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/25/000113

To

M/s. PPD Pharmaceutical Development (India) Pvt. Ltd.,
102, A Wing, Fulcrum, Hiranandani Business Park,
Sahar Road, Andheri East, Mumbai – 400099, India.

Sir,

With reference to your application no. GCT/CT04/FF/2025/51271 dated 07-Aug-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled, "**OPEN-LABEL EXTENSION STUDY TO ASSESS THE LONG-TERM SAFETY AND TOLERABILITY OF KARXT IN SUBJECTS WITH PSYCHOSIS ASSOCIATED WITH ALZHEIMER'S DISEASE (ADEPT-3)" Protocol no.: KAR-033 version no. 4.0 dated 14- OCT-2024 with a total of up-to 10 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, specifically::-

(i) **Human biological samples i.e. Whole blood, urine and Additional AD biomarkers 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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.06.10 17:37:42 +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. PPD Pharmaceutical Development (India) Pvt. Ltd., 102, A Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri East, Mumbai (India) – 400099** to conduct clinical trial of the new drug or investigational new drug as per **rotocol no.: KAR-033 version no. 4.0 dated 14- OCT-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: 2026.06.10 17:37:50 +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	KarXT/BMS-986510 Xanomeline+Trospium Chloride
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	KarXT/BMS-986510 Xanomeline+Trospium Chloride
	KarXT/BMS-986510 Xanomeline+Trospium Chloride
Therapeutic class:	muscarinic agonist and muscarinic antagonist
	muscarinic agonist and muscarinic antagonist
	muscarinic agonist and muscarinic antagonist
	muscarinic agonist and muscarinic antagonist
	muscarinic agonist and muscarinic antagonist
Dosage form:	Capsules
	Capsules
	Capsules
	Capsules
	Capsules
Composition:	xanomeline tartrate =20.0000 milligram (mg) U.S.P., Other than the above mentioned types, Ph. Eur Active Trospium Chloride =2.0000 milligram (mg) U.S.P.,Ph. Eur Active
	xanomeline tartrate =30.0000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Active Trospium Chloride =3.0000 milligram (mg) U.S.P.,Ph. Eur Active
	xanomeline tartrate =40.0000 milligram (mg) U.S.P., Other than the above mentioned types, Ph. Eur Active

	Trospium Chloride =4.0000 milligram (mg) U.S.P., Ph. Eur Active
	xanomeline tartrate =50.0000 milligram (mg) U.S.P., Other than the above mentioned types, Ph. Eur Active Trospium Chloride =5.0000 milligram (mg) U.S.P.,Ph.Eur Active
	xanomeline tartrate =66.7000 milligram (mg) U.S.P., Other than the above mentioned types, Ph. Eur Active Trospium Chloride =6.6700 milligram (mg) U.S.P., Ph. Eur Active
Indications:	ALZHEIMER'S DISEASE
	ALZHEIMER'S DISEASE
	ALZHEIMER'S DISEASE
	ALZHEIMER'S DISEASE
	ALZHEIMER'S DISEASE

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Central Institute of Behavioral Sciences, Central Institute of Behavioral Sciences, Srividya, 8, Nawab Layout, Tilak Nagar, Nagpur 440010, Maharashtra, India Nagpur Maharashtra - 440010	Institutional Ethics Committee, Rughwani Child Care Centre & Hospital (IEC-RCCCH) ECR/1444/Inst/MH/2020	Dr Shailesh Pangaonkar
2.	Deva Institute of Health care and Research Pvt Ltd, Deva Institute of Healthcare and Research Pvt Ltd, B27-70 MN, Durgakund, varanasi-221005, Uttar Pradesh, India Varanasi Uttar Pradesh - 221005	DMHC Ethics Committee (Institutional) ECR/2/Inst/UP/2013/RR-24	Dr Venu Gopal Jhanwar
3.	Asha Hospital, Asha Hospital, road No-14, Banjara Hills, Hyderabad-500034, Telangana, India Hyderabad Telangana -500034	ECHICS COMMITTEE ASHA HOSPITAL Applied for re-registration on 08-01-2025	Dr K Chandra Sekhar
4.	Institute of Neurosciences Kolkata, Institute of Neurosciences Kolkata, 185-1, A.J.C. Bose Road, Kolkata-700017 Kolkata West Bengal -700017	Institutional Ethics Committee. Institute of Neurosciences ECR/185/Inst/WB/2013/RR-19	Dr Hrishikesh Kumar
5.	Jawahar Lal Nehru Medical College, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan 305001, India Ajmer Rajasthan - 305001	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan –305001, India ECR/1156/Inst/RJ/2018/RR-22	Dr Parth Singh Meena

6.	Postgraduate Institute of Medical Education and Research, Postgraduate Institute of Medical Education and Research, Sector-12, Chandigarh 160012 Chandigarh Chandigarh - 160012	Institutional Ethics Committee PGIMER ECR/25/Inst/CH/2013/RR-25	Dr Aseem Mehra

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