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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: dci@nb.nic.in,

File No: CT/69/13 - DCG (I)

Dated: 23/05/14

To,
M/s. Novo Nordisk
Plot No. 32, 47-50,
EPIP Area, Whitefield,
Bangalore - 560 066,
Karnataka

Subject: Permission for conducting a Phase IIIa Clinical Trial entitled "Efficacy and safety of semaglutide once-weekly versus sitagliptin once-daily as add-on to metformin and/or TZD in subjects with type 2 diabetes"- regarding.

Clinical Trial NOC No.:- GCT/21/14

Reference:- Your letter No. NN/RA/CTA/NVE/2013/324 dated 14 Aug 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: NN9535-3626, version No. 2.0, dated 04 June 2013** submitted to this Directorate.

1. Dr. Nikhil M Bhagwat, BYL Nair Hospital and TN Medical College, Dept. of Endocrinology College Building, 4th floor, room no. 19, Dr A L Nair Road, Mumbai Central, Mumbai-400008.
2. Dr. Vageesh Ayyar, St. John's Medical College, Dept. of Endocrinology Sarjapur Road, Bangalore-560034.
3. Dr. Vaishali Deshmukh, Deenanath Mangeshkar Hospital and Research Centre, Pune-411004.
4. Dr. Vijay Shekar Reddy, Gandhi Hospital, Mesheerabad, Secunderabad.
5. Dr. Sanjeev Bakshi, Jehangir Clinical Development Centre Jehangir Hospital Premises 32, Sassoon Road, Pune-411001 Maharashtra.
6. Dr. Chandni, Associate Prof. of Medicine, Calicut Medical College, Kerala-673017.

7. Dr. Harish Kumar, Amrita Institute of Medical sciences & Research Centre AIMS, Dept. of endocrinology & Diabetes Ponekkara, P.O., Kochi-682041, Kerala.
8. Dr. Parminder Singh, Dayanand Medical College & Hospital (DMCH) D.M.C. Road, Tagore Nagar, Punjab
9. Dr. Tirthankar Chaudhury, Apollo Gleneagles Hospital, 58 Canal Circular Road, Kolkata.
10. Dr. Satinath Mukhopadhyay, Institute of Post Graduate Medical Education & Research and SSKM Hospital, 244, A J C Bose Road, Kolkata-700020.
11. Dr. Trivan Marwah, Sheth Vadilalsarabhai General Hospital, Endocrine department, Ellis Bridge, Ahmedabad-380 066, Gujarat
12. Dr. Jayanthi Ramesh, Osmania General Hospital, Department of Endocrinology, Hyderabad-500012
13. Dr. Pramila Kalra, M. S. Ramaiah Medical College and Hospitals, Dept. of Endocrinology New BEL Road, MSRIT Post, Bangalore-560054.
14. Dr. Krishna Seshadri, Sri Ramachandra Medical Centre, A1 Private clinic, Department of Endocrinology, Diabetes and Metabolism , Porur, Chennai-600116
15. Dr. P K Jabbar, Govt. Medical College, Department of Endocrinology Trivandrum-695011, Kerala.
16. Dr. Sujeet Jha, Max Super Speciality Hospital (A unit of Devki Devi Foundation),. 2 Press enclave Road, Saket, New Delhi-110017
17. Dr. Sandeep Mathur, SMS Medical College and attached Hospitals, JLN Marg, Jaipur-302004, Rajasthan.
18. Dr. Anil Bhansali, Post Graduate Institute of Medical Education and Research(PGIMER), Room No.3027(Endo Lab), Thrid Floor, Research Block B, Chandigarh-160012.
19. Dr. Alok Kanungo, Kanungo Institute of Diabetes Specialilties Pvt. Ltd. (KIDS) Plot No. 1120, Dumduma, Bhubaneswar-751019.
20. Dr. Yogesh Kadam, Inamdar Multispeciality Hospital, Survey No. 15, Fatimanagar, Pune-411040.

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

- a. Inclusion of DSMB and the subjects who have BMI less than 18.5 kg/m² to be excluded;
- 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 ten 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 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.
- l. 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.

- m. 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.
- n. 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)