



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
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File No. CT/24/000045

To,

M/s. AstraZeneca Pharma India Limited,
Block N1, 12th Floor Manyata Embassy,
Business Park, Rachenahalli Outer Ring Road,
Bangalore, Karnataka (India) – 560045.

Sir,

With reference to your application No. GCT/CT04/FF/2024/42369 dated 19-Mar-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase III, Randomised, Double-blind Study to Evaluate the Effect of Balcinrenone/Dapagliflozin, Compared with Dapagliflozin, on the Risk of Heart Failure Events and Cardiovascular Death in Patients with Heart Failure and Impaired Kidney Function (Balance D-HF)” Protocol No.: D6402C00012, CSP Version 2.0 dated 11 Jan 2024 and Local CSP - Addendum IND-1: Version 1.0, 06 Mar 2024 with a total of up-to 220 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) **Human biological samples i.e. Blood, urine, serum, and plasma related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (ii) 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;
- (iii) 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;

- (iv) 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;

- (v) 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;
- (vi) 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;
- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xix) 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;

(xx) 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,

(Dr. Rajeev Singh Raghuvanshi)
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. AstraZeneca Pharma India Limited, Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore, Karnataka (India) - 560045** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: D6402C00012, CSP Version 2.0 dated 11 Jan 2024 and Local CSP - Addendum IND-1: Version 1.0, 06 Mar 2024** 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 _____

(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	Balcinrenone 15 mg+Dapagliflozin 10 mg Balcinrenone 40 mg+Dapagliflozin 10 mg
Therapeutic class:	MR modulator and SGLT2i MR modulator and SGLT2i
Dosage form:	Capsules Capsules
Composition:	Balcinrenone = 15.0000 milligram (mg) In House Specification Active Dapagliflozin propanediol=12.3000 milligram (mg) In House Specification Active Balcinrenone = 40.0000 milligram (mg) In House Specification Active Dapagliflozin propanediol =12.3000 milligram (mg) In House Specification Active
Indications:	Patients with Heart Failure and Impaired Kidney Function Patients with Heart Failure and Impaired Kidney Function

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	St. Theresa's Hospital, Sanathnagar, Hyderabad, Telangana - 500018	Ethics committee St Theresa's Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad, Telangana – 500018 ECR/230/Inst/AP/2013/RR-22	Dr Ravi Teja Rao Babburi
2.	Vardhman Mahavir Medical College & Safdarjung Hospital, Ansari Nagar West, New Delhi, Delhi 110029	Institutional Ethics Committee VMMC and SJH, Vardhman Mahavir Medical College and Safdarjung Hospital, Ring Road, Ansari Nagar, New Delhi, South Delhi, Delhi – 110029 ECR/593/Inst/DL/2014/RR-20	Dr Sandeep Bansal
3.	Zydus Hospitals and Health Care Research Pvt. Ltd., Zydus Hospitals Road, S.G Highway, Thaltej, Ahmedabad -	Zydus Hospital Ethics Committee, Zydus Hospitals & Healthcare Research Pvt Ltd., Zydus Hospital Road, Near Sola Bridge S. G. Highway, Thaltej,	Dr Thanvi Sunil Shrikumar

	380054, Gujarat	Ahmedabad, Gujarat, 380054 ECR/855/Inst/GJ/2016/RR-19	
4.	Nil Ratan Sircar (NRS) Medical College and Hospital, 138, AJC Bose Road, Kolkata - 700014, West Bengal	Ethics Committee N.R.S. Medical College, NRS Medical College and Hospital, 138, A. J. C. Bose Road, Kolkata, West Bengal – 700014 ECR/609/Inst/WB/2014/RR-20	Dr Swapan Kumar Halder
5.	Institute of Post-Graduate Medical Education & Research (IPGME&R) and Seth Sukhlal Karnani Memorial (SSKM) Hospital, 244, Acharya J. C. Bose Road, Bhowanipore, Kolkata-700020, West Bengal	IPGME and Research Oversight Committee, Institute of Postgraduate Medical Education & Research, 244 Acharya JC Bose Road, Kolkata, West Bengal, 700020 ECR/35/Inst/WB/2013/RR-19	Dr Sankar Chandra Mondal
6.	Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, Department of Cardiology, Jawahar Lal Nehru Marg, New Delhi - 110002	Institutional Ethics Committee, MAMC, Maulana Azad Medical College, 3rd Floor, Room No 306B, Bahadur Shah Zafar Marg, New Delhi, Delhi – 110002 ECR/329/Inst/DL/2013/RR-19	Dr Vimal Mehta
7.	Manipal Hospital, No.85-86, Bangalore-Mysore Ring Road Junction, Bannimantapa 'A' layout, Siddiqui Nagar, Mandi Mohalla, Mysuru -570015, Karnataka	IEC Columbia Asia Hospital Mysore, Columbia Asia Hospital Mysore, No. 85-86, Bangalore-Mysore Ring Road Junction, Bannimantapa A Layout, Mandi, Mohalla, Mysuru, Karnataka - 570015 ECR/1106/Inst/KA/2018/RR-21	Dr Keshavamurthy C B
8.	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi -590010, Karnataka	Institutional Ethics Committee, KLE University's KLE Dr.PK Hospital and MRC, Nehru Nagar, Belagavi, Karnataka – 590010 ECR/211/Inst/KA/2013/RR-19	Dr Prasad Murigendrappa Renuka
9.	Max Super Speciality Hospital, Saket (East Block) (A Unit of Devki Devi Foundation), 2, Press Enclave Road, Saket, New Delhi –	Institutional Ethics Committee, Max Super Speciality Hospital, Saket (A unit of Devki Devi Foundation), 2, Press Enclave Road, Saket, New Delhi, Delhi – 110017	Dr Vijay Kumar Chopra

	110017	ECR/110/Inst/DL/2013/RR-19	
10.	Batra Hospital and Medical Research Centre (BHMRC), 1, Tughlakabad Institutional Area, M.B road, New Delhi - 110062	Scientific Research and Ethical review Committee Batra Hospital and Medical Research Centre, 1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi, South Delhi - 110062 ECR/295/Inst/DL/2013/RR-22	Dr Upendra Kaul
11.	B.J Government Medical College and Sassoon General Hospitals, Jay Prakash Narayan Road, Near Pune Railway Station, Pune, 411001, Maharashtra	Institute Ethics Committee BJ Government Medical College and Sassoon General Hospital, Jai Prakash Narayan Road, Pune, Maharashtra - 411001 ECR/433/Inst/MH/2013/RR-19	Dr Hemant Trimbak Kokane
12.	Narayana Institute of Cardiac Sciences -Unit of Narayana Health, Narayana Hrudayalaya Limited, #258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore - 560099	Narayana Health Medical Ethics Committee, Narayana Health Hospital Health City, No. 258/A, Bommasandra, Industrial Area, Anekal Taluk, Bangalore Rural, Karnataka – 560099 ECR/390/Inst/KA/2013/RR-19	Dr Srikanth K V
13.	Kasturba Medical College and Hospital, MAHE, Tiger Circle Road, Madhav Nagar, Eshwar Nagar, Manipal -576104	MAHE Ethics Committee, Manipal Academy of Higher Education, Madhav Nagar, Manipal, Udupi, Karnataka – 576104 ECR/191/Inst/KL/2013/RR-19	Dr Tom Devasia
14.	LPS Institute of Cardiology and Cardiac Surgery, GSVM Medical College, Swaroop Nagar, Kanpur - 208002, Uttar Pradesh	Ethics Committee GSVM Medical College, Kanpur, Swaroop Nagar, Kanpur, Uttar Pradesh -208002 ECR/680/Inst/UP/2014/RR-20	Dr Santosh Kumar Sinha
15.	All India Institute of Medical Sciences, Nagpur, Plot No.2, Sector 20, MIHAN, Nagpur, 441108, Maharashtra	Institutional Ethics Committee for Clinical Trial All India Institute of Medical Sciences, Nagpur, Plot No 2, Sector 20 1st floor, OPD building, MIHAN, Nagpur, Maharashtra, 441108 ECR/1392/Inst/MH/2020	Dr Arijit Kumar Ghosh

16.	Care Hospitals, 6-3-248/2, Road No.1, Banjara Hills, Hyderabad - 500034, Telangana	CARE Hospitals, Institutional Ethics Committee, 6-3-248/2, Care Hospital, In-Patient building, 4th Floor Room No. 401, Road No-1, Banjara Hills, Hyderabad, Telangana- 500034 ECR/94/Inst/AP/2013/RR-21	Dr Pannala Lakshmi Narasimha Kabardy
17.	Gleneagles AWARE Hospital, 08-16-01, Near Sagar X roads, Saroornagar, L.B Nagar, Hyderabad - 560035, Telangana	Institutional Ethics Committee, Gleneagles Global Hospitals, 6-1-82/83, Global Good Life Building, 6th Floor, Lakdikapool, Hyderabad, Telangana - 500004 ECR/158/Inst/AP/2013/RR-19	Dr Rajeev Garg
18.	Jawaharlal Nehru Medical College, Kala Bagh, Ajmer, 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan - 305001 ECR/1156/Inst/RJ/2018/RR-22	Dr Pramod Kumar Pareek
19.	Shree Krishna Hospital and Medical Research Centre, Bhaikaka University, BM Patel Cardiac Centre, Gokal Nagar, Karamsad, Anand - 388325, Gujarat	Institutional Ethics Committee, Bhaikaka University, Gokal Nagar, Karamsad, Anand, Gujarat - 388325 ECR/331/Inst/GJ/2013/RR-19	Dr Sunil Kumar Karna
20.	Govt. Siddhartha Medical College, Ring road, Gunadala, Vijayawada - 520008, Andhra Pradesh	Institutional Ethics Committee SMC and GGH, Siddhartha Medical College and Govt. General Hospital, Ring Road, Gunadala, Vijayawada - 520008, Andhra Pradesh ECR/633/Inst/AP/2014/RR-19	Dr Barama Srihari
