सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services) Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/24/000050

To,

M/s. Novartis Healthcare Private Limited,
Inspire BKC, Part of 601 & 701,
BKC Main Road Bandra Kurla Complex,
Bandra (East), Mumbai (India) – 400051, Maharashtra.

Sir,

With reference to your application No. GCT/CT04/FF/2024/42642 dated 01-Apr-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A phase IIIb study to characterize the effectiveness and safety of Adjuvant ribociclib in a wide patient population with HR+ HER2 − early breast cancer (Adjuvant WIDER)" Protocol no.: CLEE011O12001 Version no. 02 dated 08-Jan-2025 with a total of up-to 210 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:-

(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 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 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;

(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 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;

(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 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 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;

(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 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;

(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) 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;

(xix) 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
Date: 2025.07.23 15:34:05 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing 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. Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, BKC Main Road Bandra Kurla Complex Bandra (East), Maharashtra (India) - 400051 Telephone No.: 912250243588 FAX: 912250243010 E-Mail: NHPL.DRASUGAM@NOVARTIS.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: CLEE011O12001 Version no. 02 dated 08-Jan-2025** with 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 RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.07.23 15:34:26 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing 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	LEE011
Therapeutic class:	Cyclin dependent kinases CDK4 and 6 inhibitor
Dosage form:	Tablets
Composition:	LEE011 =200.0000 milligram (mg) In House Specification Active
Indications:	HR+ HER2- early breast cancer

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	All India Institute of Medical Sciences, AIIMS, Room No. 218, Second Floor, Department of Medical Oncology, Dr. B.R.A, I.R.C.H, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi-110029	Institute Ethics Committee, AIIMS, Old OT Block Room No 102, AIIMS, Hospital, Ansari Nagar, New Delhi-110029 ECR/538/Inst/DL/2014/RR-20	Dr. Ajay Gogia
2.	Room No 1102, 11th Floor, Homi Bhabha Block, Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel €, Mumbai 400012, Maharashtra India.	Institutional Ethics Committee, 3rd Floor, Main Building, IRB Department, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel (E), Mumbai 400012, Maharashtra India. ECR/170/Inst/MH/2013/RR-22	Dr. Prabhat Bhargava
3.	Haemato-Oncology Clinic Pvt Ltd, Nirmaya Complex, Ground Floor to Third Floor, B/S Pandit Dindayal Auditorium, Rajpath Club Road, Off SG Highway, Ahmedabad-380054, Gujrat, India.	Ethics Committee of CIMS (Care Institute of Medical Science), Opposite Panchamurt Banglows, Near Shakun Mall, Off Science City Road, Ahmedabad-380060 ECR/206/Inst/GJ/2013/RR-20	Dr. Chirag Desai
4.	Apollo Cancer Centre No. 320, Padma complex, Anna Salai Chennai-600035, Tamilnadu, India.	Institutional Ethics Committee-Clinical Studies; Apollo Hospitals Enterprise Limited, No. 21, Greams Land, Off Greams Road, Thousand lights, Chennai-600006, Tamilnadu, India.	Dr. Rajiv Rajendranath

		ECR/37/Inst/TN/2013/RR-19	
5.	Sahyadri Super Specially Hospital, Hadapsar, Sr. No. 163, Bhosale Nagar, Hadaspar Pune-411028, Maharashtra, India	Sahyadri Hospital Pvt Ltd. Ethics Committee Sahyadri Clinical Research and Development Centre, 33/34b, Makarand Bhave path, Karve Road, Pune-411004, Maharashtra, India. ECR/493/INST/MH/2013/RR-19	Dr. Shona Milon Nag
6.	Manipal Hospital 98, Old Airport Road, Bangalore-560017, Karnataka, India	Ethics Committee of Manipal Hospital, Manipal Hospital, #98, Airport Road, Bangalore-560017, Karnataka, India ECR/34/Inst/KA/2013/RR-19	Dr. Amit Rauthan
7.	Department of Medical Oncology, Basavatarakam Indo American Cancer Hospital and Research Institute, Road No 10, Banjara Hills, Hyderabad 500034	Institutional Ethics Committee, Basavatarakam Indo American Cancer Hospital and Research Institute, Road No 10, Banjara Hills, Hyderabad, Telangana, 500034 ECR/INST/7/AP/2013/RR-20	Dr. MVT Krishna Mohan
8.	Sparsh Hospital and Critical Care (P) Ltd, A/407/ Saheed Nagar, Bhubaneswar, Odisha, India, 751007	Institutional Ethics Committee, Sparsh Hospital, Sparsh Hospital and Critical Care (P) Ltd, A/407/ Saheed Nagar, Bhubaneswar, Odisha, India, 751007 ECR/68/INST/OR/2013/RR-22	Prof (Dr.) Ghanashyam Biswas
9.	VMMC and Safdarjung Hospital, Main OPD Building, 3rd floor, Room No 313, New Delhi 110029, India	Institutional Ethics Committee-Main OPD Building, 5th Floor, Room No 506, VMMC and Safdarjung Hospital, New Delhi-110029, India ECR/593/Inst/DL/2014/RR-20	Dr. Kaushal Kalra
10.	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-16	Dr. Dinesh Chandra Doval
11.	Regional Cancer Centre, Medical Oncology Department, Medical College Campus, Thiruvananthapuram-695011	Human Ethics Committee, RCC, Medical college campus PO, Thiruvananthapuram, Kerala, 695011 India ECR/21/Inst/Ker/2013/RR-19	Dr. Rona Joseph P

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