File No. CT/32/24-DCG(I)

pGOVERNMENT 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/24/000032

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/2024/42067 dated 05-Mar-2024, please find enclosed herewith the permission in Form CT-06 for conduct of phase 3 clinical trial titled, **"Master protocol of two independent, randomized, double-blind, Phase 3 studies comparing efficacy and safety of frexalimab (SAR441344) to teriflunomide in adult participants with relapsing forms of multiple sclerosis" Protocol No.: EFC17919 Version No. 01 Protocol Date 05-DEC-2023 with a total of up-to 55 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
Date: 2024.10.01 12:13:21 +05'30'

Yours faithfully,

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

File No. CT/32/24-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.: EFC17919 Version No. 01 Protocol Date 05-DEC-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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bb5a263a4a73d025ff4b11b680a91f08773480400a43ee361b, postalCode=110002, st=Delhi, serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.10.01 12:13:30 +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	SAR441344 /frexalimab
Therapeutic class:	Monoclonal Antibody mAb
Dosage form:	Solution for infusion
Composition:	SAR441344 / frexalimab=1200.0000 mg/8ml In House Specification Active
Indications:	adult participants with relapsing forms of multiple sclerosis

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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), Address: Room no. 18, Department of Neurology, Ground Floor, Block A, Nehru Hospital, Sector 12, Chandigarh 160012, India.	Institutional Ethics Committee EC name: IEC-Drug Trail, PGIMER EC Address: Room No 6006, 6th Floor, P N Chuttani Block, PGIMER, Chandigarh Registration Number: ECR/25/Inst/CH/2013/RR-20	Dr Dhiraj Khurana
Name: Fortis Memorial Research Institute Address: Sector 44, Opp. Huda city center, Gurugram, Haryana-122 002, India	IEC, Fortis Memorial Research Institute EC name: IEC, Fortis Memorial Research Institute EC Address: Sector-44, Opp. Huda city center, Gurugram, Haryana - 122002 India Registration Number: ECR/223/Inst/HR/2013/RR-22	Dr Praveen Gupta
Name: Department of Neurology Address: Government Medical college, Thiruvananthapuram 695011, Kerala, India	HUMAN ETHICS COMMITTEE EC name: Human Ethics Committee, EC Address: Government Medical College, Medical College PO, Thiruvananthapuram, Kerala-695011- Registration Number- ECR/370/Inst/Ker/2013/RR-2	Dr Chitra P
Name: Sahyadri Super Speciality Hospital Nagar Road Address: Survey No. 185A, Shastri Nagar, Near MSEB Office, Yerwada, Nagar Road, Pune-411 006, Maharashtra, India	SAHYADRI HOSPITALS LIMITED ETHICS COMMITTEE EC name: Sahyadri Hospitals PVT Ltd. Ethics committee EC Address: Sahyadri Clinical Research & Development Center, 33/34B, Makarand Bhave Path, Karve Road, Pune- 411004, Maharashtra, India Registration Number: ECR/493/Inst/MH/2013/RR-19	Dr Nasli R Ichaporia

Name: Nizam's Institute of Medical Sciences Address: Millennium Block, Punjagutta, Hyderabad, Telangana-500082, India	NIMS Institutional Ethics Committee EC name: NIMS Institutional Ethics Committee EC Address: Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad- Telangana-500082, India Registration Number: ECR/303/inst/AP/2013/RR-19	Dr Turaga Surya Prabha
Name: Jasleen Hospital-Brain Clinic Address: Panchasheel Square, Opp. Big Bazar, Dhantoli Nagpur Maharashtra - 440012 India	Jasleen Hospital Ethics Committee EC name: Jasleen Hospital's Ethics Committee, Nagpur EC Address: Opp. big Bazar, Panchashil Square, Dhantoli, Nagpur Maharashtra - 440012 India Registration Number: ECR/264/Inst/MH/2013/RR-20	Dr Sanjay Ganpat Ramteke
Name: Aster CMI Hospital Address: No. 43/2, New Airport Road NH 7, Outer Ring Rd, Sahakar Nagar, Bengaluru, Karnataka 560092, India	Aster CMI Hospital Institutional Ethics Committee EC name: Aster CMI - Institutional Ethics Committee, EC Address: Basement, opposite to IP Pharmacy, #43/2, New Airport road, Outer Ring Road, NH 7, Sahakar Nagar, Hebbal, Bangalore, Karnataka-560092, India- Registration Number: ECR/1084/Inst/KA/2018/RR-21	Dr Srinivasa R
Name: Apollo Adlux Hospital Address: Angamaly, Cochin, 682372 Kerala India	Apollo Adlux Hospital Ethics Committee EC name: Apollo Adlux Hospital Ethics Committee EC Address: Apollo Adlux Hospital Adlux Junction, Karukutty, Angamaly, Ernakulam, Kerala, 683576 Registration Number: ECR/1729/Inst/KL/2022.	Dr Boby Varkey Maramattom
Name: Chopda Medicare and Research Centre Pvt. Ltd, Magnum Heart Institute Address: 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner Nashik, Maharashtra - 422005 India	Magna-care Ethics Committee EC name: Magna-care Ethics Committee EC Address: Chopda Medicare and Research Centre Pvt. Ltd, Magnum Heart Institute, Canada Corner, Nashik, Maharashtra - 422005 India Registration Number:	Dr Amit Bhalchandra Yeole

	ECR/79/Inst/MH/2013/RR-19	
Name: Atal Institute of Medical Super Specialties Address: Shimla H.P.-171006 India	INSTITUTIONAL ETHICS COMMITTEE IGMC SHIMLA EC name: Institutional Ethics Committee, IGMC Shimla EC Address: Indira Gandhi Medical College, Principal Office, Shimla, H.P.- 171 001, India Registration Number: ECR/533/Inst/HP/2014/RR-20	Dr Sudhir Sharma

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