

File No. CT/51/19-DCG(I)



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/19/000053

To,

M/s. Klinera Global Services,  
801, Neelkanth Corporate Park,  
Opposite Vidyavihar Station, Vidyavihar (West),  
Vidyavihar (India) – 400086.

Sir,

With reference to your application No GCT/Form44/FF/2019/15346 (GCT/51/19) dated 26/06/19, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study Evaluating the Efficacy and Safety of Selonsertib in Subjects with Moderate to Advanced Diabetic Kidney Disease."** Protocol number **GS-US-223-1017, Original dated 01 February 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 Licensing 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 or conduct of the clinical trial at the same site;
- (iv) the Central Licensing 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

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- (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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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

(Dr. V. G. Somani)

Drugs Controller General (India)

Central Licencing Authority

Stamp

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**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. Klinera Global Services, 801, Neelkanth Corporate Park, Opposite Vidyavihar Station, Vidyavihar (West), Vidyavihar (India) – 400086** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number GS-US-223-1017, Original dated 01 February 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

Digitally signed by V. G. SOMANI  
DN: cn=V. G. SOMANI, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION,  
c=IN, email=V. G. SOMANI@CDSCO.GOV.IN,  
serial=110002, version=3,  
reason=20250103 12:30:42 +0530

(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:

<b>Names of the new drug or investigational new drug</b>	Selonsertib
<b>Therapeutic class:</b>	Apoptosis Signal regulating kinase 1 ASK1 inhibitor
<b>Dosage form:</b>	Tablets
<b>Composition:</b>	Selonsertib =18.000 milligram (mg) in House Specification Active
<b>Indications:</b>	Diabetic Kidney Disease

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Details of clinical trial site:

<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
Sir Ganga Ram Hospital, SGRH Marg, Old Rajendra Nagar ,New Delhi-110060, India	Ethics Committee, Sir Ganga Ram Hospital, SGRH Marg, Old Rajendra Nagar ,New Delhi-110060, India  ECR/20/Inst/DL/2013/RR-16	Dr. Anil Kumar Bhalla
DIACON Hospital ( Diabetes Care & Research Centre) 359-360, 19th Main, 1st Block, Rajajinagar Bangalore-560010	Diacon Hospital Ethics Committee 359-360, 19 <sup>th</sup> Main, 1st Block, Rajajinagar Bangalore- 560010  ECR/449/Inst/KA/2013/RR-16	Dr. S R Aravind
Yenepoya Medical College Hospital, University Road, Deralakatte, Mangalore 575018	Yenepoya Ethics Committee-1 ,3rd floor, Academic Block, Yenepoya Medical College Hospital, University Road, Deralakatte, Mangalore 575018  EECR/521/Inst/KA/2014/RR-17	Dr. Adhikari Prabha M.R
Nizam's Institute of Medical Sciences, Punjagutta Hyderabad, Telangana-500082, India.	Nizam's Institute of Ethics Committee, Punjagutta, Hyderabad, Telangana-500082  ECR/303/Inst/AP/2013/RR-16	Dr. D. Sree Bhushan Raju
Krishna Institute of Medical Sciences, #1-8-31/1, Krishna Institute of Medical Sciences, Minister Road, Secunderabad-500003	KIMS Ethics Committee, 1-8-31/1, Krishna Institute of Medical Sciences, Minister Road, Secunderabad-500003  ECR/142/Inst/AP/2013/RR-16	Dr. Sreedhar Reddy
Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad-387001, Gujarat, India.	Muljibhai Patel Society for Research in Nephro-Urology Ethics Committee Muljibhai Patel Urological Hospital, Dr. Virendra Desai Road, Nadiad-387001, Gujarat, India  ECR/276/Muljibhai/Inst/GJ/2013/RR-16	Dr. Umapati Hegde
Ajanta Research Centre, Ajanta Hospital and IVF Centre, 765, ABC Complex, Kanpur R Alambagh, Lucknow - 226 005	institutional Ethics committee, Ajanta Hospital & IVF Centre, 765 ABC Complex, Kanpur Road, Alambagh Lucknow-226003  ECR/611/Inst/UP/2014/RR-17	Dr. Deepak Dewan
Department of Endocrinology, 2nd Floor Unit of Hope building, ,	Institutional Ethics Committee, Ground Floor, St. John's Medical College, Sarjapur Road, Bangalore-	Dr. Ganapathi Bantwal

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560 034		
Dr. Jivraj Mehta Smarak Health Foundation & Bakeri Medical Research Center, "Rathubhai Adani Arogyadham", Jivraj Mehta Marg, Ahmedabad 380007	Dr. Jivraj Mehta Smarak Health Foundation & Bakeri Medical Research Center Institutional Ethics Committee, "Rutubhai Adani Arogyadham", Jivraj Mehta Marg, Ahmedabad 380007  ECR/274/Inst/GJ/2013/RR-16	Dr. Banshi Damodarlal Saboo
NIMS Medicity, Aralumoodu, Thiruvananthapuram-695123 Kerala	Institutional Ethics Committee, Noorul Islam Institute of Medical Science and Research Foundation, NIMS Medicity Aralumoodu, Neyyattinkara, Trivandrum-695123 Kerala India.  ECR/218/Inst/Ker/2013/RR-16	Dr. ManjuThampi
M S Ramaiah Medical College & Hospital, M S Ramaiah Nagar, MSRIT Post, Bangalore - 560054.	Ethics Committee, M S Ramaiah Medical College & Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore, 560054, Karnataka, India.  ECR/215/Inst/KA/2013/RR-19	Dr. Mahesh Eswarappa
Max Super Speciality Hospital, 1 press Enclave Road Saket New Delhi-110017	Max Health Care Ethics Committee, Max Super Speciality Hospital 2, Press Enclave Road, Saket New Delhi-110017, India.  ECR/118/Inst/DL/2013/RR-16	Dr. Dinesh Khullar
Artemis Hospital, Sector-51, Gurugram-122001, Haryana, India	Artemis Health Sciences Institutional Ethics Committee, Sector-51, Gurugram-122001, Haryana, India  ECR/ 53/Inst/HR/2013/RR-16	Dr. Manju Aggarwal
S.R.Kalla Memorial Gastro & General Hospital 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur, Rajasthan, India-302001	SR Kalla Memorial Ethics Committee For Human Research, 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur - 302001, Rajasthan, India-302001  ECR/8/Inst/Raj/2013/RR-16	Dr. Ram Dhan Meena
M.V.Hospital For Diabetes (P) Ltd, No.4 West Madha Church Street, Royapuram, Chennai - 600 013. Tamilnadu, India	Ethics Committee Prof. M Vishwanthan Diabetes Research Centre, No.4, West, Madya Church Steet, Royapuram Chennai - 600013, Tamil Nadu, India.  ECR/51/Inst/TN/2013/RR-16	Dr. Vijay Viswanathan
Pushpawati Singhania Research Institute, Press Enclave Marg, Sheikh Sarai	Pushpawati Singhania Hospital & Research Institute Ethics Committee Press Enclave Marg, Sheikh Sarai	Dr. Sanjiv Saxena

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	ECR/87/Inst/ND/2013/RR-16	
All India Institute of Medical Science, Ansari Nagar, New Delhi -110029	Institute Ethics Committee All India Institute of Medical Sciences, Ansari Nagar New Delhi-110029, India.  ECR/538/AIIMS/DL/2014	Dr. Sandeep Mahajan
Belgaum Diabetes Centre Ground and Second Floor, Maruti Street, Belgaum - 590001	Institutional Ethics Committee, Belgavi Institute of Medical Sciences, Dr B R Ambedkar Road, Belgavi, 590001 Karnataka, India.  ECR/801/Inst/KA/2016	Dr. Neeta Deshpande
Kasturba Medical College and Hospital, Madhav Nagar, Manipal - 576104	MAHE Ethics Committee, Mezzanine floor of Old KMC Library Building, Near KMC dean Office, MAHE Manipal-576104  ECR/541/Inst/Ka/2014/-RR-17	Dr. Ravindra Prabhu A
Diabetes Unit, 6th Floor Banoo Coyaji Building ,KEM Hospital, Rasta Peth, Pune- 411011	KEM Hospital Research Centre Ethics Committee, 3rd floor, TDH building ,Rasta Peth Pune- 411011  ECR/272/Inst/MH/2013/RR-16	Dr.Chittaranjan Sakerlal Yajnik
Yalamanchi Hospitals & Research Centers Pvt.Ltd. D.No:29-7-44, Venkataratnam Street, Suryaraopet, Vijayawada-520002., A.P.	Yalamanchi Hospital Ethics Committee, D.No.29-7-44 Venkataratnam Street, Suryaraopet Vijaywada-520002, Andhra Pradesh, India.  ECR/564/Inst/AP/2013/RR-17	Dr. Y. Sadasivarao -
Department of Nephrology, SMS Hospital, JLN Marg-Jaipur-302004, Rajasthan, India	Ethics Committee of SMS Medical College and Attached Hospital, Office of Ethics Committee, First Floor, Dhanwantri OPD Block, SMS Hospital, JLN Marg, Jaipur-302004  ECR/26/Inst/RJ/2013/RR-16	Dr. Dhananjai Agrawal
QQDC Building, 3rd Floor, Department of Nephrology, Osmania General Hospital, Afzalgunj, Hyderabad-500012	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana  ECR/300/Inst/AP/2013/RR-16	Dr. Manisha Sahay
ILS Hospital,Dumdum,1 Mall Road,Near Nagarbazar Flyover DumDum, Kolkata, West Bengal -700080	Institutional Ethics Committee, ILS Hospitals, Dumdum 1, Mall Road, Anudiram Bose Sarani, Kolkata-700080, West Bengal, India	Dr. Pratim Sengupta

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	ECR/130/Inst/WB/2013/RR-16	
Department of Nephrology, King George Hospital, Andhra Medical College, King George Hospital, Maharani Peta, Visakhapatnam-530002, Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Maharani Peta, Visakhapatnam, Andhra Pradesh - 530002  ECR/197/Inst/KGH/2013/RR-16	Dr. Gullipalli Prasad
Ace Hospital and Research Centre, 32/2 A, Erandwane, Gulwani Mhj Rd. Pune 411004	Institutional Ethics Committee, AMAI Trust's ACE Hospital  ECR/474/Inst/MH/2013/RR-16	Dr. Atul D. Sajgure
Medanta - The Medicity, Sector 38, Gurgaon ,Haryana	Medanta Institutional Ethics Committee, Sector-38, Gurgaon,  ECR/ 282/Inst/HR/2013/RR-16	Dr. Vijay Kher
Virinchi Hospital, Hyderabad	Virinchi Hospital Institutional Ethics Committee, Road, No. 1, P njarahills Hyderabad  ECR/993/Inst/AP/2017	Dr. Ratan Jha
Kovai Diabetes Speciality Centre & Hospital 15, Vivekananda Road, Ram Nagar, Coimbatore-641009.	Institutional Ethics Committee of Kovai Diabetes Speciality Centre and Hospital,15, Vivekananda Road, Ramnagar, Coimbatore- 641009, Tamilnadu, India  ECR/233/Inst/TN/2013/RR-16	Dr. Balamurugan Ramanathan
Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara. P.O, Kochi-682041, Kerala, India	Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, Ponekkara, Kochi- 682041, Kerala, India  ECR/129/Inst/KL/2013/RF. 6	Dr. Arun Chankramath Somasekhara
Research & Development Centre, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab-141001, India	Drugs Trial Ethics Committee Dayanand Medical College & Hospital, Basement of Hero DMC, Civil Lines, Tagore Nagar, Ludhiana- 141001, Punjab India.  ECR/101/Inst/PB/2013/RR-16	Dr. Dinesh Jain
Shalby Hospital, Opp Karnavati Club, S G Highway, Ahmedabad- 380015	Ethics Committee -Shalby Limited, Shalby Hospital, Opp Karnavati Club, S G Highway, Ahmedabad	Dr. Kamal R Goplani

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Aditya Birla Memorial Hospital, Aditya Birla Hospital Marg, Thergaon, Chinchwad-411033	Aditya Birla Memorial Hospital Ehics Committee, Aditya Birla Memorial Hospital ,Aditya Birla Hospital Marg, Thergaon, Chinchwad-411033  ECR/779/Inst/MH/2015/RR-18	Dr. Tarun Jeloka
Vinaya Hospital and Research Centre Karangalpady, Mangalore-575003, Karnataka, India	Ethics Committee Vinaya Hospital Vinaya Hospital and Research Centre, Karangalpady, Mangalore-575003 Karnataka, India  CR/664/Inst/KA/2014/RR-17	Dr. Hamsraj Alva

**Government of India**  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
**(Global Clinical Trial Division)**  
FDA Bhawan, Kotla Road, New Delhi-110002  
Tel. No: 01123236965, Fax: 01123236971  
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Date:

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13 JAN 2020

To

M/s. Klinera Global Services,  
801, Neelkanth Corporate Park,  
Opposite Vidyavihar Station, Vidyavihar (West),  
Vidyavihar (India) – 400086.

**Subject:** Amendment in CT NOC (Protocol No: GS-US-223-1017) – regarding.

**Reference:** Your online reference no. GCT/Form44/FF/2019/15346 (GCT/51/19) dated 26/June/19 on the subject mentioned above.

Sir,

This Directorate's CT NOC granted to you vide letter of even no. dated 03/01/2020 is hereby amended to read the approved version of protocol no. GS-US-223-1017 as "**Protocol Amendment 1 dated 10/June/2019**" instead of "**Original Protocol dated 01 February 2019**", subject to all other conditions and statements of the above permission remaining same.

Yours faithfully,



(Dr. V. G. Somani)  
Drugs Controller General (India)