File No CT/40/15 – DCG (I)

Clinical Trial NOC No: -GCT/07/16

29601/04.09.15

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
Tel No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/40/15 – DCG (I)

Date: 09/05/2016

To,

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

Subject: Permission for conducting a Phase III clinical trial "Efficacy and Safety of Semaglutide versus Dulaglutide as add-on to Metformin in Subjects with Type 2 Diabetes". – regarding.

Reference: -Your letter No. NN/RA/SPTP/576 dated 31 Aug 2015 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: NN9535-4216 Version 1.0 Dated 14 July 2015** submitted to this Directorate.

1. Dr. Sudip Chatterjee, Park Clinic, 4 Gorky Terrace, Kolkata 700017,West Bengal, India
2. Dr. Shailaja Kale,Inamdar Multi specialty Hospital, Hospital Building S. No. 15, Fatima Nagar, Pune 411040, Maharashtra, India.
3. Dr. Satinath Mukhopadhyay, IPGME&R and SSKM Hospital, Ronald Ross Building, 4th Floor, Room No. 9, 9A, 244, AJC Bose Road, Kolkata 700020, West Bengal, India.
4. Dr. Vaishali Chetan Deshmukh, Deenanath Mangeshkar Hospital and Research Centre, 6th Floor C-Wing C6 Erandawane, Pune 411004, Maharashtra, India.
5. Dr. Thushanth Thomas, Department of Endocrinology, Kerala Institute of Medical Sciences, Anayara P O, P.B. No 1, Trivandrum 695029, Kerala, India.
6. Dr. Vijay Shekar Reddy, Department of Endocrinology, 3rd floor, Gandhi Hospital, Musheerabad, Secunderabad, Telengana 500003, India.
7. Dr. Ankush Desai, Department of Medicine, Endocrine Unit, Goa Medical College, Bambolim, Goa 403202, India.
8. Dr. Nivedita Devabrata Moulick, LTMMC and LTMGH, Sion(W), Mumbai-400022, India.
9. Dr. Sambit Das, Apollo Hospitals, Plot No. 251, Sainik School Road, Unit 15, Bhubaneshwar 751005, Odisha, India.
10. Dr. Nihal Thomas, 810, Department of Endocrinology Diabetes and Metabolism, Christian Medical College, Vellore 632004, Tamil Nadu, India.

11 Dr. Kongara Srikanth, Endolife Speciality Hospitals Pvt Ltd, D. No. 12- 12-94, Old Club Road, Kothapet, Guntur 522001, Andhra Pradesh.
12 Dr. Premlatha Krishnamoorthy Varthakavi, Department of Endocrinology, College Building, 4th Floor, Room No 19, Topiwala National Medical College and B.Y.L. Nair Charitable Hospital, Dr. A.L. Nair Road, Mumbai 400008, Maharashtra.
13 Dr. Alapati Lakshmi Lavanya, Global Hospital, 6-1-1040/1 to 4, Lakdi-ka-pul, Hyderabad - 500 004, Telangana.
14 Dr. Dinesh Agarwal, Marwari Hospital and Research Centre, SJ Road, Athgaon, Guwahati 781008, Assam.
15 Dr. Sandeep Julka, Convenient Hospitals Ltd., CHL-Hospitals (A Unit of CHL-Group of Hospitals), Near L.I.G. Square, A.B. Road, Indore 452008, Madhya Pradesh, India.
16 Dr. Parag Rajnikant Shah, Dr. Jivraj Mehta Smarak Health Foundation, Ratubhai Adani Arogyadham, Nr. Ayojan Nagar, Ahmedabad 380007, Gujarat.
17 Dr. Kiran Pal Singh, Fortis Hospital, Sector 62, Phase VIII, Mohali 160062, Punjab, India.
18 Dr. Sandeep Garg, Room no. 120, First Floor, Department of Medicine, B.L. Taneja Block, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi 110002
19 Dr. Parminder Singh, DMC & Hospital, Tagore Nagar, Civil Lines, Ludhiana 141001, Punjab, India.
20 Dr. KAV Subrahmanyam, Dept. of Endocrinology, Superspeciality Block, King George Hospital, Maharani Peta, Visakhapatnam 530001, Andhra Pradesh.
21 Dr. Anupam Prakash, Room No. 1014, Department of Medicine, First Floor, Old Building, Lady Hardinge Medical College and S.S.K. Hospital, New Delhi
22 Dr. K. R Ravvendra, Victoria Hospital, Bangalore Medical College and Research Institute, K R Road, Fort, Bangalore-560002.
23 Dr. Rakesh Kumar Sahay, Dept. of Endocrinology, 2nd Floor, Golden Jubilee Block, Osmania Medical College & Osmania General Hospital, Afzalgunj, Hyderabad-500012, Telangana
24 Dr. M.A. Shekar, Krishna Rajendra Hospital (KR Hospital), Mysore Medical College and Research Institute, Irwin Road Mysuru, Karnataka-570001
25 Dr. Neeraj Manikath, Dept. of General Medicine, Govt. Medical College, kozhikode Kerala-673008
26 Dr. Anil Bhansali, Post Graduate Institute of Medical Education & Research, Sector 12, Near Punjab University, Chandigarh-160012
27 Dr. Yashdeep Gupta, Dept. of Endocrinology, AIIMS, Ansari Nagar, New Delhi-29
28 Dr. Harish Kumar, Department of Endocrinology and Diabetes, Amrita Institute of Medical Sciences and Research Centre, AIMS- Ponekkara. P.O., Kochi 682041, Kerala, India.
29 Dr. Mala Dharmalingam, Department of Endocrinology, M.S. Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, Bangalore 560054, Karnataka

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

a. **Dose titration with Dulaglutide should be in line with the approved prescribing information.**

b. **50% Trial sites must be Govt. sites.**

c. 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;

d. Approval of the Ethics Committee shall be obtained before initiation of the study;

e. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

f. 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;

g. 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;

h. 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;

i. 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;

j. 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.

k. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

l. 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.

m. 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.

n. 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.

o. 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. V.G. Somani)
Joint Drugs Controller (India) &
Licensing Authority