Diary No: 29848
Date: 09.08.2018

F. No. 12-01/18-DC-(Pt-301)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

Tele No.011-23236965
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FDA Bhawan, Kotla Road
New Delhi – 110002 (India)
Dated: 26-02-2019

To,
Dr. Sujoy Ghosh,
Principal Investigator,
Associate Professor, Department of Endocrinology,
Institute of Post Graduate Medical Education & Research,
Kolkata-700020

Subject: **"A Double Blind Comparative Prospective Study of the Safety of Teneligliptin and Sitagliptin to evaluate QTc prolongation in Indian Type 2 Diabetes patients"- regarding.**

Reference: Your application diary no. 29848 dated-09.08.2018 on the subject mentioned above.

CT NOC No. : CT/ND/12/2019

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: IIS/2018/01, Version 1.0, dated 26.04.2018** submitted to this Directorate.

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Sujoy Ghosh, Principal Investigator, Department of Endocrinology, Institute of Post Graduate Medical Education & Research,Kolkata-700020	IPGME&R Research Oversight committee Institute of Post Graduate Medical Education & Research, Kolkata-700020 **ECR/35/Inst/WB/2013/RR-16**
2.	AMRI Hospitals, P-4&5, Block- A, Dhakuria, Kolkata-700029	

Kindly note that the clinical trial permission is subject to the following Conditions:

a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

b) Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.

c) Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.

d) Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.

e) Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.

f) In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.

g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.

h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator

shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, Investigational drugs, etc. Related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered by Institutional Ethics committees.

j) The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc.

k) The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

l) In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

m) The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

n) It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not conveyor imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

o) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

p) **Clinical trial protocol should be improved in accordance with the below mentioned points:**

1. **The duration of the diabetes should be taken in to consideration for inclusion and exclusion criteria.**
2. **Duration of the study can be longer with multiple time points monitoring (at least two follow up points)**
3. **Better method of capturing arrhythmia (Holter) should be adopted.**

Accordingly, revised protocol should be submitted before initiation of the study.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
& Licensing Authority