File No. CT/127/23-DCG(I)

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan, 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/23/000127

To,

M/s Fortrea Development India Private Limited,
Building No. 1, Unit No. 601, Raheja Mindspace,
Plot Nos. Gen/2/1/D, E&F at MIDC TTC Area,
Shiravane, Navi Mumbai, Maharashtra (India) - 400706.

Sir,

With reference to your application No. GCT/CT04/FF/2023/39951 (GCT/127/23) dated 10-10-2023, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**CAMBRIA-2: A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a Next Generation, Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease" Protocol No.: D8535C00001 Version No. 2.0 Protocol Date 20-JUL-2023 with a total of up-to 120 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:-

1) 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;

2) 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;

3) 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;

4) 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;

5) 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;

6) 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;

7) 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;

8) 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;

9) 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;

10) 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;

11) 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;

12) 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;

13) 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;

14) 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;

15) 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;

16) 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;

17) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical tria;

18) 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;

19) 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: 2024.02.13 11:33:08 +05'30'

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

File No. CT/127/23-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 Fortrea Development India Private limited, Building no 1, Unit no 601, Raheja Mindspace Plot nos Gen/2/1D/E/F, MIDCTTC Industrial Area, Shiravane Thane (India) - 400706 Telephone No.:912268221585 FAX: 22 61793958 E-Mail : RA.INDIA@FORTREA.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: D8535C00001 Version No. 2.0 Protocol Date 20-JUL-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.

RAJEEV SINGH RAGHUVANSHI

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Date: 2024.02.13 11:33:21 +05'30'

Place: New Delhi
Date _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing 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	Camizestrant
Therapeutic class:	Anticancer
Dosage form:	Tablets
Composition:	Camizestrant = 75.0000 milligram(mg) In House Specification Active
Indications:	Breast Cancer

File No. CT/127/23-DCG(I)
Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Cytecare Hospitals Pvt. Ltd., Venkatala, Near Bagalur Cross, Yelahanka, Bangalore-560064, India	Cytecare Institutional Ethics Committee, Cytecare Hospitals Pvt. Ltd., Venkatala, Near Bagalur Cross, Yelahanka, Bangalore-560064, India ECR/1013/Inst/KA/2017/RR-20	Dr. Prasad Narayanan
2.	NH-Rabindranath Tagore International Institute of Cardiac Sciences Premises No 1489 (124), Mukundapur, E. M. Bypass, Kolkata-700099, West Bengal, India	NHRTJICS Ethics Committee 124, Mukundapur, E. M. Bypass, Kolkata-700099, West Bengal, India ECR/316/Inst/WB/2013/RR-19	Dr. Chandrakanth M V.
3.	Department of Medical Oncology 3rd Floor, Main O.P.D Building, VMMC & Safdariung Hospital, New Delhi-110029	Institutional Ethics Committee VMMC and SJH, Room no 506, 5th Floor, Main O.P.D Building, VMMC & Safdarjung Hospital, New Delhi-110029 ECR/593/Inst/DL/2014/RR-20	Dr. Kaushal Kalra
4.	Rajiv Gandhi Cancer Institute and Research Centre,Sector-5, Rohini, New Delhi -110085	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Sector 5, Rohini, New Delhi -110085 ECR/10/Inst/DC/2013/RR-19	Dr. D.C.Doval
5.	Apex wellness Hospital, Survey no 799,Plot no, 187, Behind Prakash petrol Pump, Nashik 422009, Maharashtra, India	Apex Wellness Ethics Committee, c/ o Apex Wellness Hospital, 799, plot no. 187, behind Prakash petrol pump Govind nagar Nashik, Maharashtra - 422009 ECR/1500/Inst/MH/2021	Dr. Shailesh Bondarde
6.	Tata Memorial Hospital Parel, Mumbai -400012, Maharashtra, India	Institutional Ethics Committee 3rd Floor, Main Building Tata Memorial Hospital Parel, Mumbai -400012, Maharashtra, India ECR/170/Inst/MH/2013/RR-22 ECR/414/Inst/MH/2013/RR-19	Dr. Jyoti Bajpai

7.	Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand - 248016	Ethics Committee Swami Rama Himalayan University, Swami Ram Nagar Jolly Grant , Dehradun, Uttrakhand – 248016 ECR/1741/Inst/UK/2022	Dr. Ankit Batra
8.	Jawaharlal Institute of Postgraduate Medical Education and Research, JIPMER Campus Road, Dhanvantary nagar, Gorimedu, Puducherry - 605006	Institutional Ethics Committee (Human studies) for Intervention studies, Admin Block, 1st Floor Dean Research office, JIPMER Campus Rd, Gorimedu, Dhanvantari Nagar, Puducherry, 605006 ECR/342/Inst/PY /2013/RR-19	Dr. Biswajit Dubashi
9.	KLEs Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-590010. Karnataka, India	Institutional Ethics Committee, KLE University KLE University KLE Dr. PK Hospital And MRC Nehru Nagar Belagavi. Kamataka-590010. Karnataka, India ECR/211/Inst/KA/2013/RR-19	Dr. Rohan Bhise
10.	Bharath Hospital and Institute of Oncology #438, Outer Ring Road, 1st Stage Lakshmikanth Nagar, Hebbal Industrial Area Mvsuru-570017	IEC-BHIO #438, Outer Ring Road, 1st Stage Lakshmikanth Nagar, Hebbal Industrial Area Mysuru-570017 ECR/994/lnst/KA/2017/RR-21	Dr. Srinivas K G
11.	Unique Hospital Multispeciality and Research Institute, Opp. Kiran motors, nr. Canal, civil char rasta, sosyo circle lane, off. Ring road, surat-3950002, Gujarat, India	Ethics Committee, Unique Hospital Multispeciality and Research Institute, Opp. Kiran Motor, Canal Road, Civil Hospital Char Rasta-Sosyo Circle Lane Off Ring road, Surat-395002, Gujarat, India ECR/595/Inst/GJ/2014/RR-20	Dr. Ankit Baldevbhai Patel
12.	KIMS KINGSWAY HOSPITALS, 44,Parwana Bhawan, Kingsway,Nagpur-440001,Maharashtra,lndia	KINGSWAY HOSPITALS ETHICS COMMITTEE -44, Parwana Bhawan, Kingsway, Nagpur-440001, Maharashtra, India ECR/1269/Inst/MH/2019	Dr.Saurabh Rajeshwar Prasad

13.	Tata Medical Center 14 Major Arterial Road (E-W), Rajarhat, New Town Kolkata-700160	Institutional Review Board Tata Medical Center 14 Major Arterial Road (EW) Newtown, Rajarhat Kolkata -700 160, India ECR/269/Inst/WB/2013/RR-19	Dr. Sanjoy Chatterjee
14.	All India Institute Of Medical Sciences, New Delhi, Ansari Nagar-110029	Institutional Ethics Committee, Old OT Block, Room No. 102, AIIMS Hospital, Ansari Nagar, New Delhi-110029 ECR/538/Inst/DL/2014/RR-20	Dr. Atul Batra
15.	MVR Cancer Centre and Research Institute, CP 13/516.B.C/Vellalasseri, NIT (Via), Poolacode, Kozhikode-673601, Kerala, India	Institute Ethics Committee, MVR Cancer Centre and Research Institute CP 13/526 B,C, Vellalaseri NIT(Via), Poolacode, Kozhikode,Kerala-673601 ECR/1259/Inst/KL/2019	Dr. Narayanankutty Warrier
16.	Department of Medical Oncology, Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad, Telangana - 500082	NIMS-Institutional Ethics Committee (NIEC), SRC, 2ND Floor, Old Building, Nizam 's Institute of Medical Sciences, Panjagutta, Hyderabad, Telangana, India-500082. ECR/303/Inst/AP/2013/RR-19	Dr. Meher Lakshmi Konatam
17.	HCG Manavata Cancer Centre Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra, India, 422002	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra, India, 422002 ECR/500/Inst/MH/2013/RR-20	Dr. Shruti Deepak Kate
18.	Sri Ram Cancer and Superspeciality Centre, Mahatma Gandhi Medical College and Hospital, A unit of Mahatma Gandhi University of Medical Sciences and Technology, RIICO Institutional Area, Sitapura Tonk road, Jaipur-302022 (Rajasthan), India	Institutional Ethics Committee, Mahatma Gandhi University of Medical Sciences and Technology ECR/125/Inst/RJ/2013/RR-19	Dr. Lalit Mohan Sharma

19.	Fortis Hospital, Shalimar Bagh A-Block, Delhi-110088	Institutional Ethics Committee Fortis Hospital, Shalimar Bagh A-Block, Delhi-110088 ECR/513/Inst/DL/2014/RR-20	Dr. Vineet Govinda Gupta

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