

Application no.
ND/CT04/FF/2020/20849

F. No. ND/CT/20/000068

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 28 SEP 2020

To

M/s. Eli Lilly and Company,
Sector 32, Plot No. 92
Gurgaon – 122001, India

Sub.: Application for permission to conduct Phase IV Clinical Trial entitled "A Single-Arm, Phase 4 Study of Abemaciclib, a CDK4 and CDK6 Inhibitor, in combination with Endocrine Therapy (Anastrozole/Letrozole or Fulvestrant) in Participants with Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative Locally Advanced and/or Metastatic Breast Cancer in India"- Reg.

Sir,

With reference to your application no. ND/CT04/FF/2020/20849 dated 14.08.2020; please find enclosed herewith the permission in **Form CT-06, No. CT/ND/97/2020** 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 & 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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 firm should conduct Phase-IV trial with the sample size as stipulated in the conditions of import permission issued to the firm.**

FORM CT-06

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

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

The Central Licensing Authority hereby permits **M/s. Eli Lilly and Company, Sector 32, Plot No. 92, Gurgaon – 122001, India** to conduct clinical trial of the investigational new drug as per **Protocol No. 13Y-IN-JPEC, Version: Initial dt 17.06.2020** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site: -

Names of the new drug or investigational new drug:	Abemaciclib	
Therapeutic class:	Anticancer	
Dosage form:	Film coated tablet	
Composition:	Each film coated tablet contains: Abemaciclib50mg, 100mg, 150mg and 200mg	
Indications:	Breast cancer	
Details of clinical trial sites-		
Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	Dr. Rajnish Nagarkar, HCG Manavta Cancer centre, Behind Shivang Auto, Mumbai Naka, Nasik - 422002, Maharashtra, India	Manavata Clinical Research Institute Ethics Committee HCG Manavata Cancer Centre Behind Shivang Auto Mumbai Naka Nashik Maharashtra - 422002 India ECR/500/Inst /MH/2013/RR-20
2.	Dr. Dhruv Mehta, Nirmal Hospital Pvt. Ltd, Ring Road, Surat 395002, Gujarat, India	Nirmal Hospital Ethics Committee Nirmal Hospital Pvt. Ltd. 2/1423-8-6 Sagrampura Ring Road near centre point Surat- 395002 Gujarat ECR/390/Inst /GJ/2013/RR19
3.	Dr. P. N. Mohapatra Apollo Gleneagles Hospitals, 58, Canal Circular Road, Kolkata-700054, West Bengal, India	Institutional Ethics Committee Apollo Gleneagles Hospital, Kolkata Apollo Gleneagles Hospital 58 Canal Circular Road Kolkata, West Bengal, India-700054 ECR/373/Inst /WB/2013/RR -19
4.	Dr. Anoop T. Manoharan Regional Cancer Centre, Medical College Campus, Post Bag No. 2417, Thiruvananthapuram. Kerala - 695001	Human Ethics Committee RCC Regional Cancer Centre Medical College Campus Thiruvananthapuram Kerala - 695011 India ECR/21/Inst/ Ker/2013/RR19

5.	Dr. Satheesh CT Health Care Global Enterprise Ltd., HCG Tower, # 8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bengaluru- 560020	HCG Central Ethics Committee HCG- Bangalore institute of Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bengaluru (Bangalore) Urban - 560027 ECR/386/Inst /KA/2013/RR-19
6.	Dr. Tanveer Maksud, Unique Hospital- Multispecialty & Research Institute Opp. Kiran Motor, Nr. Canal, Civil Hospital, Char Rasta, Sosyo Circle Lane, off Ring Road, Surat -395002	Ethics committee, Unique Hospital Unique Hospital Opp. kiran motors, nr. canal, civil char rasta sosyo circle lane, off. ring road, Surat Gujarat - 395002 India ECR/595/Inst /GJ/2014/RR-20
7.	Dr. Chandan Krushna Das Department of Radiotherapy & Oncology, Regional Cancer Centre, Nehru Hospital, PGIMER (Post Graduate institute of Medical Education and Research), Chandigarh, Sector 1"2, Pin-160012	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor P N Chuttani Block Chandigarh -160012 India ECR/25/Inst/ CH/2013/RR20
8.	Dr. Minish Jain Grant Medical Foundation Ruby Hall Clinic,40, Sassoon Road, Pune — 411001, Maharashtra, India	Poona Medical Research Foundation Ruby Hall Clinic 40, Sassoon road Pune, Maharashtra 411001 India ECR/24/Inst/ MH/2013/RR19
9.	Dr. Smitha Gupte Meditrina Institute of Medical Sciences, 278, Central Bazar Road Ramdaspath Nagpur, Maharashtra - 440010 India	Meditrina Institute Ethics Committee Meditrina Institute of Medical Sciences 278, Central Bazar Road, Ramdaspath, Nagpur Maharashtra - 440010 India ECR/608/Inst /MH/2014/R R-20
10.	Dr. Saurabh Prasad Kingsway Hospitals ,44, Parwana Bhawan Kingsway Nagpur, Maharashtra - 440001 India	Kingsway Hospitals Ethics Committee Kingsway Hospitals ,44, Parwana Bhawan Kingsway Nagpur, Maharashtra - 440001 ECR/1269/Ins t/MH/2019

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. Somani

(Dr. V. G. Somani)

Central Licensing Authority
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

New Delhi

Date: 28 SEP 2020