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/22/000162

To

M/s IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103
Mob.: + 91 9958881837 Email: Sneha.gupta2@iqvia.com

Sir,

With reference to your application no. GCT/CT04/FF/2022/35053 (GCT/162/22) dated 02-12-2022, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3 clinical trial titled," **An Open-label, Multicenter Trial to Assess the Safety and Tolerability of Lumateperone as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder" Protocol no. ITI-007-503, Protocol Amendment 1 dated 23/Aug/2021** with a total of up-to 112 subjects 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
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=HEAD OFFICE, 2.5.4.20=80c62f8523e4eafbe8a239774cdeb03c27690 2ae3ae1f6f4ee4b4b6c1f4b, st=TAMIL NADU, postalCode=600034, serialNumber=637F5EA7D9408B5D8F0D8DC902D0E1 [illegible], cn=RAJEEV SINGH RAGHUVANSHI
Date: 2023.04.12 12:44:14 +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. IQVIA RDS (India) Private Limited, Omega Embassy TechSquare Marathahalli - Sarjapur Outer Ring Road, Kadubeesanahalli, Bangalore – 560103, Karnataka Mob.: + 91 9958881837 Email: Sneha.gupta2@iqvia.com** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. ITI-007-503, Protocol Amendment 1 dated 23/Aug/2021** 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

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2023.04.12 12:44:26 +05'30'

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	Lumateperone
Therapeutic class:	Serotonin Dopamine Activity Modulators
Dosage form:	Capsules
Composition:	Lumateperone tosylate = 42.0000 milligram (mg) In House Specification Active
Indications:	Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	GMERS Medical College and Hospital, Department of Psychiatry, Room No. 204, 2nd Floor. GOTRI, Vadodara-390021, Gujarat	Institutional Human Ethics Committee, GMERS Medical College and Hospital, GOTRI, Vadodara-390021, Gujarat	Dr. Shah Sandip Mansukhlal
2.	Shri Hatkesh Healthcare Foundation, Sarswati Mandir Complex, Near Bhutnath Temple, College Road, Junagadh-362001, Gujarat	Shri Hatkesh Healthcare Foundation Ethics Committee Sarswati Mandir Complex, Near Bhutnath Temple, College Road, Junagadh-362001, Gujarat	Dr. Bakul Chandrakant Buch
3.	Department of Psychiatry, King George's Medical University, Shahmina Road, Chowk, Lucknow, U.P.	Institutional Ethics Committee King George's Medical University, Premie, Lucknow-226003, U.P.	Dr. Adarsh Tripathi
4.	MITR (Mental Illness Treatment And Rehabilitation) Foundation 1, Shantinagar Society, CCD Gully, B/h Holiday Inn Hotel, Ashram Road, Usmanpura, Ahmedabad-380013 Gujarat, lndia	Sangini Hospital Ethics Committee, 1st Floor Santorini Square, B/H Abhishree Complex, Opp. StarBazar, Nr Jodhpur Cross Roads Satellite, Ahmedabad- 380015 Gujarat	Dr. Shah Tarak Parmanandbhai
5.	Vinaya Hospital & Research Centre, Karangalpady, Mangalore - 575003, Karnataka, India	Ethics Committee Vinaya Hospital, Vinaya Mangalore-575003, Karnataka, India	Dr. Ravisha Thunga Airody,
6.	Centre for Psychiatric Research, Department of Psychiatry, K.S. Hegde Hospital. K.S. Hegde Medical Academy, A Unit of NITTE (Deemed to be University), K.S. Hegde Medical Science Complex, Deralakatte, Mangaluru-575018, Karnataka	Central Ethics Committee, NITTE (Deemed to be University), University Enclave, Medical Science Complex, Deralakatte, Mangalore-575018, Karnataka	Dr. Satheesh Rao
7.	Bhagwan Mahaveer Psychiatry and De-Addiction Centre, A unit of Sardarmal Khandaka Memorial Hospital, Kalwar Road, Hathoj, Jaipur-302012, Rajasthan	Institutional Ethics Committee Sardarmal Khandaka Memorial Hospital, Sardarmal Khandaka Memorial Hospital, Room No. 4, Kalwar Road, Hathoj, Jaipur-302012, Rajasthan	Dr. Ashok Goyal

8.	Chethana Centre for Neuropsychiatric Rehabilitation, Providence College Road, Malaparamba, Kozhikode, Kerala-673009	Chethana Centre for Neuropsychiatric Rehabilitation, Malaparamba, Calicut-673009	Dr. P. N. Suresh Kumar
9.	Chopda Medicare & Research Centre Pvt. Ltd., Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B. H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra Chopda Medicare & Research Centre Pvt. Ltd, Magnum Heart Institute, Clinical Research Department, Flat No. 10, Laxmanrekha Apartment, Behind Magnum Heart Institute, Patil Lane No. 1, Canada Corner, Nashik-422005, Maharashtra	Magna-Care Ethics Committee Chopda Medicare & Research Centre Pvt. Ltd., Magnum Heart Institute, Canada Corner, Nashik, Maharashtra-422005	Dr. Umesh Sureshrao Nagapurkar
10.	Central Institute of Behavioral Sciences, Srividya, 8, Nawab Layout, Tilak Nagar, Nagpur, 440010, Maharashtra	Institutional Ethics Committee, Rughwani Child care center & Hospital, 22, Sindhu Nagar, Mohanlal Rughwani marg, Jaripatka, Nagpur-440014. Maharashtra	Dr. Shailesh Vasudeo Pangaonkar
11.	Swagat Superspeciality Surgical Institute & NH, Mahapurush Damodardev Path Maligaon, Kamrup Metropolitan, Guwahati, Assam-781011	Institutional Ethics Committee, Swagat Hospital Private Limited, A.T Road, Maligaon, Kamrup Metropolitan, Guwahati, Assam-781011	Dr. Amlanjyoti Deb
12.	Research and Development Centre, Dayanand Medical College and Hospital, Civil Lines, Tagore Nagar, Ludhiana, Punjab-141001	The Drug Trial Ethics Committee, Ethics Committee Office, Basement, Hero DMC Heart Institute, Dayanand Medical College and Hospital, Civil Lines, Tagore Nagar, Ludhiana, Punjab-141001	Dr. Ranjive Kumar
13.	Department of Psychiatry, Kasturba Medical College Hospital, Attavar, Mangalore-575001, Karnataka	Manipal Academy of Higher Education (MAHE) Ethics Committee, Mezzanine Floor, KMC Old Library Building, Madhava Nagar, Manipal-576104, Karnataka	Dr. Keshava Pai K

14.	Department of Psychiatry, Research Room, Topiwala National Medical College & B.Y.L. Nair CH. Hospital & T. N. Medical College, Dr. A. L. Nair Road, Mumbai - 400008	Institutional Ethics Committee T.N.M.C Nair Hospital 'G' Building, Ground Floor, Dr. A. L. Nair Road, Mumbai - 400008	Dr. Shah Henal Rakesh
15.	Deva Institute of Healthcare and Research Pvt. Ltd., B27/70MN Durgakund, Varanasi-221005, Uttar Pradesh	DMHC Ethics Committee B27/70MN, Badhal Kothi, Durgakund, Varanasi-221005, Uttar Pradesh	Dr. Venu Gopal Jhanwar
16.	K R Hospital, Attached to Mysore College and Research Institute, Irwin Road, Mysuru-570001, Karnataka	Institutional Ethics Committee-Mysore Medical College and Research Institute an Associated Hospitals, Mysore Medical College and Research Institute, Irwin Road, Mysuru-570001, Karnataka	Dr. Narendra Kumar M S
17.	Society for Psychiatric Update & research, Shanti nursing home Kanchanwadi, Paithan road, Aurangabad-431005, Maharashtra	Ethics Committee shanti Nursing home, Kanchanwadi, Paithan road, Aurangabad-431005, Maharashtra	Dr. Vinay Laxmikantrao Barhale
18.	Vivekananda Institute of Medical Health & Neuro Sciences, C-25-D RIICO Industrial Area Malviya Nagar-302017, Jaipur, Rajasthan	IEC, Jaipur National University for Medical Sciences & Research Center, Near New RTO Office, Jagatpura, Rajasthan-302017	Dr. Anil Kumar Tambi
19.	Clinical Research Department, 4th & 5th Floor, Star Plus Complex, Lam Road, Muktidham Temple, Opposite NMC Divisional Office, Nashik Road, Nashik-422101, Maharashtra	Yash Society's Sujata Birla Hospital Ethics Committee, Sujata Birla Hospital and Medical Research Center, Opposite Bytco College, Nashik Pune Highway Nashik Road, Nashik Maharashtra-422101	Dr. Vanjari Nakul Ashok
20.	B.J. Medical College and Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat	Institutional Ethics Committee B.J. Medical College and Civil Hospital, Office of Medical Superintendent, Civil Hospital, Ahmedabad-380016, Gujarat	Dr. Parikh Minakshi Nimesh

****