File No. CT/107/21-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/21/000107

To,

M/s Kendle India Private Limited,
Building 14, Tower B, 14th Floor, DLF Cybercity,
(SEZ), DL Phase III, Haryana (India) – 122001.

Sir,

With reference to your application No. GCT/CT04/FF/2021/27670 (GCT/107/21) dated 23/08/2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Double-blind, Multi-center, Multi-regional, Randomized Controlled, Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of CKD-314 in Hospitalized Adult Patients Diagnosed with COVID-19", Protocol Number: A108_02CVD2105 Version No. 1.0 dated 03-June-2021** 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) The firm should include patient with RTPCR positive test in the study.
(ii) In primary endpoint firm should clarify time to assess the efficacy parameters.
(iii) Proposed IMP is marketed with name Nafabelltan in Japan since last 20 years. Hence the firm needs to clarify why they are using IMP code instead of the proper name of the drug to conduct this study.
(iv) The firm needs to mention the proper name of the drug in the protocol.
(v) 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;
(vi) 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;
(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) 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;

(xx) 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;

(xxi) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xxii) 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;

(xxiii) 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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb2557487324c45dd249073e55e953d9cb3b5874bee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba4152252 5ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2021.12.13 14:31:15 +05'30'

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

File No. CT/107/21-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. Kendle India Private Limited, Kendle India Private Limited Building 14, Tower B, 14th Floor, DLF Cybercity (SEZ), DLF Phase III Gurugram (India) – 122001** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: A108_02CVD2105 Version 1.0 dated 03-June-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 _____

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb2557487 32c456d249073e55e953d9cb5b58748ee3113 c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffc a0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2021.12.13 14:31:24 +05'30'

(Dr. V. G. Somani)
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	CKD 314
Therapeutic class:	Antiviral
Dosage form:	Powder for injectable solution
Composition:	Succinic Acid = 5.0000 milligram (mg) Other than the above mentioned types Inactive D Mannitol = 100.0000 milligram (mg) K.P. Inactive Nafamostat mesilate = 50.0000 milligram (mg) In House Specification Active
Indications:	COVID 19

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	B.J. Government Medical College and Sassoon General Hospital Sassoon Road, Somwar Peth, Pune - 411001	Institutional Ethics Committees, B.J Medical College and Sassoon General Hospital, Sassoon Road, Somwar Peth, Pune - 411001, Maharashtra India ECR/280/BJ/Inst/MH/2013/RR-1	Dr. Rohidas Tanku Borse
2.	Unity Trauma Center and ICU (Unity Hospital), Near D. R. World, Opp. Raghuvir Business Empire, Aai Mata Rd, , Parvat Patiya, Surat - 395010, Gujarat, India	Unity Hospital Ethics Committee, Unity Trauma Center and ICU, N-4 anki park Society, Aai Mata Road, Parvat Patiya, Surat - 395010, Gujarat, India ECR/1226/Inst/GJ/2019	Dr. Maheshkumar Vithalbhai Sutariya
3.	Maharaja Agrasen Super speciality Hospital, Central Spine Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur, Rajasthan - 302039	IEC, Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur Rajasthan - 302039, ECR/1222/Inst/RJ/2019	Dr Manish Kumar Jain
4.	Aakash Healthcare Private Limited, Hospital, Plot, Road, No. 201,Sector-3, Dwarka, New Delhi-110075	Aakash Healthcare Private Limited, Hospital Plot, Road No. 201,Sector-3, Dwarka, New Delhi-110075 ECR/1265/Inst/DL/2019	Dr. Akshay Budhraja
5.	Department of medicine, Government Medical College and Hospital, Near Hanuman Nagar, Medical Square, Nagpur-440003	Institutional Ethics Committees Department of Pharmacology, Government Medical College and Hospital, Near Hanuman Nagar, Medical Square, Nagpur-440003 ECR/43/Inst/MH/2013/RR-19	Dr. Atul Rajkondawar
6.	PCMC'S PGI Yashwantrao Chavan Memorial Hospital 2nd Floor, General Medicine Department, PCMC'S PGI Yashwantrao Chavan Memorial Hospital Rd, Sant Tukaram Nagar, Pimpri, Pune-411018	Institutional Ethics Committee Yashwantrao Chavan Memorial Hospital Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Near D.Y. Patil Medical College and Hospital, Pimpri,Pune,411018 ECR/1236/Inst/MH/2019	Dr Pravin Soni
7.	St. George's Hospital, PD' Mello Road, Behind GPO, Fort, Mumbai- 400001,	Institutional Ethics Committees, GGMC, Mumbai, Grant Government Medical College, JJ Road, JJ Hospital Compound Mumbai Central, Mumbai, Mumbai City, Maharashtra, Mumbai-	Dr Khobragade Akash Ashok Kumar

		400008, India ECR/382/Inst/MH/2013/RR-19	
8.	Victoria Hospital, Bangalore Medical College and Research Institute K.R. Road, Fort Bangalore – 560002, India	Ethics Committees of Bangalore Medical College and Research Institute K. R. Road, Fort, Bangalore –560002, India ECR/302/Inst/KA/2013/RR-20	Dr. K R Raveendra
9.	Medstar Speciality Hospital #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore- 560092, Karnataka, India	Medstar Speciality Hospital Ethics Committee, Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore- 560092, Karnataka, India ECR/1324/Inst/KA/2019	Dr. Chikkalingaiah Siddegowda
10.	KLE'S Dr, Prabhakar Kore Hospital & MRC Nehru Nagar, Belagavi-590010,	Institutional Ethics Committee of KLE Academy of Higher Education and Research, JNMC Campus, , Nehru Nagar, Belagavi-10, Karnataka, India ECR/211/Inst/KA/2013/RR-19	Dr. Jayaprakash Appajigol
11.	Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad-431003, Maharashtra, India	MGM Ethics Committee for Research On Human Subject (MGM-ECRHS),Pharmacology Department, MGM Medical College, N-6 , CIDCO Aurangabad-431003, Maharashtra, India ECR/581/Inst/MH/2014/RR-20	Dr. Anand Marutirao Nikalje
12.	Ishwar Institute of Healthcare Ishwar Heights, 1st floor, Plot No. 7, Gut No. 6/1, Beside Punjabi Bhavan, Padegaon, Aurangabad-431002, Maharashtra, India	Ethics Committee of Ishwar Institute of HealthCare, Ishwar Institute of Health Care, 3rd Floor, Plot No.07, Gut No. 6/1 Padhegaon, Beside Panjabi Bhavan Jaysingpura, Aurangabad-431002, Maharashtra, India ECR/988/Inst/MH/2017/RR-20	Dr. Zabeeuddin Imtiyazuddin Patel
13.	Sri Ramachandra Hospital Dental College Basement, Clinical Research Division, No.1, Ramachandra Nagar, Porur, Chennai- 600116, Tamil Nadu, India	Institutional Ethics Committee SRIHER, Sri Ramachandra 1, Ramachandra Nagar, Porur, Chennai-Tiruvallur, Tamilnadu - 600116, India ECR/203/Inst/TN/2013/RR-19	Dr Irfan Ismail Ayub
14.	Aster Prime Hospitals, Opp. Passportseva Kendra, Ameerpet, Hyderabad-500038, Telangana State, India	Ethics Committee-Prime Hospitals, Aster Prime Hospital, Behind Mythrivanam Beside Blue Fox Hostel, Ameerpet, Hyderabad, Telangana-500038, India ECR/381/Inst/AP/2013/RR-21	Dr Nagaraju. B

15.	SMS Hospital, JLN Marg, Jaipur -302004, Rajasthan, India	Institutional Ethics Committee, SMS Medical College and Attached Hospital, Office of Ethics Committee, Second Floor, New Academic Block, SMS Medical College, Jaipur -302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-19	Dr. Raman Sharma
16.	Orchid Speciality Hospital L-Square, Porwal Road, Sr. No. 282/3/3 Lohgaon, Pune-411047, Maharashtra, India	Orchid Speciality Hospital Ethics Committee, Orchid Speciality Hospital, L-Square, Porwal Road, Sr No 282/3/3,, Lohgaon, Pune-411047, Maharashtra, India ECR/1089/Inst/MH/2018/RR-21	Dr. Ashish Omprakash Goyal