File No. CT/51/24-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/24/000051

To,

M/s Bristol-Myers Squibb India Private Limited,
One International Center, 6th Floor, Tower 1,
Senapati Bapat Marg, Elphinstone (W),
Maharashtra (India) – 400013

Sir,

With reference to your application No. GCT/CT04/FF/2024/42648 dated 01-04-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Idiopathic Pulmonary Fibrosis" Protocol No.: IM027068 Version No. 2.0 Protocol Date 01-DEC-2023 with a total of up-to 69 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: -

(i) Condition that the firm should include more geographically distributed government sites in the study.

(ii) Human biological samples i.e. serum, plasma and whole blood, related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

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

(xx) 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;

(xxi) 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,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.10.07 11:25:40 +05'30'

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

File No. CT/51/24-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 Bristol-Myers Squibb India Pvt. Ltd., 6th Floor, Tower 1, One International Center, Senapati Bapat Marg, Elphinstone (West), Mumbai (India) - 400013 Telephone No.: 022-66288600 FAX: 022-66288700, 022-66288701 E-Mail: SONIKA.SHAH@BMS.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: IM027068 Version No. 2.0 Protocol Date 01-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

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Date: 2024.10.07 11:25:58 +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	BMS-986278 BMS-986278
Therapeutic class:	Idiopathic Pulmonary Fibrosis Idiopathic Pulmonary Fibrosis
Dosage form:	Film Coated Tablets Film Coated Tablets
Composition:	BMS-986278 =10.0000 milligram(mg) In House Specification Active BMS-986278 =60.0000 milligram(mg) In House Specification Active

Indications:	Idiopathic Pulmonary Fibrosis Idiopathic Pulmonary Fibrosis

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
Krims Hospital, 275, Central Bazar Road, Ramdaspeth Nagpur Maharashtra – 440010	KRIMS Ethics CommitteeKRIMS Hospital275, Central Bazar road Ramdas peth Nagpur Nagpur Maharashtra -440010 India ECR/323/Inst/MH/2013/RR-19	Dr Ashok Arbat
Fortis Healthcare, New Chandigarh, Fortis Hospital, Sector 62, Phase Viii, Sahibzada Ajit Singh Nagar Mohali Punjab - 160062	IEC Fortis Hospital, OPD, 3rd Floor, Fortis Hospital Sector - 62 Phase VIII Mohali Punjab -160062 India ECR/28/Inst/PB/2013/RR-19	Dr Digambar Behera
NRS Medical College andHospital, 138 AJC Bose Road Kolkata West Bengal – 700014	Ethics Committee, N.R.S. Medical College, NRS Medical College And Hospital, NRS Medical College 138, A.J.C Bose Road Kolkata, Kolkata West Bengal -700014 India ECR/609/Inst/WB/2014/RR-20	Dr Jaydip Deb
KLEs Dr Prabhakar Kore Hospital, Nehru Nagar, Belagavi Belagavi Karnataka -590010	Institutional Ethics Committee, KLE University, KLE University KLE Dr.PK Hospital and MRC, Nehru Nagar Belagavi (Belgaum), Karnataka -590010 India ECR/211/Inst/KA/2013/RR-19	Dr Jyoti Hattiholi
Marengo CIMS Hospital PvtLtd, Plot no 671, opp. panchamrut bunglows, Nr.shukan mall, off.science cityroad, Sola Ahmedabad Gujarat - 380060	EC of CIMS Hospital Care Institue of Medical Sciences, Plot no 67/1, Opp. Panchamrut bunglows, Nr Shukan Mall, Off Science City Road, Sola, Ahmedabad, Gujarat -380060, India ECR/206/Inst/GJ/2013/RR-20	Dr Nitesh Shah
St.Johns National Academy of Health Sciences, Sarjapur road Bengaluru Karnataka - 56003	Institutional Ethics Committee, St. John's Medical College Hospital, Ground Floor, St. John's Medical College, Sarjapur Road, Bangalore-560034 ECR/238/Inst/KA/2013/RR-19	Dr Priya Ramachandran

Shri Mahant Indiresh Hospital, Patel Nagar Dehradun Uttarakhand - 248001	Institutional Ethics Committee SGRR Institute Of Medical Health Sciences IEC, Administrative Building Patel Nagar Dehradun Uttarakhand -248001 India ECR/710/Inst/UK/2015/RR-21	Dr Jagdish Rawat
Midland Healthcare andResearch Center, B-55 and C-42, Mandir Marg, Mahanagar Lucknow Uttar Pradesh -226006	Institutional Ethics Committee, Midland Healthcare & Research Center, B-55 &C-42, Mandir Marg, Mahanagar Extension, Lucknow, UP. 226006 ECR/645/Inst/UP/2014/RR-21	Dr Bhanu Pratap Singh
GETWELL HOSPITAL and RESERACH INSTITUTE, DHANTOLI DR KHARE MARG Nagpur Maharashtra - 440012	Getwell Institutional Ethics Committee, Giec Secretariate, 5th Floor, Getwell Hospital And Research Institute, 20/1 Dr. Khare Marg Dhantoli Nagpur, Maharashtra-440012, India ECR/109/Inst/Maha/2013/RR-19	Dr Rajesh Swarnakar
Metro Hospital and Heart Institute, L-94 Sector 11 Noida, Delhi NCR, Noida Uttar Pradesh - 201301	Metro Ethical Review Board, Metro Hospitals and Heart InstituteL-94 Sec-11 Noida Uttar Pradesh - 201301 India ECR/335/Inst/UP/2013/RR-20	Dr Deepak Talwar
Sardar Vallabhbhai PatelInstitute of Medical Sciences and research SVPIMSR, NHL Municipal Medical College Campus, Ellisbridge Ahmedabad Gujarat - 380013	NHLIEC, Smt. NHL Municipal Medical College Dept. of Pharmacology, first floor, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad, Gujarat-380006. ECR/245/ Inst/GJ/2013/RR-19	Dr Sanjay Tripathi
Unity Hospital, Parvat Patiya, Aai Mata Road, Surat, Gujarat Surat Gujarat - 395010	Unity Hospital Ethics Committee Unity Hospital, Unity Trauma Center and ICU, N-4 Janki Park Society Aai Mate Road, Parvat Patiya, Surat, Gujarat –395010, India. ECR/1226/Inst/GJ/2019	Dr Dipak Viradia
SHREE HOSPITAL ANDCRITICAL CARE CENTRE, 799 OM NAGAR OPP TAJ SHREE BUILDING SAKKARDARA SQUARE Nagpur Maharashtra - 440009	Shree Hospital Ethics Committee Shree Hospital Unit, Plot No.786 A, 3rd Floor Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umrer Road, Sakkardara, Sq, Nagpur-440009, Maharashtra India ECR/553/Inst/MH/2014/RR-20	Dr Akash Balki

File No. CT/51/24-DCG(I)

All India Institute of Medical Sciences, Dept of Pulmonary Medicine and Sleep Disorders, AIIMS, New Delhi, Delhi, New Delhi Delhi - 110029	Institute Ethics Committee, All India Institute Of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi Delhi - 110029 India ECR/538/Inst/DL/2014/RR-20	Dr Anant Mohan
Green City Hospital, DIG Bunglow Square, near V Mart, Firdous Nagar, Bhopal, Madhya Pradesh Bhopal Madhya Pradesh - 462001	Institutional Ethics Committee Charak Hospital And Research Centre Plot No 42/219 House No 126,Old Nav Bharat Press Building Near Small Lake Jehangirabad, Bhopal Madhya Pradesh -462008 India ECR/1562/Inst/MP/2021	Dr Ashish Jain
Asthma Bhawan,, Vidhyadhar Nagar Jaipur Rajasthan - 302039	Institutional Ethics Committee, Asthma Bhawan Asthma Bhawan, R-3, Sec-6, Vidhyadhar Nagar, Jaipur-302039, Rajasthan, India ECR/750/Inst/RJ/2015/RR-21	Dr Ashish Kumar
Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Hospital Premises, 32 Sassoon Road Pune Pune Maharashtra- 411001	Jehangir Clinical Development Centre Pvt Ltd Jehangir Clinical Development Cente Pvt.Ltd Jehangir hospital premises 32, Sasoon Road Pune Maharashtra - 411001 India ECR/352/Inst/MH/2013/RR-19	Dr Mahendra Kawedia
Ace hospital and ACE hospital and research center,, No- 32, 2A, Gulawani Maharaj Road, near Hotel Abhishek, Pandurang Colony, Erandwane Pune Maharashtra - 411004	Institutional Ethics Committee - ACE HOSPITA LACE Hospital and Research Centre, S No-32/2 A, Erandawane, Gulwani Maharaj Road, near Hotel Abhishek, Pandurang Colony, Pune, Maharashtra - 411004 India ECR/474/Inst/MH/2013/RR-19	Dr Himanshu Pophale
MODI CLINIC, 205-7, LOTUSCOURT. NEAR HOTELPANCHMI, PUNE SATARAROAD, PARVATI, PUNE, Pune Maharashtra - 411009	IEC-Sai Sneh Hospital and Daignostic CentreSai Sneh Hospital and Diagnostic Centre Opp. PMT Bus Depot Pune Satara Road Katraj Pune, Maharashtra - 411046 India ECR/989/Inst/MH/2017/RR-20	Dr Mahavir Modi
Rukmani Birla Hospital, Gopalpura Bypass road, gopalpura, Jaipur, Rajasthan, Jaipur Rajasthan - 302018	Institutuinal Ethics Committee, Rukmani Birla Hospital,Room no. B3, lane No. 1, Main building, Rukmani Birla Hospital A unit of CMRI, Gopalpura Bypass road,	Dr Rakesh Godara

	gopalpura, Jaipur, Rajasthan, 302018, India ECR/1060/Inst/RJ/2018	
Max Super Speciality Hospital, Saket, 2, Press Enclave Road, Saket New Delhi Delhi -110017	Max Health care Ethic Committee, West Block, Near MS Office, Max Super Specilaity Hospital, Saket (A unit of Max healthcare Institute Limited)1, Press Enclave Road, Saket, New Delhi-110017, India ECR/110/Inst/DL/2013/RR-19	Dr Vivek Nangia

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