



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/24/000152

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/2024/46849 dated 18-Dec-2024, 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 Assess the Efficacy, Safety and Tolerability of Baxdrostat in Combination with Dapagliflozin Compared with Dapagliflozin Alone on Renal Outcomes and Cardiovascular Mortality in Participants with Chronic Kidney Disease and High Blood Pressure”** Protocol no. **D6972C00002 CSP version 2.0 dated 12 Nov 2024 and Local CSP Addendum IND-1: Version 1.0, 29 Jan 2025 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:-

- (i) **That India specific local addendum (D6972C00002, Local CSP Addendum IND-1, Version 1.0 dated 29 Jan 2025) shall be implemented.**
- (ii) **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.**
- (iii) 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;
- (iv) 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;

- (v) 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;

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

(xxi) 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. D6972C00002 CSP version 2.0 dated 12 Nov 2024 and Local CSP Addendum IND-1: Version 1.0, 29 Jan 2025** 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	Baxdrostat Tablets 1mg/Placebo
	Baxdrostat Tablets 2mg/Placebo
	Dapagliflozin Tablets 10 mg
Therapeutic class:	Selective aldosterone synthase inhibitor
	Selective aldosterone synthase inhibitor
	Sodium/glucose cotransporter 2 Inhibitors
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:	Participants with Chronic Kidney Disease and High Blood Pressure

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Nil Ratan Sircar (NRS) Medical College & Hospital, 138, AJC Bose Road, Kolkata, West Bengal -700014	Ethics Committee, N.R.S. Medical College & Hospital, 138, A.J.C Bose Road, Kolkata, West Bengal –700014 ECR/609/Inst/WB/2014/RR-20	Dr Pinaki Mukhopadhyay
2.	Atal Bihari Vajpayee Institute of Medical Sciences, Dr. Ram Manohar Lohia Hospital, Baba Kahrak Singh Marg, Near Gurudwara Bangla Sahib, Connaught Place, New Delhi, 110001	Ethics Committee, PGIMER, Dr. RML Hospital, PGIMER, Dr. Ram Manohar Lohia Hospital, Baba Khadakh Singh Marg, New Delhi –110001 ECR/78/Inst/DL/2013/RR-24	Dr Himansu Sekhar Mahapatra
3.	IPGME&R and SSKM Hospital, Department of Nephrology, 244, AJC Bose Road, Kolkata, West Bengal -700020	IPGME&R Research Oversight Committee, IPGME&R and SSKM hospital, 244 Acharya J. C. Bose Road, Kolkata, West Bengal –700020 ECR/35/Inst/WB/2013/RR-24	Dr Atanu Pal

4.	All India Institute of Medical Science, Room No.3, Porta Cabin, 4th Floor, Teaching block, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee, All India Institute of Medical Science, Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi -110029 ECR/538/Inst/DL/2014/RR-20	Dr Arun kumar Subbiah
5.	Sunrise Hospitals (A Unit of NS Healthcare Services Pvt Ltd), Opposite Corporation Bank, Bellapu Sobhanadri Road, Near Pushpa Hotel Centre, Suryaraopet, Vijayawada, Andhra Pradesh -520002	Institutional Ethics Committee Sunrise Hospital, (A Unit of NS Healthcare Services Pvt Ltd), Opp Corporation bank, Bellapu sobhanandri road, Vijayawada, Krishna, Andhra Pradesh - 520002 ECR/756/Inst/AP/2015/RR-21	Dr M V S Krishna
6.	Nizam's Institute of Medical Sciences (NIMS), Panjagutta, Hyderabad, Telangana -500082	NIMS Institutional Ethics Committee, Nizams Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana -500082 ECR/303/Inst/AP/2013/RR-19	Dr D Sree Bhushan Raju
7.	Noble Hospital Pvt. Ltd., Nephrology OPD, Noble Annex, 153 Magarpatta City Road, Hadapsar, Pune, Maharashtra - 411013	Noble Hospital Institutional Ethics Committee, Noble Hospital Pvt. Ltd., Magarpatta City Road, Pune, Maharashtra - 411013 ECR/259/Inst/MH/2013/RR-24	Dr Avinash Ignatius
8.	Max Super Speciality Hospital, Saket (West Block), (A Unit of Max Healthcare Institute Limited), 1, Press Enclave Road, Saket, New Delhi -110017	Max Healthcare Ethics Committee, Max Healthcare Institute Limited, Max Super Speciality Hospital, 2 Press Enclave Road, Saket, New Delhi -110017 ECR/118/Inst/DL/2013/RR-24	Dr Dinesh Khullar
9.	Government Siddhartha Medical College, Ring Road, Gunadala, Vijayawada -520008, Andhra Pradesh	Institutional Ethics Committee SMC & GGH, Siddhartha Medical College and Government General Hospital, Ring Road, Gunadala, Vijayawada, Krishna, Andhra Pradesh -520008 ECR/633/Inst/AP/2014/RR-19	Dr Nageswara Rao Charukupalli
10.	Vardhaman Mahavir Medical College & Safderjung Hospital (VMMC & SJH), 2nd Floor, Department of	Institutional Ethics Committee VMMC and SJH, VMMC and Safderjung Hospital, Ring Road, Ansari Nagar, New Delhi - 110029	Dr Anupam Agarwal

	Nephrology, Ansari Nagar West, New Delhi -110029	ECR/593/Inst/DL/2014/RR-20	
11.	Jaslok Hospital and Research Centre, 15, Dr. G. Deshmukh Marg, Mumbai -400026, Maharashtra	Ethics Committee Jaslok Hospital Research Centre, Jaslok Hospital and Research Centre, 15, Dr. G. Deshmukh Marg, Mumbai, Maharashtra - 400026 ECR/294/Inst/MH/2013/RR-22	Dr Madan M Bahadur
12.	CARE Hospitals, 6-3-248/2, Road no.1, Banjara Hills, Hyderabad, Telangana -500034	CARE Hospitals, Institutional Ethics Committee, 6-3-248/2, Care Hospital, Road No.1, Banjara Hills, Hyderabad - Telangana -500034 ECR/94/Inst/AP/2013/RR-21	Dr Ratan Jha
13.	Gleneagles BGS Hospital, #67, Uttarahali main road, Kengeri, Bengaluru, Karnataka - 560060	Institutional Ethics Committee, BGS Global Hospitals, BGS Health And Education City, 67, Uttarahalli Main Road, Kengeri, Bengaluru, Karnataka -560060 ECR/128/Inst/KA/2013/RR-19	Dr Anil Kumar B T
14.	Meenakshi Mission Hospital & Research Centre, Lake Area, Melur Road, Madurai, Tamil Nadu -625107	Institutional Ethics Committee, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai, Tamil Nadu-625107 ECR/398/Inst/TN/2013/RR-24	Dr Sampath Kumar Krishnaswamy
