Sciences, Punjagutta Hyderabad Telangana - 500082	NIMS Institutional Ethics Committee, Nizams Institute of Medical Sciences Punjagutta, Hyderabad- 500082, Telangana, India ECR/303/Inst/AP/2013/RR-24	Dr Sree Bhushan Raju Devaraju
7.	Manipal Hospital, 98, Old Airport Road Bangalore Karnataka - 560017	Ethics Committee of Manipal Hospitals, No. 98, Old Airport Road, Bangalore - 560017, Karnataka, India ECR/34/Inst/KA/2013/RR-24	Dr Vishwanath S

8.	All India Institute of Medical Sciences (AIIMS), G.E. Road, Tatibandh, Raipur, 492099, Chhattisgarh, India	Institution Ethics Committee AIIMS, Raipur, Room no.-2103, 2nd floor, South Wing, Medical college complex, Gate no- 5, All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur 492099 Chhattisgarh, India ECR/714/Inst/CT/2015/RR-21	Dr Vinay Rathore
9.	Max Super Speciality Hospital, Saket West Block, A unit of Max Healthcare Institute Limited, 1 Press Enclave Road, Saket New Delhi Delhi -110017	Max Healthcare Ethics Committee (MHEC), Ground Floor, Office of Ethics Committee, West Block, Near MS Office, Max Super Speciality Hospital, Saket, (West Block), (A unit of Max Healthcare Institute Limited), 1 Press Enclave Road, Saket, New Delhi 110017 ECR/118/ Inst/DL/2013/RR-24	Dr Dinesh Khullar
10.	Osmania General Hospital, Department of Nephrology, QQDC Building, 3rd Floor, Osmania General Hospital, Afzalgunj Hyderabad Telangana - 500012	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana, India ECR/300/Inst/AP/2013/RR-24	Dr Manisha Sahay
11.	Zydus Hospitals and Healthcare Research Pvt. Ltd., Zydus Hospitals Road, S.G. Highway , Thaltej Ahmedabad Gujarat - 380054	Zydus Hospital Ethics Committee, 09th Floor, Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, 09th Floor, Zydus HospitalS Road, Thaltej, Ahmedabad-380054, Gujarat India ECR/855/Inst/GJ/2016/RR-24	Dr Kamal Ramesh Goplani
12.	Government Medical College, Department of Nephrology Super Speciality Block Kozhikode Kerala - 673008	Institutional Ethics Committee, Government Medical College Kozhikode, Room No. 1 & 2, Ground Floor, Lecture Theater Complex Medical college campus, Medical College P.O. Calicut – 673008, Kerala India ECR/395/Inst/KL/2013/RR-20	Dr Biju K Gopinath
13.	Government Medical College, Thiruvananthapuram Kerala - 695011	Human Ethics Committee, Government Medical College, Thiruvananthapuram, Kerala – 695011, India ECR/370/Inst/Ker/2013/RR-20	Dr Ragi Krishnan G
14.	Christian Medical College Vellore Ranipet Campus, Department of Nephrology, Vellore Ranipet Tamil Nadu - 632517	Ethics Committee Silver, Office of Research, Ist Floor, Carman Block, Christian Medical College, Bagayam, Vellore, Tamil Nadu, 632002, India ECR/326/Inst/TN/2013/RR-19	Dr Suceena Alexander

15.	M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post Bengaluru Karnataka - 560054	Ethics Committee, M.S. Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bengaluru, 560054, Karnataka, India ECR/215/Inst/KA/2013/RR-24	Dr Mahesh Eshwarappa
16.	Sanjay Gandhi Post graduate Institute of Medical Sciences, Raibareli Road Lucknow Uttar Pradesh - 226014	Institutional Ethics Committee, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014, Uttar Pradesh, India ECR/16/Inst/UP/2013/RR-20	Dr Narayan Prasad
17.	Postgraduate Institute of Medical Education and Research, Department of Nephrology, Ground Floor, C-Block, Nehru Hospital, Sector 12 Chandigarh Chandigarh - 160012	Institutional Ethics Committee PGIMER, Room No. 6006, IEC Office, 6th Floor, PN Chuttani Block, Sector-12, Chandigarh, 160012, India ECR/25/Inst/CH/2013/RR-25	Dr Raja Ramachandran
18.	NRS Medical Collge And Hospital, NRS Medical Collge And Hospital 138, A.J.C. Bose Road Kolkata West Bengal - 700014	Institutional Ethics Committee, Nil Ratan Sircar Medical College, IEC NRSMC Office Of Principal Academic Building 138, A.J.C. Bose Road, Kolkata 700014, India ECR/609/Inst/WB/2014/RR-20	Dr Pinaki Mukhopadhyay
