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/24/000114

To,

M/s. Roche Products (India) Private Limited,
146 B, 166 A, Unit No 7, 8, 9, 8th floor, R city office,
R City Mall Lal Bahadur Shastri Marg,
Ghatkopar (West) Mumbai (India) – 400086.

Sir,

With reference to your application No GCT/CT04/FF/2024/45175 dated 03-Sep-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A PHASE III, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF INDUCTION THERAPY WITH RO7790121 IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS"**. **Protocol No.: GA45330 Version 2.0 Dated 30 Apr 2024 with a total of up-to 35 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) Uniformity with respect to screening of tuberculosis shall be maintained at each site.

(ii) Human biological samples i.e. Whole blood, plasma, serum, tissue biopsy, stool 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.

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xx) 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;

(xxi) 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
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. Roche Products (India) Private Limited, 146 B, 166 A, Unit No 7, 8, 9, 8th floor, R city office, R City Mall, Lal Bahadur Shastri Marg, Ghatkopar (West) Mumbai (India) – 400086** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: GA45330 Version 2.0 Dated 30 Apr 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	RO7790121/F05, 225 mg/1.5 ml (antibody) (RVT-3101, ANTI TL1A)
Therapeutic class:	Gastrointestinal Drug
Dosage form:	Vials
Composition:	RO7790121 =225.0000 mg per vial In House Specification Active,

	L-Histidine =1.9100 mg per vial Other than the above mentioned types, Ph.Eur Inactive, L-Histidine Hydrochloride Monohydrate =3.7100 mg per vialPh.Eur Inactive, EDTA Disodium Dihydrate=0.0750 mg per vial Other than the above mentioned types, Ph.Eur Inactive, Sucrose =97.5000 mg per vial Other than the above mentioned types, Ph.Eur Inactive, Polysorbate 80 =0.6000 mg per vial Other than the above mentioned types, Ph.Eur Inactive. Water for Injection =0.0000 QS to 1.5 mL Other than the above mentioned types, Ph.Eur Inactive
Indication	Induction and Maintenance therapy in patients with moderately to severely active ulcerative colitis.

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Site Name: SR Kalla Memorial Gastro & General Hospital, Site Address: 78-79 Dhuleshwar garden, Sardar Patel Marg, C Scheme, Jaipur, Rajasthan-302001, India	EC Name: S.R.Kalla Memorial Ethical Committee For Human Research EC Address: S. R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden Behind HSBC Bank Sardar Patel Marg, C-Scheme, Jaipur, Rajasthan -302001 India ECR/8/Inst/Raj/2013/RR-24	Dr. Mukesh Kalla
2.	Site Name: Institute of Post Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Site Address: SDLD, Dept. of Gastroenterology, 1st Floor, Animal House, 244,AJC Bose Road, Kolkata-700020 , West Bengal, India	EC Name: IPGME and R Resaerch Oversight Committee EC Address: IPGME and R, 244 Acharya J. C. Bose Road, Kolkata, West Bengal-700020, India ECR/35/Inst/WB/2013/RR-24	Dr. Rajib Sarkar
3.	Site Name: Fortis Hospital Site Address: Chandigarh Rd, Near Radha Soami Satsang Bhavan, Mundian Kalan, Mundian Khurd, Ludhiana, Punjab-141123, India	EC Name: Institutional Ethics Committee, EC Address: Fortis Hospital, Mundian Khurd, Ludhiana, Punjab-141015 India ECR/746/Inst/PB/2015/RR-22	Dr. Nitin Shanker Behl
4.	Site Name: Kingsway Hospital KIMS, Site Address: Medisearch Life Sciences Pvt. Ltd., SPANV,	EC Name: KIMS Kingsway Hospital Ethics Committee, EC Address: Kingsway Hospital	Dr. Samir Surendra Pati

	Kingsway Road, Near Kasturchand Park, Nagpur, Maharashtra-440001, India	KIMS, Medisearch Life Sciences Pvt. Ltd., SPANV, Kingsway Road, Near Kasturchand Park, Nagpur, Maharashtra-440001, India ECR/1269/Inst/MH/2019	
5.	Site Name: Sahyadri Super Speciality Hospital, Site Address: Mumbai-Agra Road, Wadala Rd, Dwarka Circle, Nashik, Maharashtra-422001, India.	EC Name: Nashik Sahyadri Hospitals Ethics Committee, EC Address: Sahyadri Super-Specility Hospital, Mumbai-Agra Road, Wadala Road, Dwarka Circle, Nashik, Maharashtra-422001, India ECR/1949/Inst/MH/2024	Dr. Dhaval Rameshchandra Choksi
6.	Site Name: AllIndia Institute Of Medical Sciences, Site Address: AIIMS HNU, Old OT Block room no. 123, 1st Floor, Near Nursing College, Ansari Nagar, New Delhi-110029 India.	EC Name: All India Institute of Medical Sciences EC Address: FDA Bhawan, Kotla Road, New Delhi-110002, India ECR/538/Inst/DL/2014/RR-20	Dr. Saurabh Kedia
7.	Site Name: Indira Gandhi Institute of Medical Sciences, Site Address: Department of Gastroenterology, Sheikhpura, Patna, Bihar-800014, India	EC Name: Institutional Ethics Committee, EC Address: Indira Gandhi institute of medical sciences, Sheikhpura, Baily Road, Patna, Bihar-800014, India ECR/640/Inst/BR/2014/RR-20	Dr. Vishwa Mohan Daya
8.	Site Name: Gujarat Gastro and Vascular Hospital, Site Address: Opposite Shree Ram Petrol Pump, Anand Mahal Road, Adajan, Surat-395009, Gujarat, India	EC Name: UNITY HOSPITAL ETHICS COMMITTEE, EC Address: 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 Prakashbhai Shah
9.	Site Name: Yashoda Hospitals, Site Address: Behind Hari Hara Kala Bhavan, SP Road, Secunderabad-500003, Telangana, India	EC Name: Yashoda Academy of Medical Education and Research, EC Address: Yashoda Hospitals, Behind Hari Hara kala Bhawan, SP Road, Secunderabad-500003, Hyderabad, Telangana, India ECR/49/Inst/AP/2013/RR-22	Dr. Ravi Shankar Bagepally
10.	Site Name: MIDAS Multispeciality Hospital, Site Address: 392, Behind Empress Palace, Opp Singh Saab Dhaba, Wardha Road, Parsodi, Nagpur-440018	EC Name: Institutional Ethics Committee Midas Multispecialty Hospital, EC Address: Midas Multispecialty Hospital, 392, Behind Empress Palace, Opp Singh Saab Dhaba, Wardha Road, Parsodi, Nagpur, India-441108.	Dr. Shrikant Vasantrao Mukewar

		ECR/494/Inst/MH/2014/RR-20	
11.	Site Name: Gandhi Hospital, Site Address: Inpatient block 5th floor, Department of Gastroenterology, Musheerabad, Secunderabad, Hyderabad, Telangana-500003, India	EC Name: Institutional Ethics Committee, EC Address: Gandhi Medical Hospital/College, Musheerabad, Secunderabad, Hyderabad, Telangana-500003, India ECR/180/Inst/AP/2013/RR-24	Dr. Porika Shravan Kumar
12.	Site Name: Surat Institute of Digestive Sciences Hospitals, Site Address: 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	EC Name: Surat Institute of digestive sciences ethics committee, EC Address: 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 ECR/813/Inst/GJ/2016/RR-19	Dr. Rajiv Manhar Mehta
13.	Site Name: King Edward Memorial Hospital, Site Address: Department of Gastroenterology, Seth G.S. Medical College and K.E.M Hopsital Ward 32A, 9th floor, M. S. Building, Parel, Mumbai, Maharashtra-400012, India	EC Name: Ethics Committe, EC Address: King Edward Memorial Hospital, Department of Gastroenterology, Seth G.S. Medical College and K.E.M Hopsital Ward 32A, 9th floor, M. S. Building, Parel, Mumbai, Maharashtra-400012, India ECR/229/Inst/MH/2013/RR-24	Dr. Arun Vaidya
14.	Site Name: SMS Superspeciality Hospital, Site Address: Department of Gastroenterology, 10-9, Vivekanand Marg, Panch Batti, Sangram Colony, Ashok Nagar, Jaipur, Rajasthan-302007, India	EC Name: Ethics Committee, EC Address: 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
15.	Site Name: Asian Institute of Gastroentereology, Site Address: IBD Department, Room No. 2, 6th floor, Main Building Tower A, Survey No 136, 4/5 Plot No 2/3, Mindspace road, P Janardhan Reddy Nagar Gachibowli, Hyderabad, Telangana-500032, India	EC Name: Institutional Ethics Committee, EC Address: Asian Institute of Gastroenterology, 6-3-661, Somajiguda, Hyderabad-500082, India ECR/346/Inst/AP/2013/RR-22	Dr. Rupa Banerjee

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