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/25/000080

To,

M/s Worldwide Clinical Trials India Private Limited,
Office 920, Unit No. 9, Corporate Park II, 9th floor,
VN Purav Marg, Near Swastik Chambers, Chembur,
Mumbai, Maharashtra, 400071 India.

Sir,

With reference to your application No. GCT/CT04/FF/2025/50141 dated 10-Jun-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Study Evaluating Monthly (Every 4 Weeks) Dosing of Atacicept in Patients with IgAN" Protocol No: VT-001-0020 Original Protocol, dated 07-FEB-2025 with a total of up-to 20 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) Rescue therapy plan shall be mentioned for the high dose of intervention drug in the protocol.
(ii) Liver function test and Renal function test (inclusive of urea and creatinine) shall be performed.
(iii) The specific rescue plan for deteriorating condition of participating subject shall be included in the study.
(iv) 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.
(v) 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;
(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) 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;

(xx) 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;

(xxi) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xxii) 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;

(xxiii) 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
Date: 2025.11.07 15:12:28 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing 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 Worldwide Clinical Trials India Private Limited, Unit No. 920, Unit No. 9 Corporate Park II, 9th Floor, V N Purav Marg, Near Swastik Chambers, Chembur (E) Mumbai (India) - 400071 Telephone No.:7045684104 FAX: 7045684104 E-Mail : REGAFFAIRSINDIA@WORLDWIDE.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No: VT-001-0020 Original Protocol, dated 07-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 _____

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.11.07 15:12:35 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing 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	Atacicept
Therapeutic class:	Immunomodulator
Dosage form:	Injection
Composition:	Atacicept =150.0000 milligram(mg) In House Specification Active
Indications:	IgA Nephropathy

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
Princess Krishnajammanni Super Speciality Hospital, Princess Krishnajammanni Super Speciality Hospital Associated with K.R.Hospital, Mysore Medical college and Research Institute. Kumbarakoppal, Gokulam 3rd Stage, Gokulam, Mysuru, Karnataka 570016 mysuru Karnataka - 570016	IEC-MMC and RI and Associated Hospital Mysore Medical College and Research Institute, Irwin Road, Mysuru, (Mysore) Karnataka – 570001 ECR/134/Inst/KA/2013/RR-19	Dr Srinivas K
Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Institute of Post Graduate	IPGME and R ResearchOversight Committee, Institute of Postgraduate Medical Education & Research, 244 Acharya J. C. Bose Road, Kolkata–700020, West	Dr Atanu Pal

Medical Education and Research and Seth Sukhlal Karnani Memorial HospitalI PGMER and SSKMH 244 AJCBose Road, Kolkata-700020, West Bengal, India Kolkata West Bengal - 700020	Bengal, India ECR/35/Inst/WB/2013/RR-24	
WMFs Villoo Poonawalla Memorial Hospital, WMFS Villoo Poonawalla Memorial Hospital, S.no 156, Pune Solapur Road, Hadapsar, Pune-411028, Maharashtra, India Pune Maharashtra	Institutional Ethics Committee Welfare Medical Foundation's Villoo Poonawala Memorial Hospital, S.No. 156, Plot No. 1/3A+3B+1+2/3, Pune Solapur road , Hadapsar, Pune, Maharashtra-411028 ECR-/1642/Inst/MH/2022	Dr Sandeep Morkhandikar
Nil Ratan Sircar Medical College and Hospital NRSMCand H, Nil Ratan Sircar Medical College and Hospital NRSMC and H Department of Nephrology, 138, Acharya Jagadish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata, West Bengal 700014 Kolkata West Bengal - 700014	Ethics Committee N.R.S. Medical College NRS Medical College and Hospital, 138, A. J. C. Bose Road, Kolkata–700014, WestBengal,India ECR/609/Inst/WB/2014/RR-20	Dr Pinaki Mukhopadhyay
Shri Mahant Indiresh Hospital, Shri Mahant Indiresh Hospital, Dehradun North Block newbuilding, 03rd floor, Nephrology OPD, ART Centre, room no 02,Kargi - Patel Nagar Bypass, Industrial Area, Govt. Industrial Estate, Patel Nagar, Dehradun, Uttarakhand 248001 Dehradun Uttarakhand - 248001	Institutional Ethics Committee, SGRR Institute of Medical Health Sciences, IEC, Administrative Building, Patel Nagar, Dehradun, Uttarakhand –248001, India ECR/710/Inst/UK/2015/RR-21	Dr Vivek Ruhela
Noble Hospital and Research Centre, Noble Hospital and Research Centre, Pune 153, Magarpatta Rd, Magarpatta, Hadapsar, Pune, Maharashtra 411013 Pune Maharashtra -411013	Noble Hospital Institutional Ethics Committee Noble Hospitals Pvt. Ltd., Room No 5, Noble Hospitals Clinical Research Department,, Noble Annex, Noble Hospitals Pvt. Ltd;152 A, Magarpatta City Road, Hadapsar, Pune, Maharashtra – 411013, India ECR/259/Inst/MH/2013/RR-24	Dr Avinash Ignatius
Justice KS Hegde Charitable Hospital, Justice KS Hegde Charitable Hospital,	Central Ethics Committee, Nitte University (Deemed to be University), University Enclave,	Dr Pradeep Shenoy M

Karnataka Research Coordinator Department, Nephrology Department, 3rd Floor, Deralakatte, Mangalore University Road, Mangalore, Karnataka- 575018 Manglore Karnataka - 575018	Medical Sciences Complex, Deralakattee, Mangalore, Karnataka –575018 ECR/119/Inst/KA/2013/RR-19	
All India Institute of Medical Sciences, All India Institute of Medical Sciences, New Delhi Department of Nephrology East Ansari Nagar, New Delhi-110029 Delhi 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 Soumita Bagchi
Christian Medical College Vellore Ranipet Campus, Kilminnal Village, Ranipet District , Tamil Nadu 632517Vellore Tamil Nadu - 632517	Institutional Review Board, Christian Medical College, Thorapadi, Bagayam, Vellore, Tamil Nadu – 63201 ECR/326/Inst/TN/2013/RR-24	Dr Suceena Alexander
Kempegowda Institute of Medical Sciences Hospital and Research Centre, K R Road, VV Puram, Bangalore-560004.Bangalore Karnataka - 560004	KIMS Institutional Ethics Committee, Kempegowda Institute of Medical Sciences, Attimabbe Road, Banashankari, 2nd Stage, Bangalore, Urban Karnataka – 560070 ECR/216/Inst/Kar/2013/RR-24	Dr Sunil R
Regency Health Superspecialty Hospital, Tedhi Pulia, Ring Road, Khurram Nagar, Lucknow-226022, Uttar Pradesh, India Lucknow Uttar Pradesh - 226022	Institutional Ethics Committee Regency Hospital, Tedhi Pulia, Ring Road, Khurram Nagar, Lucknow–226022, Uttar Pradesh, India. Pradesh ECR/1719/Inst/UP/2022	Dr Deepak Dewan

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