



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  
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E-Mail : dci@nic.in

**File No. CT/23/000049**

To,

M/s Worldwide Clinical Trials India Private Limited,  
Unit No. 9, Corporate Park II, 9th Floor, V N Purav Marg,  
Near Swastik Chambers, Chembur (E) Mumbai (India) - 400071.

Sir,

With reference to your application No. GCT/CT04/FF/2023/37494 (GCT/49/23) dated 08-05-2023, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and Entyvio® for the induction and maintenance of clinical response and remission. (UCESIVE)” Protocol No: PB016-03-01; Final V1.0, dated 01/Dec/2022 with a total of up-to 150 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) **The primary endpoint should be demonstrated at week 10 instead of week 6;**
- (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 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 Worldwide Clinical Trials India Private Limited, 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: PB016-03-01; Final V1.0, dated 01/Dec/2022** 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 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:

<b>Names of the new drug or investigational new drug</b>	PB016 (Vedolizumab) Powder for Concentrate for Solution for Infusion 300 mg
<b>Therapeutic class:</b>	Antagonist
<b>Dosage form:</b>	Powder for concentrate for solution for infusion
<b>Composition:</b>	Vedolizumab = 300.0000 milligram (mg) Not Applicable(NA) Active
<b>Indications:</b>	PB016 will be used for treatment of ulcerative colitis, crohn's disease and pouchitis

**File No. CT/49/23-DCG(I)****Annexure:**

Details of clinical trial site:

<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
Gastroplus Digestive Diseases Centre, D Block, 3 <sup>rd</sup> Floor, Galaxy Bazaar, Sunrise Park Road, Vastrapur, Ahmedabad-380054, Gujarat, India	Gastroplus Ethics Committee, Gastroplus Digestive Diseases Centre, D Block, 3 <sup>rd</sup> Floor, Galaxy Bazaar, Sunrise Park Road, Vastrapur, Ahmedabad-380054, Gujarat, India  ECR/1207/Inst/GJ/2019RR-22	Dr. Gaddhe Ravindra Laxmanbhai
ICON Hospital, Opp. Alpha One Mall, B/S KalyanPushti Haveli, Nr. Vastrapur Lake, Vastrapur, Ahmedabad-380015	Shrey Hospital Institutional Ethics Committee  ECR/1302/Inst/GJ/2019	Dr. Manish Bhatnagar
Gujarat Hospital-Gastro and Vascular Centre, Opposite Shree Ram Petrol Pump, Anand Mahal Road, Adajan, Surat, Gujarat-395009, India	Unity Hospital Ethics Committee, Unity Trauma Centre and ICU, N-4 Janki Park Society, Aai Mata Road, Parvat Patiya, Surat, Gujarat-395010, India  ECR/1226/Inst/GJ/2019	Dr. Saumin Prakashbai Shah
Shree Giriraj Hospital, 27-Navjyot Park Corner, 150 Feet Ring Road, Rajkot-360005, Gujarat, India	Shree Giriraj Hospital Research Ethics Committee  ECR/74/Inst/GJ/2013/RR-19	Dr. Chetan Nalin Mehta
Institute of Digestive & Liver Diseases, Dispur Hospitals Pvt Ltd, Ganeshguri, Guwahati - 781006, Assam, India	Ethics Committee Dispur Hospitals Pvt Ltd, Ganeshguri, Guwahati-781006, Assam, India  ECR/622/Inst/AS/2013/RR-21	Dr. Bhabadev Goswami
S.R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden Behind HSBC Bank Sardar Patel Marg, C-Scheme, Jaipur-302001, Rajasthan, India	S.R. Kalla Memorial Ethical Committee for Human Research  ECR/8/Inst/Raj/2013/RR-19	Dr. Mukesh Kalla
SIDS Hospital and Research Centre, A Unit of SIDS Healthcare Pvt. Ltd., JJ Empire and Tapi Villa Building, Vijaynagar gate No. 3, Opposite Gandhi Engineering College, Majura Gate, Ring Road, Surat-395002, Gujarat, India	Surat Institute of Digestive Sciences Ethics Committee, Surat Institute of Digestive Sciences, SIDS Hospital and Research Centre, A Unit of SIDS Healthcare Pvt. Ltd., JJ Empire and Tapi Villa Building, Vijaynagar gate No. 3, Opposite Gandhi Engineering College, Majura Gate, Ring Road, Surat-395002, Gujarat, India	Dr. Mehta Rajiv Manhar

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	ECR/813/Inst/GJ/2016/RR-19	
Midas Multispeciality Hospital Pvt. Ltd., Midas Heights, 07 Central Bazar Road, Ramdaspath, Nagpur-440010 (MS), India	Ethics Committee of Midas Multispeciality Hospital, Midas Multispeciality Hospital Pvt. Ltd., Midas Heights, 07 Central Bazar Road, Ramdaspath, Nagpur-440010 (MS), India  ECR/494/Inst/MH/2014/RR-20	Dr. Mukewar Shrikant Vasantrya
Dharamshila Narayana Superspeciality Hospital, Dharamshila Marg, Vasundhara Enclave, Near New Ashok Nagar Metro Station, New Delhi 110096	Institutional Ethics Committee  ECR/226/Inst/DL/2013/RR-22	Dr. Mahesh Gupta
All India Institute of Medical Sciences, Gastroenterology and Human Nutrition Unit, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029	Institute Ethics Committee, All India Institute of Medical Sciences, Room No. 102, First Floor, Old O.T. Block, Ansari Nagar, New Delhi-110029  ECR/538/Inst/DL/2014/RR-20	Dr. Vineet Ahuja
MS Ramaiah Medical College and Hospitals, MS Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India	Ethics Committee, M S Ramaiah Memorial Hospitals, MS Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India  ECR/215/Inst/KA/2013/RR-22	Dr. Avinash Balekuduru
Unity Trauma Centre and ICU (Unity Hospital), Nr. D.R. World, Opp Raghuvir Business Empire, Aai Mata Road, Parvat Patiya, , Surat, Gujarat-395010, India	Unity Hospital Ethics Committee, Unity Trauma Centre and ICU, N-4 Janki Park Society, Aai Mata Road, Parvat Patiya, , Surat, Gujarat-395010, India  ECR/1226/Inst/GJ/2019	Dr. Pintukmar Devshibhai Bhakhar
SMS Super Speciality Hospital, Vivekananda Marg, C-Scheme, Jaipur-302004, Rajasthan, India	Ethics Committee, S.M.S. Medical College and attached Hospitals, Jaipur, Office of Ethics Committee, Second Floor, New Academic Block, S.M.S. Medical College, J.L.N. Marg, Jaipur-302004, Rajasthan, India  ECR/26/Inst/RJ/2013/RR-19	Dr. Sandeep Nijhawan
Sai Medicity Pvt. Ltd. Hospital, Rohit Nagar, Naria, Varanasi, Uttar Pradesh-221005	Ethics Committee of Sai Medicity Pvt. Ltd  ECR/1660/Inst/UP/2022	Dr. Vivekanand Rai
Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar-800014	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar-800014	Dr. Vishwa Mohan Dayal

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	ECR/640/Inst/BR/2014/RR-20	
Vydehi Institute of Medical Sciences & Research Centre #82, EPIP Area, Whitefield, Bangalore-560066, Karnataka , India	Vydehi Institute of Medical Sciences & Research Centre #82, EPIP Area, Whitefield, Bangalore-560066, Karnataka. India ECR/747/ Inst/KA/2015/ RR-21	Dr. Praveen Mathew
Department of Gastroenterology & Hepatology, Kasturba Medical College and Hospital, Manipal-576104	MAHE (Manipal Academy of Higher Education) Ethics Committee, Mezzanine floor of KMC Old Library Building, MAHE, Manipal-576104 ECR/191/Inst/KL/2013/RR-19	Dr. Ganesh Pai Cannanore
Room No. 220, GMCANA Building, Government General Hospital, Guntur, AP-522001	Institutional Ethics Committee, GMC & GGH, Guntur, Kannavarithota, Guntur ECR/467/Inst/AP/2013/RR-19	Dr. Anumula Kavitha
Department of Surgical Gastroenterology, Gandhi Memorial & Associated Hospital, King George Medical University Lucknow, Uttar Pradesh-226003, India	Institutional Ethics Committee, King George Medical University Lucknow, Uttar Pradesh-226003, India ECR/262/Inst/UP/2013/RR-19	Dr. Abhijit Chandra
Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan ECR/1156/Inst/RJ/2018/RR-22	Dr. Manoj Kumar
Jeevan Rekha Critical Care and Trauma Hospital, Jeevan Rekha Marg, S-24, Mahal Yojna, Jagatpura, Jaipur-302025, Rajasthan, India	Jeevan Rekha Ethics Committee, Jeevan Rekha Critical Care and Trauma Hospital, Jeevan Rekha Marg, S-24, Mahal Yojna, Jagatpura, Jaipur-302025, Rajasthan, India ECR/1314/Inst/RJ/2019	Dr. Saket Kumpawat
Sterling Hospital, Opp. Inx, race Course Circle (West), Vadodara-390007, Gujarat, India	Sterling Ethics Committee ECR/528/Inst/GJ/2014/RR-20	Dr. Jain Pankaj Kumar
Department of Gastroenterology, NPR Block, 1st Floor, Liver care Unit, Research wing Osmania general Hospital, Afzalgunj, Hyderabad-500012, Telangana, India	Osmania Medical college Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana, India ECR/300/Inst/AP/2013/RR-19	Dr. B. Ramesh Kumar

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Yashoda Hospitals, Behind Hari Hara Kala Bhavan, SP Road, Secunderabad-500003, Telangana, India	Yashoda Academy of Medical Education and Research ECR/49/Inst/AP/2013/RR-22	Dr. B Ravi Shankar
Rahate Surgical Hospital and ICU, Near Telephone Exchange CA Road, Nagpur Maharashtra	Ethics Committee Rahate Surgical Hospital and ICU, 517 Kolabaswami Square, Central Avenue Road, Juni Mangalwari, Near Telephone Exchange, Nagpur-440008, MS, India ECR/601/Inst/MH/2014/RR-17	Dr. Prashant V. Rathe
Vishwaraj Multispeciality Hospital, Gate no. 499, Kadamvakvasti solapur Road, Loni Kalbhor Pune, Maharashtra-412001	Ethics Committee of MAEER'S Vishwaraj Multispeciality Hospital, Gate no. 499, Kadamvakvasti solapur Road, Loni Kalbhor Pune, Maharashtra-412001 ECR/1138/Inst/MH/2018/RR-21	Dr. Ksheetij Kothari
Apex Wellness Hospital, Survey no. 799, Plot No. 187, Behind Prakash Petrol Pump, Govind Nagar, Nashik, Maharashtra, India	Apex Wellness Ethics Committee, Apex Wellness Hospital, Survey no. 799, Plot No. 187, Behind Prakash Petrol Pump, Govind Nagar, Nashik, Maharashtra, India EC/NEW/Inst/2020/10264	Dr. Nitin Chintaman Borse
Yashoda Hospitals, Raj Bhavan Road, Somajiguda, Hyderabad-500082, Telangana, India	Institutional Ethics Committee, Yashoda Academy of Medical Education and Research, Yashoda Group of Hospitals, Yashoda Hospital, Behind Hari Hara Kala Bhavan, S.P. Road, Secunderabad-500003, Telangana State ECR/49/Inst/AP/2013/RR-22	Dr. Kiran Kumar Peddi
Grant Medical Foundation, Ruby Hall Clinic, 40 Sassoon Road, Pune-411001, Maharashtra, India E4-C to E4-F, 4 <sup>th</sup> Floor, Fifth Avenue, Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India	Institutional Ethics Committee, Poona Medical Research Foundation, E4-C to E4-F, 4 <sup>th</sup> Floor, Fifth Avenue, Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-22	Dr. Pai Nitin Vikas
Department of Gastroenterology, SP Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India	Institutional Ethics Committee SP Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India ECR/27/SP/Inst/RJ/2013/RR-19	Dr. Vinita Chaudhary

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KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India	Institutional Ethics Committee, KLE University's KLE Dr PK Hospital & MRC, Nehrunagar, Belagavi-590010, Karnataka, India  ECR/211/Inst/KA/2013/RR-19	Dr. Santosh Hajare
Chopda Medicare & Research Centre Pvt. Ltd., Magnum Heart Institute, 3/5 Patil Lane No. 1, Laxmi Nagar, Near K.B. H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India  Chopda Medicare & Research Centre Pvt. Ltd, Magnum Heart Institute, Clinical Research Department, Flat No. 10, Laxmanrekha Apartment, Behind magnum Heart Institute, Patil Lane No. 1, Canada Corner, Nashik-422005, Maharashtra, India	Magna-Care Ethics Committee, Chopda Medicare & Research Centre Pvt. Ltd., Magnum Heart Institute, Canada Corner, Nashik-422005, Maharashtra, India  ECR/79/Inst/MH/2013/RR-19	Dr. Tushar Hiralal Sankalecha
BGS Gleneagles Global Hospitals, #67, Uttarahalli Main Road, Kengeri, Bengaluru-560060, Karnataka, India	Institutional Ethics Committee, BGS Gleneagles Global Hospitals, #67, Uttarahalli Main Road, Kengeri, Bengaluru-560060, Karnataka, India  ECR/128/Inst/KA/2013/RR-19	Dr. Bhuvan Shetty
Inpatient Block, 5 <sup>th</sup> Floor, Department of Gastroenterology, Gandhi Hospital, Musheerabad, Secunderabad, Telangana-500003	Institutional Ethics Committee, Gandhi Medical/Hospital College, Musheerabad, Secunderabad, Telangana-500003  ECR/180/Inst/AP/2013/RR-19	Dr. P. Shravan Kumar
Gleneagles Global Health City, No. 439, Cheran Nagar, Perumbakkam, Chennai-600100	Institutional Ethics Committee, Gleneagles Global Health City, No. 439, Cheran Nagar, Perumbakkam, Chennai-600100  ECR/44/Inst/TN/2013/RR-19	Dr. B. Mahadevan
Samvedna Hospital, B27/88G. New Colony. Ravindrapuri Varanasi-221005	Samvedna Hospital Ethics Committee  ECR/45/Inst/UP/2013/RR-20	Dr. Hemant Kumar Gupta
Sri Ramakrishna Hospital, No. 395, Sarojini Naidu Road, Sidhapudur, Coimbatore, Tamil Nadu-641044, India	Sri Ramakrishna Hospital Ethics Committee, Sri Ramakrishna Hospital, No. 395, Sarojini Naidu Road, Sidhapudur, Coimbatore,	Dr. M. Murugesh

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	Tamil Nadu-641044, India ECR/690/Inst/TN/2014/RR-21	
VGM Hospital, 2100 Trichy Road, Coimbatore, TamilNadu-641005	Institutional Ethics Committee, VGM Hospital-Institute of Gastroenterology ECR/217/Inst/TN/2013/RR-20	Dr. V.G. Mohanprasad
AIG Hospitals, Plot No 2/3/4/5, Survey No 136/1 Mindspace Road, Gachibowli, Hyderabad - 500032, Telangana, India	Institutional Ethics committee Asian Institute of Gastroenterology (IEC-AIG) 6-3-661, Somajiguda, Hyderabad, Telangana, India-500082 ECR/346/Inst/AP/2013/RR-22	Dr. Rupa Banerjee
Gastrohub Hospital, Royal Radiance Next to Spot 18, Jagtap Diary, Sai Chowk, Pimple Saudagar, Pune, Maharashtra-411027	Royal Pune Independent Ethics Committee ECR/RENEW/IND/2019/4715	Dr. Mahesh Mahadik
F-92, 1 Floor Institute of liver Gastroenterology and Pancreatico Biliary Sciences, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060	Room No. 402, 6 <sup>th</sup> Floor, Old Building, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060 ECR/20/Inst/DL/2013/RR-19	Dr. Naresh Kumar Bansal

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