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/25/000001

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/2024/47120 dated 02-Jan-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled **"A Phase III, Randomised, Double-blind, Placebo-controlled, Event-driven Study to Evaluate the Effect of Baxdrostat in Combination with Dapagliflozin Compared with Dapagliflozin Alone on the Risk of Incident Heart Failure and Cardiovascular Death in Participants with Increased Risk of Developing Heart Failure" (BaxDuo Prevent-HF)" Protocol no. D6973C00001 CSP Version 2.0 dated 25 Nov 2024 with a total of up-to 400 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. Whole blood, serum, plasma and urine samples related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**

(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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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,

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.04.09 17:23:46 +05'30'

(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. D6973C00001 CSP Version 2.0 dated 25 Nov 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 _____

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.04.09 17:23:57 +05'30'

(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	Baxdrostat Tablets 1mg/ Placebo
	Baxdrostat Tablets 2mg/Placebo
	Dapagliflozin Tablets 10 mg
Therapeutic class:	Aldosterone synthase inhibitor
	Aldosterone synthase inhibitor
	SGLT2 inhibitor
Dosage form:	Tablets
	Tablets
	Tablets
Composition:	Baxdrostat=1.0000 milligram (mg) In House Specification Active
	Baxdrostat=2.0000 milligram (mg) In House Specification Active
	Dapagliflozin propanediol=12.3000 milligram (mg) In House Specification Active
Indications:	Risk of Incident Heart Failure and Cardiovascular Death in Participants with Increased Risk of Developing Heart Failure

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, 500018, Telangana	Ethics committee St Theresa Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad–500018, Telangana ECR/230/Inst/AP/2013/RR-22	Dr Ravi Teja Rao Babburi
2.	Vardhman Mahavir Medical College (VMMC) & Safdarjung Hospital, Ansari Nagar, New Delhi –110029, Delhi	Institutional Ethics Committee VMMC and SJH, Vardhman Mahavir Medical College and Safdarjung Hospital, Ring Road, Ansari Nagar, New Delhi - 110029, Delhi ECR/593/Inst/DL/2014/RR-20	Dr HS Isser
3.	Zydus Hospitals and Health Care Research Pvt. Ltd., Zydus Hospitals Road, SG Highway, Thaltej, Ahmedabad - 380054, Gujarat	Zydus Hospital Ethics Committee, Zydus Hospitals & Healthcare Research Pvt Ltd., Zydus Hospital Road, Near Sola Bridge, SG Highway, Thaltej, Ahmedabad–380054, Gujarat ECR/855/Inst/GJ/2016/RR-19	Dr Thanvi Sunil Shrikumar

4.	Nil Ratan Sircar (NRS) Medical College and Hospital, 138, Acharya Jagadish Chandra Bose Road, Kolkata -700014, West Bengal	Ethics Committee NRS Medical College, NRS Medical College and Hospital, 138, A. J. C. Bose Road, Kolkata -700014, West Bengal ECR/609/Inst/WB/2014/RR-20	Dr Swapan Kumar Halder
5.	Atal Bihari Vajpayee Institute of Medical Sciences, Dr Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, New Delhi –110001, Delhi	Ethics Committee, PGIMER, Dr Ram Manohar Lohia (RML) Hospital, Baba Khadakh Singh Marg, New Delhi –110001, Delhi ECR/78/Inst/DL/2013/RR-24	Dr Bhagya Narayan Pandit
6.	Institute of Post-Graduate Medical Education & Research (IPGME&R) and Seth Sukhlal Karnani Memorial (SSKM) Hospital, 244, Acharya J C Bose Road, Kolkata-700020, West Bengal	IPGME and Research Oversight Committee, IPGME&R SSKM Hospital, 244 Acharya JC Bose Road, Kolkata –700020, West Bengal ECR/35/Inst/WB/2013/RR-24	Dr Tushar Kanti Patra
7.	Jawaharlal Nehru (JLN) Medical College, Kala Bagh, Ajmer -305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer - 305001, Rajasthan, ECR/1156/Inst/RJ/2018/RR-22	Dr Pramod Kumar Pareek
8.	Govt. Siddhartha Medical College, Ring Road, Gunadala, Vijayawada, Krishna -520008, Andhra Pradesh	Institutional Ethics Committee SMC and GGH, Siddhartha Medical College and Govt. General Hospital, Ring Road, Gunadala, Vijayawada, Krishna -520008, Andhra Pradesh ECR/633/Inst/AP/2014/RR-19	Dr Barama Srihari
9.	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 –441108, Maharashtra ECR/1392/Inst/MH/2020	Dr Arijit Kumar Ghosh
10.	Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, First Floor, Academic Block, Department of Cardiology, Jawahar Lal Nehru Marg, New Delhi –	Institutional Ethics Committee MAMC, Maulana Azad Medical College, 3rd Floor, Bahadur Shah Zafar Marg, New Delhi – 110002, Delhi ECR/329/Inst/DL/2013/RR-24	Dr Vimal Mehta

	110002, Delhi		
11.	Shri B.D Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Athwa gate, Ring Road, OPD area, Surat - 395001, Gujarat	Shri BD Mehta Mahavir Heart Institute Ethics Committee, Shri B. D. Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Opp. Vanita Vishram Ground, Athwagate, Ring Road, Surat –39500, Gujarat ECR/850/Inst/GJ/2016/RR-20	Dr Atul Damodar Abhyankar
12	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 –500034, Telangana ECR/94/Inst/AP/2013/RR-21	Dr Pannala Lakshmi Narasimha Kabardy
13	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi –590010, Karnataka	Institutional Ethics Committee, KLE University KLE Dr. PK Hospital and MRC, Nehru Nagar, Belagavi –590010, Karnataka ECR/211/Inst/KA/2013/RR-24	Dr Prasad Murigendrappa Renuka
14	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 –500004, Telangana ECR/158/Inst/AP/2013/RR-19	Dr Rajeev Garg
15.	Bhaikaka University, BM Patel Cardiac Centre, Shree Krishna Hospital and Medical Research Centre, Gokal Nagar, Karamsad, Anand - 388325, Gujarat	Institutional Ethics Committee, Bhaikaka University, Gokal Nagar, Karamsad, Anand, Gujarat –388325 ECR/331/Inst/GJ/2013/RR-24	Dr Sunil Kumar Karna
16.	Batra Hospital and Medical Research Centre (BHMRC), 1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi – 110062, Delhi	Scientific Research and Ethical review Committee Batra Hospital and Medical Research Centre, 1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi– 110062, Delhi	Dr Upendra Kaul

		ECR/295/Inst/DL/2013/RR-22	
17	Max Super Speciality Hospital Saket (East Block) (A Unit of Devki Devi Foundation), 2, Press Enclave Road, Saket, New Delhi – 110017, Delhi	Institutional Ethics Committee, Service Floor, Office of Ethics Committee, Max Super Speciality Hospital, Saket (A unit of Devki Devi Foundation), 2, Press Enclave Road, Saket, New Delhi–110017, Delhi ECR/110/Inst/DL/2013/RR-19	Dr Vijay Kumar Chopra
18	Medanta -The Medicity, Sector 38, Gurugram, 122001, Haryana	Medanta Institutional Ethics Committee, Medanta -The Medicity, Sector -38, Gurugram –122001, Haryana ECR/282/Inst/HR/2013/RR-20	Dr Rajneesh Kapoor
19	Sunshine Global Hospital, Beside Big Bazar, Gaurav Path, Dumas Road, Surat –395007, Gujarat	Institutional Ethics Committee, Sunshine Global Hospital, Dumas Road, Beside Big Bazar, Piplod, Surat –395007, Gujarat ECR/1341/Inst/GJ/2020	Dr Pritesh Sureshchandra Parekh
20	Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bannerghatta Road, 9th block, Jayanagar, Bengaluru Urban– 560069, Karnataka	Sri Jayadeva Ethics Committee, Sri Jayadeva Institute of Cardiovascular Sciences & Research, Bannerghatta Road, 9th block, Jayanagar, Bangalore Urban –560069, Karnataka ECR/423/Inst/KA/2013/RR-19	Dr Satvic C Manjunath

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