File No. CT/5/24-DCG(I)

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

सत्यमेव जयते

File No. CT/24/000005

To,

M/s Sanofi Healthcare India Private Limited,
Sanofi House, CTS No. 117-B, L&T Business Park,
Saki Vihar Road, Powai, Mumbai (India) – 400072.

Sir,

With reference to your application no. GCT/CT04/FF/2024/41458 (GCT/5/24) dated 12-Jan-2024, please find enclosed herewith the permission in Form CT-06 for conduct of phase 3 clinical trial titled, **"A double-blinded extension study to evaluate the long-term safety and tolerability of itepekimab in patients with chronic obstructive pulmonary disease (COPD) who participated in either EFC16750 or EFC16819 clinical studies" Protocol No.: LTS18133 Version No. Version 1 Protocol Date 24-OCT-2023 with a total of up-to 80 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:-

1) 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;

2) 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;

3) 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;

4) 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;

5) 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;

6) 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;

7) 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;

8) 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;

9) 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;

10) 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;

11) 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;

12) 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;

13) 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;

14) 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;

15) 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;

16) 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;

17) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

18) 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;

19) 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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.06.04 12:42:45 +05'30'

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

File No. CT/5/24-DCG(I)

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 Sanofi Healthcare India Private Limited, Sanofi House, CTS No. 117-B, L And T Business Park Saki Vihar Road, Powai Mumbai (India) – 400072** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: LTS18133 Version No. Version 1 Protocol Date 24-OCT-2023** 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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Date: 2024.06.04 12:42:55 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
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	REGN3500 (Itepekimab) 300 mg (150 mg/mL) Solution
Therapeutic class:	human IgG 4P monoclonal antibody
Dosage form:	Solution for injection
Composition:	REGN3500 (Itepekimab) =150.0000 mg/ml In House Specification Active
Indications:	It is indicated for chronic obstructive pulmonary disease

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Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Attn: Prof Dheeraj Gupta, Sector 12 Chandigarh Chandigarh - 160012	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research (PGIMER), Sector- 12, Chandigarh -160012, India Reg No: ECR/25/Inst/CH/2013/RR-20	Dr Sahajal Dhooria
Orange city Hospital, Orange city Hospital Instituional ethics committee ,office of OCHIEC, 19 Pandey lay out veer Sawarkar sqaure, nagpur, 40015, Maharsathra, INDIA nagpur Maharashtra - 440015	Orange City Hospital & Institutional Ethics Committee, 19, Pandey Layout Veer Sawarkar Square, Nagpur-440015, Maharashtra, India Reg No: ECR/219/Inst/MH/2013/RR-19	Dr Vinit Prabhudas Niranjane
Govt. Medical College, Govt. Medical College, Kozhikode, 4th Floor, Golden jubilee Annex, Institute of Maternal and Child Health, Calicut Kerala - 673008	Institutional Ethics Committee, Address: 4th Floor, Golden Jubilee Annex, Institute of Maternal and Child Health Kozhikode, Kozhikode, Kerala - 673008 Reg No: ECR/395/Inst/KL/2013/RR-20	Dr K P Suraj
Shree Hospital , The Chairman,Shree Hospital Ethics Committee,3rd Floor, 799 Omnagar, Opp. Tajshree Building,Mirchi Bazaar, SakkardaraChowk, Umred Road, Nagpur Maharashtra - 440009	Shree Hospital Ethics Committee, Shree Hopsital Unit, Plot No. 786 A, Third Floor, Behind Shree Hospital and Critical Care Centre, Mirchi Bazar, Umrer Road, Sakkardara Square, Nagpur-440009, Maharashtra, India Reg No: ECR/553/Inst/MH/2014/RR-20	Dr Balki Akash Lataru

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Siddhi Hospital Institutional Ethics Committee (SHIEC), Siddhi Hospital Institutional Ethics Committee (SHIEC), P-67, MIDC Satpur, Behind ITI, Trimbak Road, Nashik Maharashtra -422007	Ethics Committee (SHIEC} P-67, MIDC Satpur, Behind ITI, Trimbak Road, Nashik-422007, Maharashtra India Reg No: ECR/739/Inst/MH/2015/RR-21	Dr Mutha Abhinandan Bhikchand
The Chairman, LPR Lifepoint Multispeciality Hospital Pvt. Ltd., The Chairman, LPR Ethics Committee,Lifepoint Multispeciality Hospital Pvt. Ltd.,145/1, Mumbai Banglore Highway,Near Hotel Sayaji, Wakad, Pune Maharashtra - 411057	LPR Ethics Committee, Lifepoint Multispeciality Hospital,145/1, Mumbai-Bangore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India Reg No: ECR/751/Inst/MH/2015/RR-21	Dr Rajkumar Nikalje
Criticare Hospital and Research Institute, 4th Floor Dhanshree Complex Near Hotel Hardeo Sitabuldi Maharashtra - 440010	Criticare Hospital Ethics Committee Criticare Hospital and Research Institute 4th Floor Dhanshree Complex Near Hotel Hardeo SitabuldiNagpur Maharashtra - 440010 India Reg No: ECR/1011/Inst/MH/2017/RR-20	Dr Vivek Gupta
Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Rajasthan - 302039	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Sector-7, Central Spine, Vidyadhar Nagar, Jaipur (RJ)-302039 Reg No: ECR/1222/Inst/RJ/2019/RR-22	Dr Manish Kumar Jain
Asthma Bhawan, R-3, Sector-6, Vidhyadhar Nagar Jaipur Rajasthan - 302023	Institutional Ethics Committee Asthma Bhawan. Asthma Bhawan, R-3, Sector-6, Vidhyadhar Nagar Jaipur Jaipur, Rajasthan - 302039 India. Reg No: ECR/750/Inst/RJ/2015/RR-21	Dr Sharad Tikkiwal

Yashoda Hospitals, Hitech City, Cyber Towers to JNTU Road, Hyderabad Hyderabad Telangana - 500084	Institutional Ethics Committee Yashoda Academy of Medical Education and Research Yashoda Hospital Behind Hari Hara Kala Bhavan, Alexander Road Secunderabad-500 003, Telangana State, India Reg No: ECR/49/Inst/AP/2013/RR-22	Dr Venkata Nagarjuna Maturu
RESPIRA Chest and Critical Care, 5th Floor, Plot no. 5, Shree Radhey Health Heights, Central Bazar Road, Ramdaspeth, Nagpur, Maharashtra 440010 Nagpur Maharashtra - 440010	lnstitutional Ethics Committee-Rhughwani Child Care center and Hospital, 22, Sindhu Rughwani Marg, Jaripatka, Nagpur, 44OOL4, Maharashtra, lndia. Reg No: ECR/1444/Inst/MH/2020	Dr Gautam Moharil
Apollo Spectra Hospital, Apollo Speciality Hospital Pvt Ltd., 14138, Chinni Ganj, Kanpur, UP, 208002 Kanpur Uttar Pradesh - 208002	Kanpur Ethics Committee, Apollo Specialty Hospital Pvt. Ltd., 14/138, Chunni Ganj, Kanpur-208001, Uttar Pradesh Reg No: ECR/1327/Inst/UP/2019	Dr Sandeep Katiyar

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