



File No. BIO/CT/24/000035

Dated 05-09-2024

To

M/s INTAS PHARMACEUTICALS LIMITED,
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad 380054,
Gujarat, INDIA

Subject: Application for grant of permission to conduct Clinical trial titled "A Phase 3, Randomized, Double-Blind, Multicenter, Active Controlled, Two-Arm, Parallel Group Study to Compare the Efficacy, Safety, Immunogenicity and Pharmacokinetics of the Proposed Biosimilar of Vedolizumab (INTP53) Intravenous Injection and Vedolizumab Reference for Induction and Maintenance Therapy in Patients with Moderate to Severe Active Ulcerative Colitis" vide protocol no. 0046-24 Version 1.0 dated 23.02.2024 – regarding.

Ref.: Your Application No BIO/CT04/FF/2024/42511 dated 21-03-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2024/42511 dated 21-03-2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019. Further the Insurance certificate mentioning the protocol number and number of subjects should be submitted to CDSCO before initiating the trial.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (I) 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;
- (II) 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;
- (III) 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;
- (IV) 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;
- (V) 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;
- (VI) 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;

- (VII) 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;
- (VIII) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;
- (IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
- (X) 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 Licensing 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;
- (XI) 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;
- (XII) 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;
- (XIII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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;
- (XIV) 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;
- (XV) The Central Licensing 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;
- (XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVII) 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.
- (XVIII) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.
- (XIX) 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.
- (XX) The firm should submit Clinical study report (CSR) to this office after completion of trial.

RAJEEV SINGH
RAGHUVANSHI

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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
COMMISSION, ou=HEALTH AND FAMILY WELFARE
DEPARTMENT, ou=CENTRAL DRUGS STANDARD
CONTROL, email=rajeev.singh@cdsc.gov.in,
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

The Central Licencing Authority hereby permits M/s INTAS PHARMACEUTICALS LIMITED, Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380054, Gujarat, INDIA Telephone No. 07939837000 FAX: 912717661106 E-Mail: SANJAY_DIXIT@INTASPHARMA.COM to conduct clinical trial of the new drug or investigational new drug study titled **“A Phase 3, Randomized, Double-Blind, Multicenter, Active Controlled, Two-Arm, Parallel Group Study to Compare the Efficacy, Safety, Immunogenicity and Pharmacokinetics of the Proposed Biosimilar of Vedolizumab (INTP53) Intravenous Injection and Vedolizumab Reference for Induction and Maintenance Therapy in Patients with Moderate to Severe Active Ulcerative Colitis”** vide protocol no. 0046-24 Version 1.0 dated **23.02.2024** in the below mentioned clinical trial site(s).

2. Details of 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: 05.09.2024

**RAJEEV SINGH
RAGHUVANSHI**

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:**Details of new drug or investigational new drug:**

Name of the new drug or investigational new drug	Vedolizumab powder for concentrate for solution for infusion 300mg/vial		
Therapeutic class	Immunosuppressant		
Dosage form:	Powder for concentrate for solution for infusion		
Composition:	Name of Ingredient	Function	Quantity mg/ml
	Vedolizumab In house	Active ingredient	60.00 mg
	L-Histidine USP, BP/Ph.Eur., JP	Buffering agent	4.59 mg
	L-Histidine monohydrochloride BP/Ph.Eur./JP	Buffering agent	4.28 mg
	Sucrose Ph.Eur., In-house	Stabilizer, tonicity modifier and bulking agent	80.00 mg
	Glycine USP, Ph.Eur., BP, JP, ChP.	Stabilizer, tonicity modifier and bulking agent	30.00 mg
	L-lysine HCl USP/BP/Ph.Eur.	Viscosity reduce	8.00 mg
	L-methionine Ph.Eur.	Anti-oxidant	0.75 mg
	Polysorbate 80 USP, Ph.Eur., JP	Surfactant	0.60 mg
Indications:	Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF) antagonist.		

Details of clinical trial site(s):

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	SIDS Hospital and Research Centre, A Unit of SIDS Healthcare Private Limited. Off Ring Road, Near Shell Petrol Pump, Ring Road- Sosyo Circle lane, Surat- 395002, Gujarat, India	Surat Institute of digestive sciences EC A unit of SIDS healthcare Pvt.Ltd J J Empire Vijay Nager-3, Beside Nirmal Bhavan, Majura Gate Surat - 395002, Gujarat, India. <u>EC Reg. No.</u> ECR/813/Inst/GJ/2016/RR-19.	Dr. Kabrawala Mayank Vasantlal

2	Gandhi Hospital Inpatient block, 5th Floor, Dep. of Gastroenterology, Gandhi Hospital, Musheerabad, Secunderabad (Hyderabad) - 500003, Telangana, India.	Institutional Ethics Committee GANDHI MEDICAL COLLEGE AND HOSPITAL MUSHEERABAD SECUNDERABAD Hyderabad-500003, Telangana, India <u>EC Reg. No.</u> ECR/180/Inst/AP/2013/RR-19	Dr. P. Shrvan Kuma
3	Samvedna Hospital, B 27/88G, New colony, Ravindrapuri, Varanasi-221005, Uttar Pradesh, India.	Samvedna Hospital Ethics Committee, Samvedna Hospital, B-22/88 G New Ravindra Puri Colony, Varanasi, Uttar Pradesh-221005 India. <u>EC Reg. No.</u> ECR/45/Inst/UP/2013/RR-20	Dr. Hemant kumar Gupta
4	G.S.V.M. Medical College, Swaroop Nagar, Kanpur Nagar-208002, Uttar Pradesh, India	ETHICS COMMITTEE GSVM MEDICAL COLLEGE, KANPUR, SWAROOP NAGAR, Kanpur Nagar, Uttar Pradesh - 208002, India. <u>EC Reg. No.</u> ECR/680/Inst/UP/2014/RR-20	Dr. Vinay Kumar
5	NRS Medical College And Hospital, 138, A.J.C Bose Road, Sealdeah, Kolkata, West Bengal - 700014, India.	Ethics Committee, N.R.S. Medical College NRS Medical College And Hospital NRS Medical College 138, A.J.C Bose Road, Kolkata, West Bengal - 700014, India. <u>EC Reg. No.</u> ECR/609/Inst/WB/2014/RR-20	Dr. Pinaki Roy
6	Post graduate Institute of Medical Education and Research, Sector- 12, Chandigarh- 160012, India.	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research, Room No. 6006, IEC Office, 6th Floor, P N Chuttani Block, Chandigarh - 160012 India. <u>EC Reg. No.</u> ECR/25/Inst/CH/2013/RR-20	Dr. Anupam Kumar Singh
7	TNMC BYL NAIR HOSPITAL Anand Rao Nair Road, Mumbai Central East Mumbai 400 008, Maharashtra, India.	Institutional Ethics Committee TNMC NAIR HOSPITAL, Topiwala National Medical College Nair Hospital, Dr A L Nair Road, Mumbai Central, Mumbai City, Maharashtra - 400008 India. <u>EC Reg. No.</u> ECR/22/Inst/Maha/2013/RR-19	Dr. Sanjay Jagdish Chandnani
8	Sir Sayajirao General Hospital, MedicalCollegeBaroda, Jail Road, Indian Avenue, Vadodara390001, Gujarat, India	Institutional Ethics Committee for Human Research, Medical College, BarodaMedical College, Baroda Anandpura, Vadodara - 390001, Gujarat India <u>EC Reg. No.</u> ECR/85/Inst/2013/RR-19	Dr. Keyur Madan Brahme

9	Government General Hospital, Room no. 220, Second Floor, GMCANA Building, Department of Gastroenterology, Guntur-522001, Andhra Pradesh, India.	ETHICS COMMITTEE GMC and GGH Guntur Medical College Kannavari Thota Main Road, Guntur - 522004, Andhra Pradesh, India. <u>EC Reg. No</u> ECR/467/Inst/AP/2013/RR-19	Dr. Anumula Kavitha
10	King George's Medical University, Department of Medicine, Shahmeena Road. Chowk, Lucknow 226003, Uttar Pradesh, India.	Institutional Ethics Committee King Georges Medical University, Shahmina Road, Chowk, Lucknow, Uttar Pradesh - 226003 India <u>EC Reg. No</u> ECR/262/Inst/UP/2013/RR-19	Dr. Ajay Kumar
11	Origin Hospital, A Unit of C.L.R.D.2-5-36/ CLRD 11, Chitalmet X Road, Near Pillar No. 177, PVNR Expressway, Attapur, Hyderabad - 500048, Telangana, India	Institutional Ethics Committee, Origin Hospital 2-5-36/CLRD/1 Chintalmet X Road, Rajendra Nagar(M), Ranga Reddy, Hyderabad - 500048, Telangana, India <u>EC Reg. No</u> ECR/1689/Inst/TG/2022	Dr. MD. Aejaaz Habeeb
12	Department of Gastroenterology, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi- 110026, India.	Maharaja Agrasen Hospital Institutional Ethics Corn, Maharaja Agrasen Hospital, Punjabi Bagh, New Delhi, West Punjabi Bagh, West Delhi, Delhi -110026 India. <u>EC Reg. No</u> ECR/745/Inst/DL/2015/RR-21	Dr. Vivek Bhatia
13	Prime Institute of Digestive Sciences LLP, Panchvati Society main Road, Atithi Chowk, Beside Chandresh Vadi, Rajkot, Gujarat- 360001, India	Prime Hospital Institutional Ethics committee Prime Institute Of Digestive Science LLP Plot Number 82 And 83, Atithi Chowk, Nr. Chandresh Vadi, Panchvati Main Road, Rajkot - 360001, Gujarat, India <u>EC Reg. No</u> ECR/1745/Inst/GJ/2022	Dr. Chintan Kansagra
14	MMFHA Joshi Hospital, 778, Opp. Kamala Nehru Park, Pune- 411004, India.	IEC MAHARASHTRA MEDICAL RESEARCH SOCIETY, Maharashtra Medical Foundation, Joshi Hospital, 778 Shivajinagar, Pune - 411004, Maharashtra, India <u>EC Reg. No</u> ECR/311/inst/MH/2013/RR-19	Dr. Sandeep Kulkarni
15	United CIIGMA Institute of Medical Sciences Pvt. Ltd. Plot No 6, 7, Survey No 10. Shahnoorwadi Dargah Road, Aurangabad, 431005, Maharashtra, India.	ECKMHGCH United CIIGMA Institute of Medical Sciences Pvt.Ltd. 3rd Floor, Plot No. 6,7 Survey No.10, Shahnoor Wadi, Dargah Road, Aurangabad-431005, Maharashtra, India. <u>EC Reg. No</u> ECR/45/Inst/MH/2013/RR-19	Dr. Takalkar Unmesh Vidyadha

16	Fortis Memorial Resrarch Institute, Sector 44 (Opp. Huda City Centre Metro Station), Gurugram-122002, Haryana, India.	IEC, Fortis Memorial Research Institute Fortis Memorial Research Institute Fortis Memorial Research Institute Sector-44 Gurugram, Haryana - 122002, India. <u>EC Reg. No.</u> ECR/223/Inst/HR/2013/RR-22	Dr. Gourdas Choudhari
17	PCMC'S PGI Yashwantrao Chavan Memorial Hospital, 2nd Floor, General Surgery Department, Sant Tukaram Nagar, Pimpri, Pune411018, Maharashtra, India.	Institutional Ethics Committee Yashwantrao Chavan Memorial Hospital, Pimpri. Sant Tukaram Nagar, Near D.Y.Patil Medical College, Vallabhnagar, Near Fire Brigade Station, Pimpri Pune, Maharashtra - 411018 India <u>EC Reg. No.</u> ECR/1236/Inst/MH/2019	Dr. Thorat Santosh Dashrath
18	MTES's Sanjeevan Hospital, Plot No. 23, Off Karve Road, Erandawane, Pune- 411004, India.	Ethics Committee Sanjeevan Hospital Sanjeevan Hospital Plot no 23 off Karve Road, Erandvane, Pune, Maharashtra - 411004, India. <u>EC Reg. No.</u> ECR/54/Inst/Maha/2013/RR-19	Dr. Kulkarni Bahar Dattatraya
19	Dr. D Y Patil Medical College, Hospital & Research Centre, Sector- 5, Nerul, Navi Mumbai400706, Maharashtra, India.	Institutional Ethics Committee D Y Patil Medical College, Sector 5, Nerul, Navi Mumbai, Thane, Maharashtra - 400706, India. <u>EC Reg. No.</u> ECR/195/Inst/MH/2013/RR-19	Dr. Ahire Dipak Sudam
20	SMS Super Speciali ty Hospital, Vivekanand Marg, C- Schema, Jaipur-302004, Rajasthan, India	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg, Jaipur- 302004, Rajasthan, India <u>EC Reg. No.</u> ECR/26/Inst/RJ/2013/RR-19	Dr. Sudhir Maharshi
21	Mission Gastro Hospital, 603 Golden Icon, Opp. Medilink Hospital, between Shivranjani Shyamal Cross Road 132 Fett Ring Rd. Satellite Ahmedabad-380015, Gujarat, India.	Shrey Hospital Institutional Ethics Committee Shrey Hospital Private Limited 270/B/5 Near AMCO Bank, Stadium Circle Navrangpura Ahmedabad- 380009, Gujarat, India <u>EC Reg. No.</u> ECR/1302/Inst/GJ/2019	Dr. Shah Chirag Narendrakumar
22	Rameswara Nursing Home Private Limited, 155/ I, C.I.T. Scheme - VIIM, CIT Rd, Bidhan Nagar, Murari Pukur, Ultadanga, Kolkata-700054, West Bengal, India.	Hurip Independent Bioethics Committee TAAB BIOSTUDY SERVICES 69 Ibrahimpur Road, Jadavpur, Kolkata- 700032, West Bengal, India. <u>EC Reg. No.</u> ECR/103/Indt/WB/2013/RR-19	Dr. Soumik Ghosh

23	Dr. Lunia Gastro Liver and advance Endoscopy Centre, Lunia Tower, Plot No. 05, Hanuman Nagar, Kalibadi Chauk, Raipur- 492001, Chhatisgarh, India.	IEC JEEVAN ANMOL HOSPITAL TAGORE NAGAR NEAR MALA GUEST HOUSE, Raipur- 492001, Chhattishgarh, India. <u>EC Reg. No.</u> ECR/1796/Inst/CG/2023	Dr. Manish Kumar Lunia
24	Gastro Plus Digestive Disease Centre, D- Block, 3rd Floor, Galaxy Bazar, Sunrise Park Road, Vastrapur, Ahmedabad- 380054, Gujarat, India.	Gastroplus Ethics Committee Gastroplus Digestive Disease Centre, D Block, 3rd floor, Galaxy Bazaar Sunrise park Road, Vastrapur, Ahmedabad - 380054, Gujarat, India. <u>EC Reg. No.</u> ECR/1207/Inst/GJ/2019/RR-22	Dr. Ravindra Laxman Bhai Gaadhe
25	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi 590010, Karnataka, India.	Institutional Ethics Committee, KLE University KLE University KLE Dr.PK Hospital and MRC Nehru Nagar, Belagavi (Belgaum), Karnataka - 590010, India. <u>EC Reg. No.</u> ECR/211/Inst/KA/2013/RR-19	Dr. Santosh Hajare
26	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer- 305001, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan – 305001, India. <u>EC Reg. No.</u> ECR/1156/Inst/RJ/2018/RR-22	Dr. Mahavir Prasad Sharma
27	Belagavi Institute of Medical Sciences, 3rd Floor, BIMS building, Dr. B R Ambedkar Road, Belagavi- 590001, Karnataka, India.	Institutional Ethics Committee BIMS Belagavi Institute Of Medical Sciences, Belagavi Dr B R Ambedkar Road, Belagavi (Belgaum), Karnataka - 590001 India. <u>EC Reg. No.</u> ECR/801/Inst/KA/2016/RR-20	Dr. Srishail Hanagandi