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/25/000120

To,

M/s Veeda Clinical Research Limited,
Shivalik Plaza-A Near I.I.M Ambawadi,
Ahmedabad (India) – 380015.

Sir,

With reference to your application No. GCT/CT04/FF/2025/51475 dated 20-Aug-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled, "**A randomized, double-blind, parallel-group study to compare the pharmacokinetics, efficacy, pharmacodynamics, safety, and immunogenicity of CYB704 (proposed ocrelizumab biosimilar) and Ocrevus® in participants with relapsing multiple sclerosis (RMS)" Protocol No.: CCYB704A12301 version no. 3.0 dated 18-JUL- 2025 with a total of up-to 50 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) **Human biological samples i.e. Whole blood, serum and plasma, CSF samples 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 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) 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,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.03.12 15:32:26 +05'30'

(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 Veeda Clinical Research Limited, Shivalik Plaza-A Near I.I.M., Ambawadi Ahmedabad (India) - 380015** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: CCYB704A12301 version no. 3.0 dated 18-JUL- 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: 2026.03.12 15:32:36 +05'30'

(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	CYB704 (Ocrelizumab) 300mg/ 10 mL concentrate for solution for infusion
Therapeutic class:	Monoclonal Antibody
Dosage form:	concentrate for solution for infusion
Composition:	Ocrelizumab =300.0000 mg/10ml In House Specification Active
Indications:	For the treatment of Subjects with relapsing multiple sclerosis (relapsing remitting MS or active secondary progressive MS)

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Noble Hospital Private Limited, 153, Magarpatta City road, Hadapsar Pune Maharashtra - 411013	NOBLE HOSPITAL INSTITUTIONAL ETHICS COMMITTEE Noble Hospital Pvt. Ltd. Magarpatta City Road Pune, Maharashtra - 411013 India ECR/259/Inst/MH/2013/RR-24	Dr Shripad Pujari
2.	Medstar Multispeciality Hospital, 641, 17, 1, 3, kodigehalli main road, sahakarnagar, Bangalore Karnataka - 560092	Medstar Speciality Hospital Ethics Committee Medstar Speciality Hospital, No 641/17/1/3 Kodigehalli Main Road sahakarnagar Post Bangalore Bengaluru (Bangalore) Urban, Karnataka - 560092 India ECR/1324/Inst/KA/2019/RR-24	Dr Varadarajulu Reginald
3.	Yashoda Hospitals, Hitec city, Yashoda Healthcare Services Pvt. Ltd., Hitec city, cybertowerto JMtU road Hyderabad	Yashoda Academy of Medical Education and Research, Yashoda Hospitals, Behind Hari Hara kala Bhawan SP Road, Secunderabad, Hyderabad	Dr Rupam Borgohain

	Telangana - 500054	Telangana 500003 India ECR/49/Inst/AP/2013/RR-22	
4.	Atal Institute of Medical Super Specialities, AIMSS Shimla Himachal Pradesh - 171006	INSTITUTIONAL ETHICS COMMITTEE IGMC SHIMLA INDIRA GANDHI MEDICAL COLLEGE SHIMLA, PRINCIPAL OFFICE INDIRAGANDHI MEDICAL COLLEGE SHIMLA Shimla Shimla Himachal ECR/533/Inst/HP/2014/RR-25	Dr Sudhir Sharma
5.	Sahyadri Super Speciality Hospital, 185 A, Shasthrinagar, near MSEB office, yerwada Pune Maharashtra - 411006	Sahyadri Hospitals Private Limited Ethics Committee Sahyadri Hospitals Private Limited, Survey No 89 and 90 Plot No 54 Lokmanya Colony Kothrud Pune Maharashtra - 411038 India ECR/493/Inst/MH/2013/RR-24	Dr Nasli Ichaporia
6.	NRS Medical College and Hospital, 138, AJC Bose Road, Sealdah Kolkata West Bengal- 700014	Ethics Committee, N.R.S. Medical College, NRS Medical College And Hospital, NRS Medical College 138, A.J.C Bose Road Kolkata, Kolkata West Bengal - 700014 India ECR/609/Inst/WB/2014/RR-25	Dr Manamita Mondal
7.	Medipoint Hospitals Pvt. Ltd., 241-1, new D.P. road, Aundh, Pune Maharashtra - 411007	Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd 241/1, New D.P. Road, Near Sai Heritage, Aundh Pune Maharashtra - 411007 India ECR/357/Inst/MH/2013/RR-25	Dr Pande Amit kumar Vardhaman
8.	Max Superspeciality Hospital, Vaishali, W-3, Sector-1, Vaishali Ghaziabad Uttar Pradesh - 201012	Institutional Ethics Committee, Max Super Speciality Hospital, Vaishali, W-3, Sector -1 Vaishali, Ghaziabad, Uttar Pradesh - 201012 India ECR/360/Inst/UP/2013/RR-24	Dr Kamakshi Dhamija
9.	Nizams Institute of Medical Sciences, Nizams Institute of Medical Sciences Punjagutta Hyderabad Telangana - 500082	NIMS Institutional Ethics Committee, Nizams Institute Of Medical Sciences Punjagutta, Hyderabad, Telangana 500082 ECR/303/Inst/AP/2013/RR-24	Dr Reshama Sultana

10.	Dr D Y Patil Medical College, Hospital and Research Centre, Sector 5, Nerul, Navi Mumbai Mumbai Maharashtra - 400706	Institutional Ethics Committee of Aayush Hospital, 102-1, 1st Floor, Laxman Arcade Vivekanand Co-op, Hsg 90 Feet Road Dharavi Mumbai City, Maharashtra - 400017 India ECR/361/Inst/MH/2013/RR-24	Dr Pradeep Tiwari
11.	Postgraduate Institute of Medical Education and Research, Department of Neurology, Ground Floor, Block A, Nehru Hospital, Postgraduate Institute of Medical Education and Research PGIMER, Sector 12, Chandigarh Chandigarh -160012	Institutional Ethics Committee, R No, 6006, 6th Floor, Research Block B (P N Chuttani Block), PGIMER, Sector 12, Chandigarh ECR/25/Inst/CH/2013/RR-25	Dr Dheeraj Khurana
12.	Sparsh Superspecilaity Hopsital, 146 Infantry Road, opp commissioners office Bangalore Karnataka - 560001	Institutional Ethics committee Sparsh Hospital, Sparsh Hospital For Advanced surgeries No. 146 Oppostite Police commissioner Office Infantry Road Bangalore Bengaluru (Bangalore) Urban Karnataka – 560001 ECR/520/Inst/KA/2013/RR-25	Dr Rajesh B Iyer
13.	AIIMS Bilaspur, VPO Kothipura, Bilaspur Himachal Pradesh - 174037	Institutional Ethics Committee Clinical Trials, All India Institute of Medical Sciences, Village Kothipura, Bilaspur, Himachal Pradesh -174037 ECR/1808/Inst/HP/2023	Dr Ashish Sharma
14.	Shree Gangaram Hospital, Sir Ganga Ram Hospital SGRH Marg, Rajendra Nagar Delhi Delhi - 110060	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital, Ethics Committee, Sir Ganga Ram Hospital Old Rajinder Nagar New Delhi - 110060 India ECR/20/Inst/DL/2013/RR-24	Dr Anshu Rohatgi
15.	City Neurology Centre, S 8-110A Hamrautia, Back Side of Gautam Upvan, Maqbool Alam Road Varanasi Uttar Pradesh-221002	Shubham Sudbhawana Super. Hosp. Ethics Committee, Shubham Sudbhawana Superspeciality Hospital, B 31/80, 23B - Bhogabeer, Lanka, Varanasi, UP - 221005 India ECR/667/Inst/UP/2014/RR-20	Dr Abu Zafar Ansari

16.	Rajalakshmi Hospital and Research centre, 21-1 Lakshmipura Main Road, Vidyaranyapura Post Bangalore Karnataka - 560097	Rajalakshmi Hospital Institutional Ethics Committee Rajalakshmi Hospital 21/1, Lakshmi Pura, Main Road, Opp. Lakshmipura Lake, Vidyaranyapura Post, Bangalore Bengaluru (Bangalore) Urban Karnataka – 560097 ECR/809/Inst/KA/2017/RR-25	Dr Janardhan DC
17.	Karnataka Medical College and research institute, Old PB road, Vijaynagar, Hubbali Karnataka- 580022	KMCRI ETHICS Karnataka Medical College And Research Institute, Office of the Principal Vidyanagar HUBBALLI, Dharwad Karnataka - 580021 India ECR/486/Inst/KA/2013/RR-25	Dr Amruth
18.	Sardar Vallabhbhai Patel Institute of Medical Sciences and Research, SVPIMSR, Nr VS Hospital, Ellisbridge, Ahmedabad Gujarat - 380006	Institutional Ethics Committee, NHLIEC Smt. NHL Municipal Medical College, V S Hospital Campus, Ellis bridge, Ahmedabad Gujarat - 380006 India ECR/245/Inst/GJ/2013/RR-24	Dr Shalin D Shah

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