

30251/10.10.16

GOVERNMENT OF INDIA

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)

(Global Clinical Trial Division)

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Tel No: 01123236965, Fax: 01123236971

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File No: CT/46/16 – DCG (I)

Date: 27-02-17

To,

M/s Sanofi-Synthelabo (I) Pvt. Ltd.,
Sanofi House, CTS No. 117-B, L&T Business Park,
Saki Vihar Road, Powai, Mumbai-400072

Subject: Permission for conducting a Phase IV clinical trial titled “International, Randomized, Open label Study to Compare the Safety and Efficacy of Lixisenatide vs Sulfonylurea on top of Basal Insulin Treatment in Type 2 Diabetes Mellitus Subjects Who Elect to Fast During Ramadan . – regarding.

Reference: - Your letter No. 2016/10/07/LPS14410/01 dated 07/10/2016 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under the supervision of the investigators mentioned herein and as per Protocol No: LPS14410, Version 1.0, dated 27/July/2016 submitted to this Directorate.

1. Dr. Shaikh Shehla Sajid Akhtar, Prince Aly Khan Hospital Aga Hall, Nesbit Road Mazagaon, Mumbai-400010, Maharashtra.
2. Dr. Paramesh S, Bangalore Diabetes Centre No. 426, 4th Cross, 2nd Block, Kalyan Nagar Bangalore-5600143, Karnataka.
3. Dr. Parag Shah, Dr. Jivraj Mehta Smarak Health Foundation and Bakeri Medical Research Centre, Rataubhai Adani Arogyadham, Near Aayojannagar, Ahmedabad-380007.
4. Dr. Gupta Jugal Bihari, Eternal Hospital, A unit of Eternal Heart Care Centre And Research Institute Pvt. Ltd., 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017.
5. Dr. Kanajenahalli Narayanappa Satish Babu, BGS Global Hospitals, BGS Health and Education City, #67, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka.
6. Dr. Faraz Farishta, Medwin Hospitals, Raghava Ratna Towers, Chirag Ali Lane, Rhagava Ratna Towers, Nampally, Hyderabad-500001, Telangana.
7. Dr. Paturi Vishnupriya Rao, Kumudini devi Diabetes Research Centre, IInd floor, Ramdevrao Hospital Kukatpally, Hyderabad-500072.
8. Dr. Hemant Thacker Premji, Bhatia Hospital, Tukaram Javji Road, Tardeo, Mumbai-400007.
9. Dr. Rajeswari Janakiraman, Colombia Asia Referral Hospital Yeshwanthpur, 26/4, Brigade Gateway, Malleshwaram west Besides Metro, Bangaluru-560055.
10. Dr. Neeraj Manikant, Dept. of General Medicine, Govt. Medical College, Kozhikode, Kerala 673008.

11. Dr. Alapati Lakshmi Lavanya, Global Hospitals, 6-1-1070/1 to 4, Lakdi ka-pool, Hyderabad-500004.
12. Dr. Sanjeev R Phatak, DHL Research Centre, 2nd Floor, DHL Research Centre, Thakershy Charitable Trust Hospital, Near Shivrangani Cross Road, satellite, Ahmedabad- 380015.
13. Dr. Sunil Gupta, Sunil's Diabetes Care & Research Centre Pvt. Ltd., 42, Lendra Park, Ramdaspath, Nagpur-440010.

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

- a. **Blood glucose level should be monitored 8-12 hours after the last meal atleast thrice a week.**
- b. 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.
- c. Approval of the Ethics Committee shall be obtained before initiation of the study.
- d. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.
- e. 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.
- f. 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.
- g. 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.
- h. 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.
- i. 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.
- j. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

- 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. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials 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.
- m. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or 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.

Yours faithfully,



(Dr. G.N. Singh)
Drugs Controller General (I)

