File No. CT/133/21-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
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

सत्यमेव जयते

File No. CT/21/000133

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/2021/28500 (GCT/133/21) dated 11-Oct/2021 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Randomized, Double-Blind, Placebo controlled Study Assessing the Long-term Effect of Dupilumab on Prevention of Lung Function Decline in Patients with Uncontrolled Moderate to Severe Asthma", Protocol No.: LPS16676, Version: 1.0 dated 20/August/2021** 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) In India, the study should be considered as Phase III and accordingly, only Phase III part of the proposed study should be conducted in India;
(ii) The firm should perform QuantiFERON-TB Gold test during screening visit to exclude latent- TB subjects from the study;
(iii) The firm should perform serum pregnancy test during screening visit and at every visit of women of child bearing potential as precautionary measures;
(iv) 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;
(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) 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;

(xx) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xxi) 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;

(xxii) 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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),
pseudonym=12046a34e21727bacb25574 8732c456d249073e55e953d9cb5b58748ee 3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525f fca0705074b4997e6b2f4b5c8d81cf282ade af5d, cn=VENUGOPAL G SOMANI
Date: 2022.06.23 16:25:48 +05'30'

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

File No. CT/133/21-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&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.: LPS16676, Version: 1.0 dated 20/August/2021** 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 _________________

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb25574 8732c456d249073e55e953d9cb5b58748ee 3113c, postalCode=110002, st=DELHI, serialNumber=e971241aa0c0bba41522525ff ca0705074b4997e6b2f4b5c8d81cf282adeaf 5d, cn=VENUGOPAL G SOMANI
Date: 2022.06.23 16:25:56 +05'30'

(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	Dupilumab/Dupixent®
Therapeutic class:	Antiasthmatic
Dosage form:	Injection

Composition:	Polysorbate-80 = 4.0000 milligram(mg) E.P.,J.P. Inactive Sucrose = 100.0000 milligram (mg)E.P.,J.P. Inactive Glacial Acetic Acid = 1.5000 milligram (mg) U.S.P.,E.P.,J.P. Inactive Sodium Acetate Trihydrate = 1.5000 milligram (mg)U.S.P.,E.P.,J.P. Inactive L- Arginine Monohydrochloride = 10.5000 milligram (mg) U.S.P., E.P.,J.P. Inactive L--Histidine Monohydrochloride Monohydrate= 6.200 milligram(mg) E.P.,J.P. Inactive L- Histidine = 6.2000 milligram (mg) U.S.P.,E.P.,J.P. Inactive REGN668 = 300.0000 milligram(mg) In House Specification Active
Indications:	Uncontrolled Moderate to Severe Asthma

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Asthma Bhawan, R-3, Sector 6, Vidhyadhar Nagar, Jaipur-302039	Institutional Ethics Committee Asthma Bhawan, Jaipur ECR/750/Inst/RJ/2015/RR-21	Dr. Ashish Kumar
2.	Dept. of Pulmonary Medicine, Institute of Chest Diseases, Govt. Medical College, Kozhikode, Kerala-673008	4th Floor Golden Jubilee Annex, Institute of Maternal and Child Health, Medical College P.O. Kozhikode-673008, Kerala ECR/395/Inst/KL/2013/RR-20	Dr. Suraj K.P
3.	Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh - 160012	Institutional Ethics Committee, Department of Pulmonary Medicine, Postgraduate Institute of Medical Education and Research, Sector 12, Chandigarh – 160012 ECR/25/Inst/CH/2013/RR-20	Dr. Sahajal Dhooria
4.	JSS Hospital, Department of Respiratory Medicine. JSS Hospital, Mahatma Gandhi Road, Mysore	Institutional Human Ethics Committee, JSS Medical College and Hospital, 3rd Floor, JSS Medical College Mysore-570015 Karnataka ECR/387/Inst/KA/2013/RR-19	Dr. MAHESH P A
5.	Vinaya Hospital and Research Centre (A Unit o Karnataka Institute of Medical Sciences) Karangalpady, Mangaluru-	Institutional Ethics Committee Vinaya Hospital and Research Centre, P.O. Box No. 717, Karangalpady, Mangalore - 575003, Karnataka, India	Dr. Hamsraj Alva

	575003	ECR/664/Inst/KA/2014/RR/20	
6.	Super Specialty Hospital, Government Medical College and Hospital, Medical College Square Road, Tukdoji Square, Nagpur-440009, Maharashtra, India	Institutional Ethics Committee, Department of Pharmacology, Government Medical College and Hospital, Medical College Square Road,Nagpur-440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Meshram Sushant Hiraman
7.	Hindusthan Hospital, 522/3, 523/3 Nava India Road, Udaiyampalayam, Coimbatore-641028, Tamil Nadu, India	Institutional Human Ethics Committee, Hindusthan Hospital, 522/3, 523/3 Nava India Road, Udaiyampalayam, Coimbatore-641028, Tamil Nadu, India ECR/1376/Inst/TN/2020	Dr. Srikanth Krishnamurthy
8.	Getwell Hospital & Research Institute, 20/1 Dr Khare Marg, Dhantoli, Nagpur-440012	Getwell Institutional Ethics Committee ECR/109/Inst/Maha/2013/RR-19	Dr. Rajesh Nathuram Swarnakar
9.	Fortis Escorts Heart Institute, Okhla Road, New Delhi -110025	Institutional Ethics Committee Academic & Research Department, Room no. A-23,2nd Floor, RC Building, Residential Tower Okhla Road, New Delhi 110025, India ECR/261/Inst/DL/2013/RR-19	Dr. Avi Kumar
10.	Criticare Hospital and Research Institute, 4th Floor, Dhanshree Complex, Near Hotel Hardeo, Sitabuldi, Nagpur - 440012 Maharashtra, India	Criticare Hospital Ethics Committee, Criticare Hospital and Research Institute, 4th Floor, Dhanshree Complex, Near Hotel Hardeo, Sitabuldi, Nagpur -440012 Maharashtra, India ECR/1011/Inst/MH/2017/RR-20	Dr. Gupta Vivek
11.	Grant Government Medical College & Sir JJ Group of Hospitals, OPD No. 24, Department of Pulmonary medicine, 1st floor, JJ Marg, Byculla, Mumbai, Maharashtra- 400008	Institutional Ethics Committee, Department of Pharmacology, Grant Government Medical College & Sir J.J group of Hospitals, Byculla, Mumbai 400008 Maharashtra, India ECR/382/Inst/MH/2013/RR-19	Dr. Meshram Priti Lokesh
12.	Department of Respiratory Medicine, 2nd Floor, GMERS Medical College and General Hospital, Gotri, Gotri Road, Old TB	Institutional Human Ethics Committee, GMERS Medical College and General Hospital, Gotri, Old TB Hospital Campus, Gotri Main Road, Vadodara,	Dr. Patel Anand Kishorbhai

	Campus, Vadodara-390021, Gujarat, India	Gujarat-390021, India ECR/28/Inst/GJ/2013/RR-19	
13.	CIMS Hospital Pvt. Ltd. Opp. Panchamrut Bunglows, Nr. Shukan Mall, Off Science City Road, Sola, Ahmedabad - 380060, Gujarat, India	Ethics Committee of CIMS, CIMS Hospital Pvt. Ltd. Opp. Panchamrut Bunglows, Nr. Shukan Mall, Off Science City Road, Sola, Ahmedabad - 380060, Gujarat, India ECR/206/Inst/GJ/2013/RR-20	Dr. Amit Harishchandra Patel
14.	Midland Health Care and Research Centre, B-55 and C-42 Mandir Marg Mahanagar Extension, Lucknow, Uttar Pradesh, India	IEC of Midland Health Care and Research Centre, B-55 and C-42 Mandir Marg Mahanagar Extension, Lucknow, Uttar Pradesh ECR/645/Inst/UP/2014/RR-21	Dr. Bhanu Pratap Singh

****