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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/72/2013-DCGI **Dated:** 24-03-2014

To

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

Subject: Permission for conducting a phase IV clinical study entitled, "Efficacy and safety of liraglutide versus sulphonylurea both in combination with metformin during Ramadan in subjects with type 2 diabetes." – regarding.

Clinical Trial NOC No.:- GCT/08/14

Reference: Your letter no. NN/RA/CTA/NVE/2013/352 dated 03 Sep 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: NN2211-3987 versions 1.0 dated 09 July 2013** submitted to this Directorate.

1. Dr. M. A. Shekar, Dept. of Endocrinology, KR Hospital, Mysore Medical College & Research Institute, Irwin Road, Mysore-570001
2. Dr. K. R. Raveendra, Bangalore Medical College and Research Institute, Room No 72/A, 2nd Floor-C-Block, Victoria Hospital Fort, Bangalore -560002
3. Dr. Abhay Amrutlal Mutha, Ruby Hall Clinic, 40, Sassoon Road, Pune 411001.
4. Dr. Shehla Sajid Akhtar Shaikh, Prince Aly Khan Hospital, Aga Hall, Nesbit Road, Mazagaon, Mumbai 400 010
5. Dr. Manoj Chawla, BSES Municipal General Hospital, S.V. Road, opposite railway station, Andheri (west), Mumbai-400058

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6. Dr. H. Basavanna Gowdappa, JSS Hospital, MG Road, Agrahara, Mysore, 570004.
7. Dr. Rakesh Kumar Sahay, Department of Endocrinology, 2nd Floor, Golden Jubilee Block, Osmania General Hospital, Afzalgunj, Hyderabad, 500012
8. Dr. Bipin Kumar Sethi, Care Hospital, Care Out Patient Centre, 8-2-620/A-E, Road No-10, Banjara Hills, Hyderabad-500034
9. Dr. Dinesh Kumar Dhanwal, Director Professor of Medicine, Room No. 115, Department of Medicine, B. L. Taneja Block, Maulana Azad Medical College & Associated Hospitals, New Delhi - 110002
10. Dr. Banshi Damodarlal Saboo, Dr. Jivraj Mehta Health Foundation, Bakeri Medical Research Centre, Ayojan Nagar, near Shreyas Crossing Road, Jivraj Mehta Marg, Jivraj Park, Ahmedabad – 380007
11. Dr. Nikhil Madhusudan Bhagwat, Department of Endocrinology, Topiwala National Medical College & B.Y.L. Nair Charitable Hospital and, Dr A. L. Nair road, Mumbai-400008

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)

21/3/2014