



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
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File No. CT/20/000064

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/2020/20540 (GCT/65/20) dated 09-07-2020, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A multi-centre long-term extension study to assess the safety and efficacy of GSK3196165 in the treatment of rheumatoid arthritis”**, **Protocol number: 209564 dated 14/10/2019** 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) **Safety issues during the study need to be incorporated on need basis.**
- (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;

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- (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) 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 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. 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: 209564 dated 14/10/2019** 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. 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	Otilimab
Therapeutic class:	Immunosuppressant drug
Dosage form:	Injection
Composition:	GSK3196165 Injection = 150.0000 mg/ml In House Specification Active GSK3196165 Injection = 90.0000 mg/ml In House Specification Active
Indications:	Rheumatoid arthritis

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Shri Nidaan Hospital & Hope Fertility Centre, 2 7 -Vidhut Nagar-A Ajmer Road Jaipur - 302021, Rajasthan,India	Swastic Ethics Committee, Shri Nidaan Hospital & Hope Fertility Centre, 2 7 -Vidhut Nagar-A Ajmer Road Jaipur -302021, Rajasthan, India ECR/434/Inst/RJ/2013/RR-19	Dr. Avinash Agarwal
7-Orange Hospital, Pawana Nagar, Next to Jain School, Near Chapekar Chowk, Chinchwad, Pune-411033, Maharashtra, India	Institutional Ethics Committee of Sai Sneh Hospital & Diagnostic Centre, Opp. PMT Bus Depot, Pune-Satara Road, Katraj, Pune-411046, Maharashtra ECR/989/Inst/MH/2017	Dr. Girish Gokuldas Bhatia
Nirmal Hospital Pvt. Ltd. Ring Road, Surat , Gujarat-395002, India	Nirmal Hospital Pvt. Ltd. Ethics Committee, Nirmal Hospital Pvt. Ltd., Ring Road, Surat , Gujarat-395002, India ECR/390/Inst/GJ/2013/RR-19	Dr. Bankimchandra Nanubhai Desai
Department of Clinical Immunology & Rheumatology, IPGME&R SSKM Hospital, 5 th Floor, 244 A.J.C Bose Road., Kolkata – 700020, West Bengal, India	IPGME&R Oversight Ethics Committee, (Institutional Ethics Committee for Research Involving Human Subjects) Office of The Dean, College Building, 5 th Floor, Institute of Postgraduate Medical Education and Research, 244 A.J.C Bose Road, Kolkata – 700020,West Bengal, India ECR/35/Inst/WB/2013/RR-19	Dr. Alakendu Ghosh
Sushruta Multispeciality Hospital & Research Centre Pvt. Ltd., P. B. Road, Vidyanagar, Hubballi-580021, Karnataka, India	Sushruta Hospitals Ethics Committee, C/o Sushruta Multispeciality Hospital & Research Centre Pvt. Ltd., P. B. Road, Vidyanagar, Hubballi-580021, Karnataka, India ECR/372/Inst/KA/2013/RR-19	Dr. Vikram Murlidhar Haridas
Sujata Birla Hospital & Medical Research Centre, Opposite to Bytco College, Nashik Pune Highway, Nashik Road, Nashik – 422101, Maharashtra, India	Yash Society's Sujata Birla Hospital Ethics Committee, Sujata Birla Hospital & Medical Research Centre, Opposite to Bytco College, Nashik Pune Road, Nashik Road, Nashik – 422101, Maharashtra, India ECR/98/Inst/MH/2013/RR-19	Dr. Praveen Pratap Jadhav

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Suretech Hospital & Research Centre Pvt. Ltd. 13-A, Banerjee Marg, Dhantoli, Nagpur – 440012, Maharashtra, India	Institutional Ethics Committee Suretech Hospital & Research Centre Pvt. Ltd., 13-A, Banerjee Marg, Dhantoli, Nagpur-440012, Maharashtra, India ECR/1048/Inst/MH/2018/RR-18	Dr. Nirmal Jaiswal
Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060, Delhi, India	Sri Ganga Ram Hospital Ethics Committee, SGRH Marg Rajinder Nagar, New Delhi, Delhi-110060 ECR/20/Inst/DL/2013/RR-19	Dr Atul Kakar
Department of Rheumatology, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi – 110026	Institutional Ethics Committee, 6 th Floor, Maharaja Agrasen Hospital West Punjabi Bagh, New Delhi – 110026 ECR/745/Inst/DL/2015/RR-18	Dr. Alok Kumar Kalyani
Department of Clinical Research, 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, S.R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg C-Scheme, Jaipur -302001, Rajasthan, India ECR/8/Inst/Raj/2013/RR-19	Dr Katta Rahul
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	Magna-Care Ethics Committee, C/o Chopda Medicare & Research Centre Pvt. Ltd; Magnum Heart Institute, Patil Lane No. 1, Near K.B.H. Vidyalaya, Canada Corner, Nashik – 422005, Maharashtra, India ECR/79/Inst/MH/2013/RR-19	Dr Naisar Dilip Nahar
Rheumatic Disease Clinic, 4th Floor , Vedanta Institute of Medical Sciences, Near Samved Hospital, Commerce College Road, Navrangpura, Ahmedabad – 380009, Gujarat, India	Avron Multispeciality Hospital Ethics Committee, Avron Multispeciality Hospital 4, Shantiniketan Park, Beside Anjali Emporium, Near Lakhodi Cross Road, Near Sardar Patel Statue, Naranpura, Ahmedabad-380013 ECR/1136/Inst/GJ/2018	Dr. Sapan Pandya
Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune - 411057, Maharashtra, India	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune - 411057, Maharashtra, India ECR/751/Inst/MH/2015/RR-19	Dr. Patil Nilesh Jayavant

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Post Graduate Institute of Medical Education & Research Sector-12, Chandigarh-160012	Institutional Ethics Committee, Room No 6006,6th Floor, Research Block B, PGIMER, Chandigarh ECR/25/Inst/CH/2013/RR-20	Dr. Vijay G. Goni
St. Theresa's Hospital, Sanathnagar, Hyderabad – 500018, Telangana State, India	Ethics Committee, St. Theresa's Hospital, Sanathnagar, Hyderabad-500018, Telangana State, India ECR/230/Inst/AP/2013/RR-19	Dr. A Venkateshwar Rao
Sterling Hospital, Opp. Inox, Race Course Circle (West), Vadodara-390007, Gujarat, India	Sterling Ethics Committee, Sterling Hospital, Phase-I, 4 th Floor, Opp. Inox, Race Course Circle (West), Vadodara-390007, Gujarat, India ECR/582/Inst/GJ/2014/RR-17	Dr. Ripal Shah
Swastik Rheumatology Clinic, B-101, Shilp Aaron, Sindhubhavan Road, Bodakdev, Ahmedabad-380054, Gujarat, India	Sangini Hospital Ethics Committee, First Floor, Santorini Square, B/h Abhishree Complex, Opp Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat, India ECR/147/Inst/GJ/2013/RR-19	Dr. Reena Sharma
Avron Multi Specialty Hospitals, 4, Shantiniketan Park, Near Sardar Patel Colony, Naranpura, Ahmedabd-380013	Avron Multi specialty Hospitals Ethics Committee, Avron Multi specialty Hospitals, 4, Shantiniketan Park, Beside Anjali Emporium, Nr. Lakhudi Cross Road, Nr. Sardar Patel Statue, Naranpura, Ahmedabd-380013 ECR/1136/Inst/GJ/2018	Dr. Vishnu Sharma
JSS Hospital, MG Road, Mysuru-570004	Institutional Ethics Committee, JSS Medical College & Hospital, JSS Hospital, MG Road, Mysuru-570004 ECR/387/Inst/KA/2013/RR-19	Dr. Ramaswamy Subramanian
KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi - 590010, Karnataka, India	Institutional Ethics Committee KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi 590010 ECR/211/Inst/KA/2013/RR-19	Dr. Archana Uppin
Panchshil Hospital, Near Sabarmati Police Station, Highway, Ramnagar, Sabarmati, Ahmedabad-380005, Gujarat, India	Panchshil Institutional Ethics Committee, Office of Ethics Committee, First Floor, Panchshil Hospital, Highway, Ramnagar, Sabarmati, Ahmedabad-380005 ECR/833/Inst/GJ/2016	Dr. Puja Srivastava

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Shree Hospital & Critical Care Centre, 799, Om Nagar, Opp. Tajshree Building, Sakkardara Sqr. Nagpur-440009, Maharashtra	Shree Hospital Ethics Committee, Shree Hospital Unit, Plot No. 786A, 3rd Floor, Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umred Road, Sakkardara Square, Nagpur-440009 ECR/553/Inst/MH/2014/RR-17	Dr. Ashish Bhaiyyaji Pongde
Government Medical College & Shri Sayajirao General Hospital, Jail Road (Indira Avenue), Vadodara-390001, Gujarat, India	Institutional Ethics Committee for Human Research Medical College Baroda (IECHR), Pharmacology Department of Medical College and SSG Hospital, Anandpur, Vadodara-390001, Gujarat, India ECR/85/Inst/GJ/2013/RR-16	Dr. Rajiv Daveswar
Shree Giriraj Multispeciality Hospital, A Unit of Shree Giriraj Lifecare Private Limited, 27-Navjyot Park Corner, 150 Feet Ring Road, Rajkot-360005, Gujarat, India	Shree Giriraj Hospital Research Ethics Committee, C/O Shree Giriraj Multispeciality Hospital, A Unit of Shree Giriraj Lifecare Private Limited, 27-Navjyot Park Corner, 150 Feet Ring Road, Rajkot-360005, Gujarat, India ECR/74/Inst/GJ/2013/RR-19	Dr. Manishkumar Bavaliya
Department of Orthopedics, B.J. Medical College and Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India	Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Office of the Medical Superintendent, Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India ECR/72/Inst/GJ/2013/RR-19	Dr. Himanshu Panchal
Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra, India	Institutional Ethics Committee, Poona Medical Research Foundation, E-4 C to E-4 F, 4 th Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-19	Dr. Nalawade Ajit Bapurao