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/24/000081

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/2024/43829 dated 14-Jun-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled, "**A Parallel-Group Treatment, Double-Blind, 2-Arm Study to Investigate the Comparative Efficacy, Safety, and Immunogenicity Between Intravenous AVT16 and Entyvio® in Male and Female Subjects Aged 18 to 80 Years Inclusive With Moderate to Severe Active Ulcerative Colitis" Protocol No. AVT16-GL-C01 version 3.0 (protocol amendment 2.0) dated 02-FEB-2024 with a total of up-to 109 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, Stool, 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 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
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
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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. AVT16-GL-C01 version 3.0 (protocol amendment 2.0) dated 02-FEB-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 _____

RAJEEV SINGH RAGHUVANSHI

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(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	AVT16 (INN Vedolizumab)
Therapeutic class:	Recombinant Humanized IgG1 Monoclonal
Dosage form:	Solution for Infusion
Composition:	AVT 16=300.000 U.S.P.,Ph. Eur Active
Indications:	Moderate to Severe Active Ulcerative Colitis

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Fortis Hospital Noida, B-22, Sector-62 Noida Uttar Pradesh -201301	Fortis Hospital Institutional Ethics Committee Room no –1341, IPD 3rd floor, Fortis Hospital-NoidaB-22, Sector-62, Noida, Uttar Pradesh, India -201301 ECR/69 /Inst/UP /2013/RR-20	Dr Ajay Bhalla
2.	Lokmanya Tilak Municipal Medical College and Lokmanya Tilak Municipal General Hospital, Department of Gastroenterology, Sion West, Mumbai-400022, Maharashtra	Institutional Ethics Committee Human Research Lokmanya Tilak Municipal Medical College & General Hospital, L.T.M Medical College Building, 2ndfloor, Room No. 17, Sion, Mumbai-400022, Maharashtra, India ECR/266/Lokmanya/Inst/MH/2013	Dr Meghraj Ingle
3.	S R Kalla Memorial Gastro and General Hospital, 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur Rajasthan -302001	S R Kalla Memorial Ethical Committee For Human Research 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur-302001 Rajasthan, India ECR/8/Inst/Raj/2013/RR-24	Dr Mukesh Kalla
4.	KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar Belagavi, Karnataka –59001, India	Institutional Ethics Committee, KLE University's KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, JNMC Campus, Nehrunagar Belagavi, Karnataka - 590010, India ECR/211/Inst/KA/2013/RR-19	Dr Santosh Hajare
5.	Sushruta Multispecialty Hospital and Research Centre Pvt. Ltd., P.B. Road, Vidyanagar Hubballi-580021, Karnataka, India	Sushruta Hospitals Ethics Committee, P.B. Road, Vidyanagar, Hubbali-580021, Karnataka ECR/372/Inst/KA/2013/RR-19	Dr Laxmikant Desai
6.	Yashoda Hospitals, Behind HariHara Kala Bhavan, SP Road, Secunderabad Telangana -500003	Institutional Ethics Committee Yashoda Academy of Medical Education and Research (IEC-YAMER) Yashoda Hospital, Behind Harihara Kala Bhavan, Secunderabad-500003 (Telangana) ECR/49/Inst/AP/2013/RR-22	Dr B Ravi Shanka

7.	Sterling Hospital, Racecourse Opp Inox, near Natubhai circle, Harinagar west Vadodara Gujarat -390007	Sterling Ethics Committee Sterling Hospital, Racecourse, Opp Inox, near Natubhai circle, Harinagar west Vadodara Gujarat -390007, India ECR/582/Inst/GJ/2014/RR-20	Dr Pankaj Jain
8.	Gujarat Gastro and Vascular Hospital, Opposite Shree Ram Petrol Pump, Anand Mahal Road, Adajan, Surat, Gujarat -395009, India	Unity Hospital Ethics Committee, Unity Trauma Center and ICU, N-4 Janki Park Society Aai Mata Road, Paravat Patiya, Surat, Gujarat, -395010, India ECR/1226/Inst/GJ/2019	Dr Saumin P Shah
9.	Sheth Vadilal Sarabhai General Hospital, Sheth Vadilal Sarabhai General Hospital Madalpur Gam, Paldi Road, Ellisbridge Ahmedabad Gujarat -380006	Sangini Hospital Ethics Committee, First floor, Sangini Hospital, Santorini Square, Opp. Star Bazar Lane, B/H Abhishree Complex Satellite, Ahmedabad-380015, Gujarat ECR/147/Inst/GJ/2013/RR-19	Dr Parth Shah
10.	Dispur Hospitals Private Limited, Institute of Digestive and Liver Diseases Ganeshguri Guwahati Assam –781006, India	Ethics Committee Dispur Hospitals Pvt Ltd Ganeshguri, Guwahati-781006, Assam, India ECR/622/Inst/AS/2013/RR-21	Dr Bhabadev Goswami
11.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg Rajinder Nagar New Delhi Delhi -110060	Sir Ganga Ram Hospital Ethics Committee ECR/20/Inst/DL/2013/RR-19	Dr Anil Arora
12.	Indira Gandhi Institute of Medical Sciences, Department of Gastrosurgery, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar –800014	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar -800014 India ECR/640/Inst/BR/2014/RR-20	Dr Saket Kumar
13.	Acharya Vinoba Bhave Rural Hospital, Sawangi-Meghe Wardha Maharashtra -442004	Institutional Ethics Committee, Datta Meghe Institute of Higher Education & Research, Sawangi (Meghe), Wardha-442107, Maharashtra, India ECR/440/Inst/MH/2013/RR-19	Dr Vijendra Kirnake
14.	Max Super Speciality Hospital, Vaishali, A Unit of Crosslay Remedies Ltd., W-3, Sector-1, Vaishali, Ghaziabad -201012, Uttar Pradesh, India	Institutional Ethics Committee, Max Super Speciality Hospital, Vaishali, A Unit of Crosslay Remedies Ltd., Max Super Speciality Hospital, Vaishali, Ghaziabad-201012, Uttar Pradesh, India ECR/360/Inst/UP/2013/RR-19	Dr Premashis Kar

15.	Government Medical College, Department of Medical Gastroenterology Government Medical College, Medical College PO Thiruvananthapuram, Kerala - 695011	Human Ethics committee Govt Medical College, Medical College P.O, Thiruvananthapuram-695011, Kerala, India. ECR/370/Inst/Ker/2013/RR-20	Dr. Krishnadas Devadas
16.	Samvedna Hospital, B27/88G New Colony, Ravindrapuri Varanasi, Uttar Pradesh - 221005	Samvedna Hospital Ethics Committee, B 27/88G, New Colony, Ravindrapuri, Varanasi, 221005, Uttar Pradesh, India ECR/45/Inst/UP/2013/RR-20	Dr Hemant Kumar Gupta
17.	P.D. Hinduja National Hospital and Medical Research Centre, Veer Savarkar Marg, Mahim Mumbai –400016, Maharashtra	Institutional Ethics Committee (IEC) 21st floor, Research Department, S2 building, P.D. Hinduja Hospital & Medical Research Centre, Veer Savarkar Marg, Mahim, Mumbai-400016 ECR/61/Inst/MH/2013/RR-19	Dr Devendra Desai
18.	SIDS Hospital and Research Centre, A unit of SIDS Healthcare Pvt. Ltd., Off Ring Road, Near Shell Petrol Pump, Ring Road-Sosyo circle lane Surat –395002, Gujarat, India	Surat Institute of Digestive Sciences Ethics Committee, SIDS Hospital and Research Centre, A unit of SIDS Healthcare Pvt. Ltd., Off Ring Road, Near Shell Petrol Pump, Ring Road-Sosyo circle laneSurat –395002, Gujarat, India ECR/813/Inst/GJ/2016/RR-19	Dr Mayank Kabrawala
19.	SMS Super speciality Hospital, Department of Gastroenterology, Vivekanand Marg, C-Scheme, Jaipur Rajasthan -302004	Ethics Committee S.M.S Medical College and Attached Hospitals, 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 Gaurav Kumar Gupta
20.	Shree Giriraj Hospital, 27 Navjyot Park Corner, 150 feet ring road, Rajkot, Gujarat - 360005	Shree Giriraj Hospital Research Ethics Committee 27-Navjyot Park Corner, 150 feet ring road, Rajkot, Gujarat -360005 ECR/74/INST/GJ/2013/RR-19	Dr Chetan Nalin Mehta
21.	GSVM Medical College, Swaroop Nagar Kanpur Uttar Pradesh -208002	ETHICS COMMITTEE GSVM MEDICAL COLLEGE Room No. 125, First Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002 ECR/680/Inst/UP/2014/RR-20	Dr Vinay Kumar
22.	ICON Hospital, Beside Kalyan Pushti Haveli, Opposite Alpha One (Ahmedabad One) Mall Exit, Near Vastrapur Lake, Vastrapur, Ahmedabad Gujarat -380015	Shrey Hospital Institutional Ethics Committee Shrey Hospital Pvt Ltd, 270/B/5 near AMCO bank, Stadium circle, Navrangpura, Ahmedabad, 380009, Gujarat, India ECR/1302/Inst/GJ/2019	Dr Manish Bhatnagar

23.	Midas Hospital, 392, Behind Empress Palace, Opposite Singh Saab Dhaba, Wardha Road, Parsodi Nagpur Maharashtra -441108	Institutional Ethics Committee Midas Multispeciality Hospital Pvt Ltd. Midas Hospital, 392, Behind Empress Palace, Opposite Singh Saab Dhaba, Wardha Road, Parsodi Nagpur Maharashtra - 441108 ECR/494/Inst/MH/2014/RR-20	Dr Shrikant Vasantrao Mukewar
24.	Gastroplus Hospital, 3rd Floor, D-Block, Galaxy Bazar, Sunrise Park Road Ahmedabad -380054, Gujarat	Gastroplus Ethics Committee Gastroplus Digestive Centre, D block, 3rd floor, Galaxy Bazar, Sunrise Park Road, Vastrapur-380054, Ahmedabad ECR/1207/Inst/GJ/2019/RR-22	Dr Ravindra Gaadhe

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