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GOVERNMENT OF INDIA

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

(Global Clinical Trial Division)

FDA Bhawan, Kotla Road, New Delhi-110002

Te No: 01123236965, Fax: 01123236971

E-mail: dcg@nb.nic.in,

File No: CT/76/2013-DCGI

Dated:

To

M/s. Novo Nordisk India Private Ltd.
Plot No.32, 47 - 50,
EPIP Area, Whitefield,
Bangalore - 560 066

24/3/2014

Subject: Permission for conducting a phase IIIb clinical study entitled, "A trial comparing cardiovascular safety of insulin degludec versus insulin glargine in subjects with type 2 diabetes at high risk of cardiovascular events" – regarding.

Clinical Trial NOC No.: GCT/07/14

Reference: Your letter no. NN/RA/CTA/NVE/2013/387 dated 03 Oct 2013 and NN/RA/CTA/NVE/2013/483 dated 13 Dec 2013 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 following investigators and as per the **Protocol No: EX1250-4080 versions 2.0 dated 19 July 2013** submitted to this Directorate.

1. Dr. Nikhil Bhagwat Madhusudan, Department of Endocrinology, Topiwala National Medical College & B.Y.L. Nair Charitable Hospital, Dr A. L. Nair road, Mumbai-400008, Maharashtra.
2. Dr Bandgar Tushar Ramkrishna, Department of Endocrine, Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai – 400012, Maharashtra.
3. Dr Nivedita Devabrata Moulick, Professor & Head Of Medicine Department, Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai-400022

(Signature) (SHANILAPPA) 0/c
24.03.14

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4. Dr Bipin Kumar Sethi, CARE Outpatient Centre, Door No. 8-2-620/A-E, Babu Khan Chambers, Road No.10, Banjara Hills, Hyderabad – 500034 AP.
5. Dr Subhankar Chowdhury, Head, Department Of Endocrinology, IPGME&R & SSKM Hospital, Ronald Ross Building, 4th floor, 244-AJC Bose Road, Kolkata-700020
6. Dr Tirthankar Chaudhury, Consultant Diabetes & Endocrinologist, Apollo Gleneagles Hospitals, 58, Canal Circular Road, Kolkata-700054, West Bengal.
7. Dr Sambit Das, Apollo Hospitals, Plot No: 251, Sainik School Road Unit-15, Bhubaneswar - 751005
8. Dr Tiven Marwah, Department of Endocrinology, Sheth Vadilal Sarabhai General Hospital, Second Floor, Next to trauma centre, Ellis Bridge, Ahmedabad-380006.
9. Dr. Parminder Singh, Dayanand Medical College & Hospital, 3rd Floor, Department of Endocrinology, Civil Lines, Tagore Nagar, Ludhiana-141001, Punjab.
10. Dr K.P.Singh, Fortis Hospital, Sector 62, Phase - 8, Mohali – 160062, Punjab.
11. Dr. Arpandev Bhattacharyya, Department of Diabetes & Endocrinology, Manipal Hospital, 98, HAL Airport Road Bangalore – 560017
12. Dr Nikhil Tandon, Department of Endocrinology and Metabolism, Room no.312, Biotechnology Block, 3rd Floor, Biotechnology Block, All India Institute of Medical Sciences, New Delhi-110029
13. Dr. Ambrish Mittal, Division of Endocrinology & Diabetes, Medanta The Medicity Sector – 38, Gurgaon, Haryana 122001
14. Dr Jayanthi Ramesh, Department of Endocrinology, Osmania General Hospital, Afzal Gunj, Hyderabad.
15. Dr Ankush Desai, Dept. of Medicine, Goa Medical College, Bambolim, Goa - 403202
16. Dr Sushil Kumar Gupta, Department of Medical Endocrinology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014.
17. Dr. Asha N. Shah, D4 Medicine Department, BJ Medical college and civil Hospital, Ahmedabad-380016

18. Dr. Bindu Kulshreshtha, Dept. of Endocrinology, 307, PGIMER, Dr RML Hospital, New Delhi- 110001
19. Dr Sanjeev Pathak Ratnakar, Sterling Hospital, Sterling Hospital Road, Memnagar, Ahmedabad-380052
20. Dr Ganapathy Bantwal, Department of Endocrinology, St. John's Medical College & Hospital, Bangalore - 560034.
21. Dr Chandini R, Department Of Medicine, Calicut Medical College, Govt. Medical College, Kozhikode, Kerala, India.
22. Dr Shaikh Shehla, Prince Aly Khan Hospital, Aga Hall, Nesbit Road, Mazagaon, Mumbai- 400010.
23. Dr Shailaja Kale, Inamdar Multispecialty Hospital, Survey No. 15, Behind Kpct Mall, Fatima Nagar-Wanwadi, Pune- 411040
24. Dr Girithara Gopalakrishnan Jayaram Naidu, Department of Diabetology, K G Hospital & Post Graduate Medical Institute, No 5 Arts College Road, Coimbatore-641018
25. Dr Anupam Prakash, Department of Medicine, Lady Hardinge Medical College & Smt. Sucheta Kriplani Hospital, Shahid Bhagat Singh Marg, New Delhi-110001.
26. Dr Abhay Amrutlal Mutha, Ruby Hall Clinic, 40, Sassoon Road, Pune- 411001

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 ten days of its occurrence

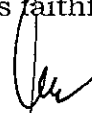
as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

- 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 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. However, under no circumstances the number of trials should be more than three at a time.
- 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. You are also informed that audio visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done duly adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. All the sponsors /investigators /institutes/Organizations and other stake holders involved in

conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.

- 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 (India)

24/3/2014

O/C 
20/3/2014

