File No CT/28/16-DCG(I) Clinical Trial NOC No: GCT/51/16

20165/27.06.16

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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File No: CT/28/16-DCG (I) Date: 03/01/17

To,

M/s Novo Nordisk India Pvt. Ltd.,
Plot No: 32, 47-50, EPIP Area, Whitefield,
Bangalore-560066, India

Subject: Permission for conducting a Phase IIIb clinical trial titled "A 38 week Trial Comparing Effect and Safety of Insulin Degludec/Insulin Aspart vs. Insulin Glargine plus Insulin Aspart in Subjects with Type 2 Diabetes Treated with Basal Insulin with or without Oral Antidiabetic Treatment in need of Treatment Intensification."– regarding.

Reference: Your letter No. NN/RA/SPTP/134 dated 20/June/16 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 supervision of the investigators mentioned in below and as per the **Protocol No: NN5401-4266 Version 3.0 dated 04/May/2016** submitted to this Directorate.

1. Dr. Kirtikumar Dharmshibhai Modi, Care Hospitals 5-4-199, Jawaharlal Nehru Road, Near Exhibition Ground, Nampally, Hyderabad-500001, Telangana.
2. Dr. Anupam Prakash, Lady Hardinge Medical College and Asso. Hospitals, Shahid Bhagat Singh Marg, New Delhi-110001.
3. Dr. Ranjit Unnikrishnan, Madras Diabetes Research Foundation #4, Conran Smith Road Gopalapuram Chennai-600086.
4. Dr. S. Prabhu, Victoria Hospital, Bangalore Medical College and Research Institute, Fort, Bangalore-560002.
5. Dr. Amit Patel, B.S.E.S Municipal General Hospital, S.V. Road, Opp. Railway Station, Andheri (West), Mumbai-400058.
6. Dr. Desai Piyush Harshadrai, Nirmal Hospital Pvt. Ltd., Ring Road, Surat-395002. Gujarat.
7. Dr. Chandni Radhakrishnan, Dept. of General Medicine Govt. Medical College, Kozhikode, 673008, Kerala.
8. Dr. Yashdeep Gupta, Department of Endocrinology and Metabolism, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029.
9. Dr. Girithara Gopalakrishnan Jayram Naidu, KG Hospital & Post Graduate Medical Institute, No 5 Arts College Road, Coimbatore-641018, Tamil Nadu, India.
10. Dr Sambit Das, Apollo Hospitals, Bhubaneshwar, ARI Room No C-10 5th Floor Plot No. 251, Sainik School Road, Unit 15, Bhubaneshwar 751005, Odisha.

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 the Ethics Committee shall be obtained 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 14 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 Institutional Ethics committees.

j. 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.

k. 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.

l. 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)