File No. CT/78/19-DCG(I)

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

सत्यमेव जयते

File No. CT/19/000080

To,

M/s. CliniRx Research Pvt. Ltd.,
Patriot House, 4th Floor, Bahadur Shah Zafar Marg,
New Delhi - 110002, India.

Sir,

With reference to your application No GCT/Form44/FF/2019/16978 dated 11/10/2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A phase II, prospective, multi-center, randomized, 4-week, double-blind, placebo-controlled, multiple-dose study, designed to determine the safety, tolerability, EEG effects and preliminary efficacy of fixed oral doses of 7.5 and 15 mg bid of evenamide (NW-3509) in patients with chronic schizophrenia who are symptomatic on their current second-generation antipsychotic (aripiprazole, clozapine, quetiapine, olanzapine, paliperidone or risperidone) medication" Protocol number : NW-3509/008/II/2019, Version 2.0, Amendment 1, dated 05/December/2019** 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) 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,

V G SOMANI

Digitally signed by V G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, 2.5.4.20=111d9c06dbcb941e6f5d9fad4caa2e841:42a22ecae4ab1511c2cbeeb52029f8f, ou=DGHS/CID - 6445798, postalCode=110002, st=Delhi, cn=V G SOMANI
Date: 2019.12.31 18:09:29 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Stamp

File No. CT/78/19-DCG(I)

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. CliniRx Research Pvt. Ltd., Patriot House, 4th Floor, Bahadur Shah Zafar Marg, New Delhi – 110002, India** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number: NW-3509/008/II/2019, Version 2.0, Amendment 1, dated 05/December/2019** 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 _____

V G SOMANI

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Date: 2019.12.31 18:09:37 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing 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	Evenamide
Therapeutic class:	Anti-Psychotic
Dosage form:	Capsules
Composition:	16 Capsules packed in each FDPE Bottle
Indications:	Schizophrenia

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Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
IQRAA Psychiatric Care and Rehabilitation Centre, Near Vyapar Bhavan, Civil Station (PO), Eranhipalam, Kozhikode, Kerala-673020.	Institutional Ethics Committee, IQRAA International Hospital and Research Centre, Malaparamba, Kozhikode, Kerala (India)-673009 ECR/18/Inst/KL/2013/RR-16	Dr. Pattath Narayanan Suresh Kumar
Department of Psychiatry, Research & Development Centre, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab-141001, India.	Drug Trial Ethics Committee, Dayanand Medical College & Hospital, Basement Hero DMC, Opp. Library, Tagore Nagar, Civil Lines, Ludhiana, Punjab-141001, India ECR/101/Inst/PB/2013/RR-16	Dr. Ranjive Mahajan
Sri Ramachandra Hospital, Sri Ramachandra University, No. 1, Sri Ramachandra Nagar, Porur, Chennai-600116, India.	Institutional Ethics Committee, Sri Ramachandra Medical College & Research Institute, No. 1, Sri Ramachandra Nagar, Porur, Chennai, Tamil Nadu-600116, India. ECR/203/Inst/TN/2013/RR-16	Dr. Ramanathan Sathianathan
Department of Psychiatry, Old Government General Hospital, Two Town, Hanumanpet, Vijayawada-520002, Andhra Pradesh, India.	Institutional Ethics Committee, Siddhartha Medical College & Govt. General Hospital (IEC SMC & GCH), Govt. Siddhartha Medical College Campus, Ring Road, Gunadala, Vijayawada-520008,Andhra Pradesh, India. ECR/633/Inst/AP/2014/RR-17	Dr. Radhika Reddy V
Deenanath Mangeshkar Hospital and Research Center, Department of Neurology, Near Mhatre Bridge, Erandwane, Pune, Maharashtra-411004, India.	Institutional Ethics Committee, Deenanath Mangeshkar Hospital and Research Center, Near Mhatre Bridge, Erandwane, Pune, Maharashtra-411004, India. ECR/15/Inst/Maha/2013/RR-16	Dr. Sanjay Phadke
Mangala Hospital and Mangala Kidney Foundation, Vajra Hills, Kadri Road, Mangalore-575003, Karnataka, India.	Mangala Institutional Ethics Committee, Vajra Hills, Kadri Road, Mangalore-575003, Karnataka, India. ECR/567/Inst/KA/2014/RR-17	Dr. Supriya Hegde
St. John's Medical College & Hospital, Sarjapur Main Road, Bangalore-560034, Karnataka, India	Institutional Ethics Committee, St. John's Medical College Hospital, Sarjapur Road, Bangalore, Karnataka-560034, India ECR/238/Inst/KA/2013/RR-16	Dr. Johnson Pradeep

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Ahana Hospitals LLP, No. 11, Subburam Street, Gandhi Nagar, Madurai, Tamil Nadu – 625020, India	Ethics Committee, Radianz Healthcare and Research, Ahana Hospitals, No. 11, Subburam Street, Gandhi Nagar, Madurai, Tamil Nadu – 625020, India ECR/546/Inst/TN/2014/RR-17	Dr. Vikhram Ramasubramanian
Saoji Tupkari Hospital, 4, Vijay Nagar, Opp. Jawahar Nagar Police Station, Garkheda, Aurangabad MS	Saoji Tupkari Hospital Ethics Committee, 4, Opp. Jawahar Nagar Police Station, Garkheda, Aurangabad MS ECR/117/Inst/MH/2019	Dr. Sanjeev Gopal Saoji
National Institute of Mental Health & Neurosciences (NIMHANS), Department of Psychiatry, NIMHANS, Hosur Road, Wilson Garden, Bengaluru-560029, India	NIMHANS Ethics Committee, Administrative Block, National Institute of Mental Health and Neurosciences, Hosur Road, Bangalore, Karnataka-560029, India ECR/427/Inst/KA/2013/RR-16	Dr. Vijaya Kumar KG
Post Graduate Institute of Medical Education and Research (PGIMER), Nehru Hospital, Department of Psychiatry, Cobalt Block, PGIMER Chandigarh- I60012, India.	Institutional Ethics Cornrnittee, PGIMER Roorn # 6006, 6th floor, PN Chuttani block, Chandigarh- 160012, India. ECR/25/Inst/CH/2013/RR-16	Dr. Sandeep Grover
Asha Hospital, Road No: 14, Banjara Hills, Hyderabad-500034,	Ethics Committee - Asha Hospital, Room No. 125, First Floor, Asha Hospital, Road No. 14, Banjara Hills, Hyderabad-500034 ECR/177/Inst/AP/2013/RR-16	Dr. Gundugurti Prasad Rao