File No. CT/28/20-DCG(I)

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/20/000025

14 OCT 2020

To,

M/s. IQVIA RDS (India) Private Limited,
2nd Floor Etamin Block, Prestige Technology Park II,
Sarjapur - Marathahalli Outer Ring Road,
Bangalore- 560103 Karnataka, India.

Sir,

With reference to your application No GCT/CT04/FF/2020/19068 (GCT/28/20) dated 20-03-2020, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Multicenter, Randomized, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severely Active Crohn's Disease", Protocol number: APD334-202 Protocol Amendment 2.0, dated 11/June/2020** 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 majority of clinical trial sites should be Govt. Centers.

(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) 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. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority
Stamp

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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. IQVIA RDS (India) Private Limited, 2nd Floor Etamin Block, Prestige Technology Park II, Sarjapur - Marathahalli Outer Ring Road, Bangalore-560103 Karnataka, India** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number: APD334-202 Protocol Amendment 2.0, dated 11/June/2020** 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 14 OCT 2020

(Dr. V. G. Somani)
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:

Names of the new drug or investigational new drug	Etrasimod
Therapeutic class:	sphingosine 1 Phosphate receptor
Dosage form:	Immediate release Film Coated Tablet
Composition:	Etrasimod L-arginine = 1.3810 milligram (mg) in House Specification Active Etrasimod L-arginine = 2.7620 milligram (mg) in House Specification Active
Indications:	Subjects with moderately to Severely Active Crohn's Disease

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Details of clinical trial site:

Sr. No.	Names and address	Ethics committee details	Name of investigator
1.	International Gastro Institute, 7th floor Isha hospital, Old Sarabhai campus, Behind Atlantis height, Opp. Vadodara central, Sarabhai road, Vadodara-390007, Gujarat	Ethics committee Isha hospital, Isha hospital, Behind Atlantis, Opp. Vadodara central, Sarabhai campus, Subhan Pura Vadodara-390007, Gujarat **ECR/1120/Inst/GJ/2018**	Dr. Ashish kumar Sethi
2.	Fortis Memorial Research Institute, Sec-44, Opp-Huda City Centre Metro Station, Gurgaon-122002, Haryana	Institutional Ethics Committee Fortis Memorial Research Institute, Sec-44, Opp-Huda City Centre Metro Station, Gurgaon-122002, Haryana **ECR/223/Inst/HR/2013/RR-19**	Dr. Gourdas Choudhuri
3.	SR Kalla Memorial Gastro & General Hospital, 78-79, Dhuleshwar Garden, S P Marg, Behind HSBC Bank, C-Scheme, Jaipur-302001, Rajasthan	SR Kalla Memorial Ethical Committee for Human Research, 78-79, Dhuleshwar Garden, S P Marg, Behind HSBC Bank, C-Scheme, Jaipur-302001, Rajasthan **ECR/8/Inst/Raj/2013/RR-19**	Dr. Mukesh Kalla
4.	Grant Medical Foundation Ruby Hall Clinic, Survey No 40, B S Dhole Patil Road, Sasoon Road, Pune-411001, Maharashtra	Institutional Ethics Committee Poona Medical Research Foundation Ruby Hall Clinic, Survey No 40, B S Dhole Patil Road, Sasoon Road, Pune-411001, Maharashtra **ECR/24/Inst/MH/2013/RR-19**	Dr. Nitin Pai
5.	Surat Institute of Digestive Sciences, Vijay Nagar Gate No-3, Besides Nirman Bhavan, Opposite Gandhi College, Majura Gate, Ring Road, Surat- 395002, Gujarat	Surat Institute of Digestive Sciences Ethics Committee, Surat Institute of DigestiveSciences, Vijay Nagar Gate No-3, Besides Nirman Bhavan, Opp. Gandhi College, Majura Gate,Ring road, Surat-395002, Gujarat **ECR/813/Inst/GJ/2016/RR-19**	Dr. Rajiv Mehta
6.	Yashoda Hospitals, Behind Hari Hara Kala Bhavan, SP Road, Secunderabad - 500003, Telangana	Yashoda Academy of Medical Education & Research, Yashoda Hospitals, Behind Hari Hara Kala Bhavan, SP Road, Secunderabad - 500003, Telangana **ECR/49/Inst/AP/2013/RR-19**	Dr. B. Ravi Shankar
7.	Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara Post, Kochi-682041, Kerala	Institutional Ethics Committee Amrita Institute of Medical Sciences & Research Centre, AIMS Ponekkara, Kochi -682041, Kerala	Dr. Sadashivan Shine

		ECR/129/Inst/KL/2013/RR-19	
8.	Gujarat Hospital – Gastro and Vascular Centre, Opp. Shree Ram Petrol Pump, Anand Mahal Road, Adajan, Surat – 395009, Gujarat	Unity Hospital Ethics Committee Unity Trauma Center and ICU, N-4 Janki Park Society Aai Mata Road, Paravat Patiya, Surat - - 395010, Gujarat **ECR/1226/Inst/GJ/2019**	Dr. Saumin Shah
9.	Midas multispecialty Hospital Midas Heights, 7, Central Bazar Road, Ramdaspeth, Nagpur-440010, Maharashtra	In stitutional Ethics Committee Heights, 7, Central Bazar Road, Ramdaspeth, Nagpur-440010, Maharashtra **ECR/494/Inst/MH/2014**	Dr. Shrikant Mukewar
10.	Kasturba Medical college, Dr. B. R. Ambedkar Circle,Mangalore-575001, Karnataka	MAHE Ethics Committee Manipal Academy of Higher Education Madhav Nagar, Manipal Udupi Udupi-576104, Karnataka **ECR/191/Inst/KL/2013/RR-19**	Dr. Tantry B. Vishwanath
11.	Maharaja Agrasen Hospital, Dept of Gastroenterology, West Punjabi Bagh, New Delhi -110026, Delhi	Institutional Ethics Committee,6th Floor, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi-110026, Delhi **ECR/745/Inst/DL/2015/RR-18**	Dr. Vivek Bhatia
12.	Institute of Medical Sciences & SUM Hospital, SOA University, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar - 751030, Odisha	Institutional Ethics Committee, Institute of Medical Sciences & SUM Hospital, SOA University, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar-751030, Odisha **ECR/627/Inst/OR/2014/RR-17**	Dr. Ayaskanta Singh
13.	Vinaya Hospital and Research Centre, Karangalpady, Mangalore - 575003, Karnataka	Ethics Committee Vinaya Hospital, Vinaya Hospital and Research Centre,Karangalpady, Mangalore-575003, Karnataka **ECR/664/Inst/KA/2014/RR/17**	Dr. Hamsraj Alva
14.	Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, Delhi	Ethics Committee, Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, Delhi **ECR/20/Inst/DL/2013/RR-2019**	Dr. Naresh Kumar Bansal
15.	Asian Institute of Gastroenterology Pvt Ltd, Plot No 2/3/4/5, Survey No. 136/1 Mindspace Road, Gachibowli Hyderabad – 500032, Telangana	Institutional Ethics Committee Asian Institute of Gastroenterology, 6-3-661, Somajiguda, Hyderabad - 500082, Telagana **ECR/346/Inst/AP/2013/RR-19**	Dr. Rupa Banerjee

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16.	KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka	Institutional Ethics Committee, KLE University, JMNC Campus, Belgaum -590010, Karnataka **ECR/211/Inst/KA/2013/RR-2019**	Dr. Santosh Hajare
17.	Gandhi Hospital, In-Patient Block, 5th Floor, Gandhi Hospital, Musheerabad, Secunderabad-500003,Telanagana	Institutional Ethics Committee, Gandhi Hospital, Musheerabad, Secunderabad-500003, Telanagana **ECR/180/Inst/AP-2013/RR-19**	Dr. .P. Shravan Kumar
18.	Aster Medcity, Aster DM Healthcare Ltd. Kuttisahib Road,Near Kothad Bridge, South Chittoor P.O, Cheranalloor, Kochi-682027, Kerala	Institutional Ethics Committee, Aster Medcity, Aster DM Healthcare Ltd., Kuttisahib Road, Near Kothad Bridge, South Chittoor P.O, Cheranalloor, Kochi-682027, Kerala **ECR/737/Inst/KL/2015/RR-18**	Dr. G. N. Ramesh
19.	Department of Gastroenterology, Osmania General Hospital, Afzalgunj, Hyderabad-500012, Telangana	Institutional Ethics Committee, OsmaniaMedical College, Koti, Hyderabad-500095, Telangana **ECR/300/Inst/AP/2013/RR-19**	Dr. Macherla Ramanna