

F. No. ND/CT/20/000093
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

30 DEC 2020

To

M/s. AstraZeneca Pharma India Limited,
Block N1, 12th Floor, Manyata Embassy Business Park,
Outer Ring Road, Bangalore-560045

Subject: Grant of Permission to conduct Phase IV Clinical Trial entitled "A prospective, multi - center, phase IV clinical trial to assess the safety and efficacy of Acalabrutinib capsules in Indian adult patients with chronic lymphocytic leukemia and relapsed and refractory mantle cell lymphoma" - regarding.

Sir,

With reference to your application dated 28.09.2020, please find enclosed herewith the permission in Form CT-06, No. **CT/ND/129/2020** to conduct the subject mentioned clinical trial under the provisions of **New Drugs and Clinical Trial Rules, 2019** granted based on evaluation in consultation with Subject Expert Committee (Oncology and Haematology).

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

Yours faithfully



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

Condition 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 Licencing 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 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;
- (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 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;
- (viii) 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;
- (ix) 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;
- (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 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 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 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;
- (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 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;
- (xiii) 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 authorized 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;

- (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 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;
- (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 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;
- (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) The results of Phase IV should be submitted for review within two years as stipulated in the import permission no. IMP-ND-122-2019 dated 18.10.2019.**

FORM CT-06

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

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

Number of the permission and date of issue **CT/ND/129/2020** dated **30 DEC 2020**

1. The Central Licensing Authority hereby permits M/s. AstraZeneca Pharma India Limited, Block N1, 12th Floor, Manyata Embassy Business Park, Outer Ring Road, Bangalore-560045 to conduct clinical trial of the new drug as per **D8220C00022, Version 1.0, 01/09/2020** in the below mentioned clinical trials sites.
2. Details of new drug or investigational new drug and clinical trial sites: -

Names of the new drug or investigational new drug:	Acalabrutinib 100 mg capsules.
Therapeutic class:	Anticancer
Dosage form:	Capsule
Composition:	Each Capsule Contains Acalabrutinib 100mg
Indications	For the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

Details of clinical trial site			
Sl No.	Investigator Name	Address of Site	Name of Ethics Committee and address with Ethics Committee registration No
01	Dr. Vivek S Radhakrishnan	Tata Medical Center, 14, MAR(EW), Newtown, Rajarhat, Kolkata - 700160	Institutional Review Board, Tata Medical Center, 14, MAR(EW), Newtown, Rajarhat, Kolkata-700160 ECR/269/Inst/WB/2013/RR-19
02	Dr. Dinesh Bhurani	Rajiv Gandhi Cancer Institute & Research Centre, Sector-5, Rohini, New Delhi-110085	Institutional Review Board (IRB), RGCI&RC, Sector-5, Rohini, New Delhi-110085 ECR/10/Inst/DC/2013/RR-19

03	Dr. Hari Menon	Cytecare Cancer Hospital, Venkata, Bagalur Cross, Yelahanka, Bengaluru-560064 Karnataka	Cytecare Institutional Ethics Committee, Cytecare Cancer Hospital, Venkata, Bagalur Cross, Yelahanka, Bengaluru- 560064 Karnataka ECR/1013/Inst/KA2017
04	Dr. Biju George	Department of Haematology, Christian Medical College, Vellore-632004, Tamilnadu, India	Institutional Review Board, Christian Medical College, Thorapadi Post, Bagayam , Vellore - 632012, Tamilnadu, India. ECR/326/Inst/TN/2013/RR- 19
05	Dr. Mallikarjun Kalashetty	Manipal Hospital, #98, HAL Airport Road, Bangalore- 560017, Karnataka, India	Ethics Committee of Manipal Hospitals, Manipal Hospital, #98, HAL Airport Road, Bangalore-560017, Karnataka, India ECR/34/Inst/KA/2013/RR- 19
06	Dr. Sandip Abhaykumar Shah	Hemato Oncology Clinic Ahmedabad Pvt. Ltd, 1st floor, Vedanta Institute of medical sciences, Near Samved Hospital, Stadium Commerce College Road, Navrangpura, Ahmedabad-380009, Gujarat, India	Ethics Committee of Care Institute of Medical Sciences, Care Institute of Medical Sciences, Opp. Panchamrut Bunglows Near Shukan Mall, Off Science City Road, Sola, Ahmedabad-380060, Gujarat, India ECR/206/Inst/GJ/2013/RR- 20
07	Dr. Sameer Ramesh Melinkeri	LMMF's Deenanath Mangeshkar Hospital & Research Centre, Erandwane, Pune- 411004	Institutional Ethics Committee, LMMF's Deenanath Mangeshkar Hospital & Research Centre, Erandwane, Pune-411004 ECR/15/Inst/Maha/2013/RR -19
08	Dr. Manju Sengar	Tata Memorial Hospital, Dr. E Borges Marg, Parel, Mumbai-400012, Maharashtra, India	Tata Memorial Centre, Tata Memorial Hospital, Institutional Review Board, IRB Office, Dr. Ernest Borges Marg, Parel, Mumbai-400012, India. ECR/414/Inst/MH/2013/RR -19

09	Dr. Prasanth Ganesan	Jawaharlal Institute of Postgraduate Medical Education and Research, JIPMER, Puducherry-605009, India	Institutional Ethics Committee (Human Studies), 1St Floor, Administrative Block, JIPMER Campus, Dhanvanthri Nagar, JIPMER, Gorimedu, Puducherry-605006 ECR/342/Inst/PY/2013/RR-19
10	Dr. Sharat Damodar	Mazumdar Shaw Medical Centre, Narayana Hrudayalaya Limited, Bommasandra Industrial Area, Bengaluru -560099, Karnataka	Narayana Health Medical Ethics Committee, Narayana Hrudayalaya Limited, 258/A, Bommasandra Industrial Area, Bengaluru-560099, Karnataka ECR/390/Inst/KA/2013/RR-19

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.

New Delhi

Date: 30 DEC 2020


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

डॉ. वी. जी. सोमानी
ओपधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ
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