



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

File No. CT/23/000131

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/2023/40097 (GCT/131/23) dated 19-10-2023, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of abelacimab in high-risk patients with Atrial fibrillation who have been deemed unsuitable for oral antiCoagulation (LILAC)” Protocol No.: ANT-010 Version No. 4.1 Protocol Date 29-SEP-2023 with a total of up-to 200 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 Licensing 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 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;

- 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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 trial;
- 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
RAGHUVANSI
(Dr. Rajeev Singh Raghuvansi)
H Drugs Controller General (India) &
Central Licencing Authority
Stamp

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.: ANT-010 Version No. 4.1 Protocol Date 29-SEP-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
 (Dr. Rajeev Singh Raghunishi)
 RAGHUNISHI
 Drugs Control
 Central Licensing Authority
 Stamp

Digitally signed by RAJEEV SINGH RAGHUVA NSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=RAJEEV SINGH RAGHUVA NSHI,
2.5.4.06.c26fa623e4efabfe8c293774dceb03c2769
401015a06f5ee4bf67f54b75dbd1cb,
postalCode=110002, serialNumber=
Serial Number = 657F5E47D940985D8F03BDC902DOE
IFR4C8A7F4F56A0406A19A98,
cn=RAJEEV SINGH RAGHUVA NSHI
(General India) &
Jeevan Authority

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	Abelacimab
Therapeutic class:	Antithrombotic
Dosage form:	Solution for infusion
Composition:	Abelacimab = 150.0000 mg/ml In House Specification Active
Indications:	Atrial fibrillation

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Room No. 125, 1 st floor, Department of Cardiology, Academic Block, Gate No. 2, G.B. Pant Institute of Post Graduate Medical Education and Research, 1, Jawaharlal Nehru Marg, 64 Khamba, Raj Ghat ,New Delhi, Delhi 110002	Institutional Ethics committee, 3 rd Floor, Room No. 306A, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi-110002 ECR/329/Inst/DL/2013/RR-19	Dr. Girish MP
2.	Government Medical College & Super Speciality Hospital, Tukdoji Square, Nagpur-440009, Maharashtra, India	Institutional Ethics Committee, GMC, Nagpur GMC Government Medical College and Hospital, Medical Square, Hanuman Nagar, Nagpur-440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-22	Dr. Sunil Nilkanthrao Washimkar
3.	Postgraduate Institute of Medical Education and Research, Sector-12, Chandigarh 160012	Institutional Ethics Committee PGIMER ECR/25/Inst/CH/2013/RR-20	Dr. Samir Malhotra
4.	Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara. P.O., Kochi-682041, Kerala, India	Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS Ponekkara, Kochi, Edappally, Ernakulam, Kerala-682041, India ECR/129/Inst/KL/2013/RR-19	Dr. Jaideep Channayil Menon
5.	Deenanath Mangeshkar Hospital and Research Centre, Erandawane, Pune-411004, India	Ethics Committee : Institutional Ethics Committee, DMHRC, 14th floor Super Speciality Building Deenanath Mangeshkar Hospital & Research Center, Erndawane, Pune 411004 ECR/15/Inst/Maha/2013/RR-22	Dr Prashant Ravindra Mishra
6.	SMS Jaipur Medical College and Hospital, J.L.N. marg, Jaipur-302004, Rajasthan, India	Ethics Committee SMS Medical College and Hospitals, .L.N. marg, Jaipur-302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-19	Dr. Chandra Bhan Meena

File No. CT/131/23-DCG(I)

7.	ABVIMS, Dr Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, New Delhi-110002	Ethics Committee, ABVIMS, Dr. RML Hospital ABVIMS, Dr Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, New Delhi-110001 ECR/78/Inst/DL/2013/RR-19	Dr. Bhagya Narayan Pandit
8.	Max Super Speciality Hospital, Vaishali (A unit of Crosslay Remedies Ltd.) W-3, Sector-1, Vaishali, Ghaziabad-201012,U .P	Institutional Ethics Committee Max Super Speciality Hospital, Vaishali (A unit of Crosslay Remedies Ltd.) W-3, Sector-1, Vaishali,Ghaziabad-201012,U.P ECR/360/Inst/UP/2013/RR-19	Dr. Gaurav Minocha
9.	KIMS hospital, 1-8-31 /I, Minister road, Secunderabad - 500003, Telangana	KRISHNA INSTITUTE OF MEDICAL SCIENCES LIMITED 1-8-31/1, Minister Road Krishna Nagar Colony, Begumpet. Secunderabad Hyderabad Telangana -500003 India ECR/142/Inst/AP/2013/RR-19	Dr. Rajendra Kumar premchand
10.	Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad-380054, Gujarat, India	Zydus Hospital Ethics Committee, Zydus Hospitals & Healthcare Research Pvt. Ltd, Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad-380054, Gujarat, India ECR/855/Inst/GJ/2016/RR-2019	Dr. Thanvi Sunil Shrikumar
11.	Bangalore Medical College and Research Institute, 2nd Floor, Department of Cardiology, BMCRI Super Speciality Hospital, Victoria Hospital Campus, KR Road, Fort, Bangalore 560002, India	Ethics Committee of Bangalore Medical college and Research Institute, K R Road, Fort, Bangalore 560002, India ECR/302/Inst/KA/2013/RR-20	Dr Divyaprakash Mada
12.	MEDI COVER HOSPITALS, Door No 1-1-83, Main Road, Venkojipalem, Visakhapatnam - 530022 Andhra Pradesh India	Ethics Committee, Medicovert Hospitals Vishakapatnam 1-1-83, Main Road, Venkojipalem, Visakhapatnam -530022, Andhra Pradesh India ECR/1845/Inst/AP/2023	Dr G. Ravi Kumar
13.	P.D. Hinduja National Hospital, Veer Savarkar Marg, Mahim, Mumbai - 400016. Maharashtra,	Institutional Ethics Committee P.D. Hinduja National Hospital, Veer Savarkar Marg, Mahim, Mumbai -400016. Maharashtra,	Dr. Ameya Ramrao Udyavar

	INDIA	INDIA	
		ECR/61/Inst/MH/2013/RR-19	
14.	IPGME&R and SSKM Hospital 244, AJC Bose Road, Kolkata, West Bengal-700020, India	IPGME&R Research Oversight Committee, 244, AJC Bose Road, Kolkata, West Bengal-700020, India	Dr. Sankar Chandra Mondal
		ECR/35/Inst/WB/2013/RR-19	
15.	KIMS Kingsway Hospital, 44, Kingsway, Near Kasturchand Park, Nagpur - 440001, Maharashtra, India	Ethics Committee Kingsway Hospitals Ethics Committee, Kingsway Hospitals 44, Parwana Bhawan Kingsway Nagpur-440001, Maharashtra India	Dr Rishi Vinod Lohiya
		ECR/1269/Inst/MH/2019	
16.	Viveka Super Specialty Hospitals and Research Center private Limited, Plot no 1A, Naik Layout, Subhash Naear, Nagpur-440022, Maharashtra, India	Viveka Hospital Ethics Committee, Viveka Super Specialty Hospitals and Research Center private Limited, Plot no 1A, Naik Layout, Subhash Nagar, Nagpur-440022, Maharashtra, India	Dr. Prashant Manohar Jaetap
		ECR/1639/Inst/MH/2021	
17.	WMF'S Viloo Poonawala Memorial Hospital Pune S.No. 156, Soli Poonawalla Road Solapur Road, Hadapsar, Pune-411028 India	Institutional Ethics Committee WMF'S Viloo Poonawalla Memorial Hospital, Viloo Poonawalla Memorial Hospital, S No. 156 Plot No.1/3A , 3B, 1, 2/3 Pune Solapur Road, Hadapsar, Pune, Maharashtra-411028 India	Dr. Hemant T. Kokane
		ECR/1642/Inst/MH/2022	
18.	AIIMS, Bhubaneswar, Sijua, Patrpada. Dumduma, Odisha. India. 751019	Institutional Ethics Committee AIIMS, Bhubaneswar, Sijua, Patrpada, Dumduma, Odisha, India, 751019	Dr.Rama Chandra Barik
		ECR/534/Inst/OD/2014/RR-20	
