

Dairy No.:
ND/CT04/FF/2021/29691
dated 29.12.2021

Tele No.011-23236965
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F. No. ND/CT/21/000101
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 25 FEB 2022

To

M/s. Pfizer Products India private Ltd.,
The Capital, 1802/1901, Plot No. C-70,
G Block, Bandra Kurla Complex, Bandra (E), Mumbai,
Maharashtra(India)-400051.

Subject: Grant of permission to undertake Phase-III Clinical Trial protocol titled "A randomized, open-label, parallel-group, study to evaluate the safety and efficacy of Abrocitinib 100 mg and 200 mg tablets in participants aged 12 years and older with moderate to severe atopic dermatitis in India" - regarding.

CT NOC No.: CT/ND/07/2022

Sir,

With reference to your application no. ND/CT/21/000101 dated 29.12.2021, please find enclosed herewith the permission in Form CT-06, No. CT/ND/07/2022 to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully,



(Dr. V. G. Somani)
Central Licensing Authority

Conditions of Permission

- (i) 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 Licensing Authority under rule 8;
- (ii) 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;

- (iii) 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;
- (iv) The Central Licensing 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;
- (v) 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;
- (vi) 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;
- (vii) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (viii) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;
- (ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
- (x) 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 Licensing 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 of the New Drugs and Clinical Trials Rules, 2019;
- (xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;
- (xii) 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 the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;

- (xiii) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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;
- (xiv) 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 Licensing 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;
- (xv) The Laboratory owned by any person or a company or any other legal entity and utilized 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;
- (xvi) The Central Licensing 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;
- (xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
- (xix) It may kindly be noted that merely granting permission to conduct Clinical Trial study with the drug doesn't convey or imply that based Clinical Trial data generated with the drug, permission to market this drug will automatically be granted to you.
- (xx) The study protocol should be revise to make it a phase-III clinical trial.**
- (xxi) The firm should, in addition, perform the study assessment through "SCORAD" scoring and photography should be utilized to capture accurate images of initial status, end of treatment outcome and follow up status of all study population.**
- (xxii) Revised protocol should be submitted to CDSCO before initiation of the study.**

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

Authority hereby permits M/s. Pfizer Products India private Ltd., The Central Licensing the capital, 1802/1901, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (E), Mumbai, Maharashtra(India)-400051.Telephone No.: 0226693200, E-Mail: regulatoryindiapfizerproducts@pfizer.com to conduct clinical trial of the new drug as per protocol no. B7451094 (final protocol), dated 21.12.2021 in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Abrocitinib 100 mg and 200 mg tablets		
Therapeutic class:	Dermatological preparation JAK1inhibitor		
Dosage form:	Tablets		
Composition:	Abrocitinib 100mg and 200mg		
Indications:	Treatment of moderate to severe atopic dermatitis		
Details of clinical trial sites-			
Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number	
1.	Dr. Dipak A Patel Nirmal Hospital Pvt Ltd, Ring Road, Surat - 395002, Gujarat, India.	Nirmal Hospital Pvt. Ltd. Ethics Committee. ECR/390/Inst/GJ/2013/RR-19	
2.	Dr. Ramesh Bhat M Father Muller Medical College Hospital Father Muller Road, Kankanady, Mangalore-575002, India	Father Muller Institutional Ethics Committee. ECR/540/Inst/KA/2014/RR-20	
3.	Dr. Somesh Gupta All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029	All India Institute of Medical Sciences, Institute Ethics Committee ECR/538/Inst/DL/2014/RR-20	
4.	Dr. Davinder Parsad Post Graduate Institute of Medical Education and Research, Sector 12- Chandigarh-160012 India	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research ECR/25/INST/CH/2013/RR-20	
5.	Dr. Rashmi Sarkar Lady Hardinge Medical College, Shaheed Bhagat Singh Marg, DIZ Area, Connaught Place, New Delhi. 110001	Institute Ethics Committee Lady Hardinge Medical College and associated hospitals ECR/435/Inst/DL/2013/RR-20	

6.	Dr. Hari Kishan Kumar. Y Rajarajeswari Medical College and Hospital No.202,Mysore Road, kengeri satellite town, kambipura, karnataka-560074	Institutional Ethics Committee Rajarajeswari Medical College and Hospital ECR/56/Inst/KA/20B/RR-19 EC/RENEW/INST/2019/2717
7	Dr. Saswati Halder Calcutta School of Tropical Medicine 108, Chittaranjan Avenue, Calcutta Medical College, College Square, Kolkata-700073, West Bengal, India	Clinical Research Ethics Committee (CREC-STM), School of Tropical Medicine ECR/194/Inst/WB/2013/RR-20
8	Dr Nipul Vara S.S.G.Hospital Jail Rd, Indira Avenue, Vadodara, Gujarat 390001, Vadodara, Gujarat, 390001, India.	Institutional Ethics Committee For Human Research (IECHR) Medical College Baroda EC/RENEW/85/Inst/GJ/2013-RR-19
9	Dr. Suneel Vartak Sujata Birla Hospital & Medical Research Center, Opposite Bytco College, Nashik Pune Highway Nashik road, Nashik, Maharashtra-422101, India	Yash Society's Sujata Birla Hospital Ethics Committee, Sujata Birla Hospital & Medical Research Center ECR/98/Inst/MH/2013/RR-19
10	Dr. Ashutosh Mehta Orange City Hospital and Research Institute, 19 Pandey , Layout Veer Sawarkar Square Nagpur - 440015	Orange City Hospital and Institutional Ethics Committee ECR/219/Inst/MH/2013/RR-19
11	Dr. Subhash Chandra Bharija Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-10060, India	Sir Ganga Ram Hospital Ethics Committee ECR/20/Inst/DL/2013/RR-19 EC/RENEW/INST/2019/2764
12	Dr. Ashish Ramchandrarao Deshmukh MGM Medical College & Hospital, N6,CIDCO Aurangabad 431003 MH India	MGM Ethics Committee for Research on Human Subjects ECR/581/Inst/MH/2014/RR-20
13	Dr Vineet Relhan Maulana Azad Medical College, Bahadur Shah Zafer Marg, New Delhi – 110002	Institutional Ethics Committee Maulana Azad Medical College ECR/329/Inst/DL/2013/RR-19
14	Dr. Pradyumna Vaidya Jehangir Clinical Development Centre Pvt. Ltd. Jehangir Hospital Premises, 32 Sassoon Road, Pune-411001	Ethics Committee Jehangir Clinical Development Centre Pvt. Ltd ECR/352/INST/MH/2013/RR-19
15	Dr.Anjeeta Dhawan Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi-110026	Institutional Ethics Committee, Maharaja Agrasen Hospital ECR/745/Inst/DL/2015/RR-21

16	Dr.Sharmila Patil Dr. D.Y.Patil Medical College, Hospital & Research Centre Sector-5, Nerul, Navi Mumbai, Thane, Maharashtra-400706, India	Institutional Ethics Committee, Dr.D.Y.Patil Medical College ECR/195/Inst/MH/2013/RR-19 EC/RENEW/INST/2019/2298
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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.

V-G

(Dr. V. G. Somani)

Central Licensing Authority
Stamp

New Delhi

Date:

25 FEB 2022

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

