File No CT/03/16 – DCG (I)

Clinical Trial NOC No: - GCT/22/16

1976/20.01.16

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/03/16 – DCG (I)

Date: 02/08/16

To,

M/s Novartis Healthcare Pvt. Ltd.,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai-400018

Subject: **Permission for conducting a clinical trial titled "A Phase Ib/II, Open-Label, Multicenter Trial with Oral cMET Inhibitor INC280 Alone and in Combination with Erlotinib Versus Platinum/Pemetrexed in Adult Patients with EGFR Mutated, cMET-Amplified, Locally Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLC) with Acquired Resistance to Prior EGFR Tyrosine Kinase Inhibitor (EGFR TKI)."** – regarding.

Reference: - Your letter No. Nil dated 13 January 2016 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: CINC280B2201, v01 Clean Version (Amended Protocol Version), dated 20-Nov-2015** submitted to this Directorate.

1. Dr. Ullas Batra, Rajiv Gandhi Cancer Institute and Research Centre, Room No. 2251, Sector-V, Rohini, New Delhi 110085, Delhi, India.
2. Dr. Govind Babu Kanaka Setty, Health Care Global (HCG) Enterprise Ltd, #88, 17th Main, 2nd Cross, 5th Block, Kormangala, Bangalore - 560095, India.

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

a. **Additional PK/PD studies should be conducted in the enrolled patients in India who are on the Investigational product arm (INC280).**
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 fourteen 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. 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.

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 (I)

File No CT/04/16 – DCG (I) Clinical Trial NOC No: - GCT/23/16

2389/22.01.16

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/04/16 – DCG (I) Date: 04/08/16

To,

M/s AstraZeneca Pharma India Limited,
Block N1, 12th Floor, Manyata Embassay Business Park,
Rachenahalli, Outer Ring Road Bangalore-560045

Subject: **Permission for conducting clinical trial titled "A Phase III Randomized, Open Label, Multi-center, Global Study of MEDI4736 Alone or in Combination with Tremelimumab Versus Standard of Care in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients."** – regarding.

Reference: - Your letter No. REG/2015/CT/DGHS/071 dated 14 January 2016 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: D419LC00001, Amendment No. 01, dated 31/March/2016** submitted to this Directorate.

1. Dr. B J Srinivasa, Healthcare Global Enterprises Limited, HCG Towers, #8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore - 560027, Karnataka, India.
2. Dr. Satheesh C T, Sri Venkateshwara Hospital, #86, Hosur Main Road, Madiwala, Bangalore - 560068, Karnataka, India.
3. Dr. Ashish Singh, Christian Medical College, Ida Scudder Road, Vellore - 632004, TN, India.
4. Dr. K S Kirushna Kumar, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai - 625107, Tamil Nadu, India.
5. Dr. Arumugham Rajkumar, G. Kuppuswamy Naidu, Memorial Hospital, Post Box No. 6327, Nethaji Road, P.N.Palayam, Coimbatore - 641037, TN, India.
6. Dr. Hemant Malhotra, R K Birla Cancer centre, SMS Medical college Hospital, Jaipur - 302004, Rajasthan, India.
7. Dr. Piyush Kedia, B.P. Poddar Hospital & Medical Research Ltd., 71/1, Humayun Kabir Sarani, Block - G, New Alipore, Kolkata - 700053, West Bengal, India.
8. Dr. Sushant Mittal, Artemis Hospital, Sector-51, Gurgaon-12200, Haryana

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

a. **Comprehensive training of Investigators especially with regards to immunological toxicities must be provided.**

b. **A system of instant electronic communication between subjects and study site should be in place to ensure prompt adverse event reporting and management.**

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. G.N. Singh)
Drugs Controller General (I)

File No CT/09/16 – DCG (I)

Clinical Trial NOC No: - GCT/29/16

6618/24.02.2016

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/09/16 – DCG (I)

Date: 08/08/16

To,

M/s Novartis Healthcare Pvt. Ltd.,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai-400018

Subject: **Permission for conducting a Phase I clinical trial titled "A Multi-Center, Randomized Open Label Study to Assess the Systemic Exposure, Efficacy, and Safety of 450 mg Ceritinib taken with a Low-Fat Meal and 600 mg Ceritinib taken with a Low-Fat Meal as Compared with that of 750 mg Ceritinib taken in the Fasted State in Adult Patients with ALK Rearranged (ALK-positive) Metastatic Non-Small Cell Lung Cancer (NSCLC).." – regarding.**

Reference: - Your letter No. Nil dated 11 Feb 2016 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: CLDK378A2112, Amended Protocol Version 02 (Clean), dated 16/10/2015** submitted to this Directorate.

1. Dr Ullas Batra, Rajiv Gandhi Cancer Institute and Research Centre, Sector 5, Rohini Clinical Trials Dept, New Delhi- 110085.

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 fourteen 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. 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.

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 (I)

File No CT/46/15 – DCG (I)

Clinical Trial NOC No: - GCT/24/16

35504/21.10.15

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/46/15 – DCG (I)

Date: 08/08/16

To,

M/s AstraZeneca Pharma India Limited,
Block N1, 12th Floor, Manyata Embassay Business Park,
Rachenahalli, Outer Ring Road Bangalore-560045

Subject: **Permission for conducting clinical trial titled "A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) (NEPTUNE)."** – regarding.

Reference: - Your letter No. REG/2015/CT/DGHS/053 dated 20th Oct 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: D419AC00003, Local Amendment No. 1, Edition No. 01, dated 21/March/2016** submitted to this Directorate.

1. Dr. Shyam Aggarwal, Dept. of Medical Oncology, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060.
2. Dr. Ashish Singh, Department of Medical Oncology, Christian Medical College, Ida Scudder Road, Vellore - 632004, Tamil Nadu.
3. Dr. K. Pavithran, Amrita Institute of Medical Sciences and Research Centre, Ponekkara P.O., Cochin - 682041, Kerala.
4. Dr. Hemant Malhotra, R K Birla Cancer Centre, SMS Medical College Hospital, Jaipur - 302001, Rajasthan.
5. Dr. Shekar Gowda Patil, Health Care Global Enterprises Limited, HCG Towers, #8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore - 560027, Karnataka.
6. Dr. Balasubramanium Sivanesan, G. Kuppuswamy Naidu Memorial Hospital, Post Box No. 6327, Nethaji Road, P.N. Palayam, Coimbatore - 641037, Tamil Nadu.
7. Dr. Harsha .P. Panchal, The Gujarat Cancer & Research Institute, M.P Shah Cancer Hospital, New Civil Hospital Campus, Asarwa, Ahmedabad, - 380016, Gujarat.
8. Dr. Krishnakumar Rathnam, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai - 625107, Tamil Nadu.
9. Dr. Sachin Vamanrao Almel, Dept. of Oncology, P.D.Hinduja National Hospital & Medical Research Centre, Ground Floor, Wing No 1, OPD Building, Room No 106, Veer Savarkar Marg, Mahim West, Mumbai - 400016, Maharashtra.
10. Dr. Dinesh Chandra Doval, Rajiv Gandhi Cancer Institute and Research Centre, Sector-V, Rohini, New Delhi – 110085.

11. Dr. Sankar Srinivasan, Apollo Speciality Hospital, Padma Complex, No. 320, Anna Salai, Chennai -600035, Tamil Nadu, India.
12. Dr. Sushant Mittal, Artemis Hospital, Sector-51, Gurgaon-12200, Haryana.

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

a. **A system of instant electronic communication between subjects and study site should be in place to ensure prompt adverse event reporting and management.**

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 fourteen 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. 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.

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 (I)

File No CT/19/16 – DCG (I)

Clinical Trial NOC No: - GCT/28/16

14031/29.04.16

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/19/16 – DCG (I)

Date: 09/08/16

To,

Prof. (Dr.) G. Karthikeyan
Dept. of Cardiology,
AIIMS, New Delhi-29

Subject: Permission for conducting a clinical trial titled INVICTUS TRIALS "Investigation of Rheumatic AF Treatment Using Vitamin K Antagonists Rivaroxaban or Aspirin Studies." – regarding.

Reference: - Your letter No. Nil dated 27 April 2016 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 submitted **Protocol Version 1.0, dated 31 July 2015** to this Directorate.

1. Dr. G. Karthikeyan, Department of Cardiology, AIIMS, Ansari Nagar, New Delhi-110029.

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 fourteen 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. 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.

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 (I)

File No CT/01/16 – DCG (I).

Clinical Trial NOC No: - GCT/27/16

311/05.01.2016

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/01/16 – DCG (I)

Date: 11/08/16

To,

M/s Excel Life Sciences Pvt. Ltd.,
D-62, 1st Floor, Sector-02, Noida,
Uttar Pardesh-210301, India

Subject: Permission for conducting a clinical trial "PEACHTREE: A Phase 3, Randomized, Masked, Controlled Clinical Trial to Study the Safety and Efficacy of Triamcinolone Acetonide Injectable Suspension (CLS-TA) for the Treatment of Subjects with Macular Edema associated with Non-Infectious Uveitis."– regarding.

Reference: - Your letter No. Nil dated 05 Jan 2016 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: CLS1001-301 Version 2.2 (IN), dated 25 May 2016** submitted to this Directorate.

1. Dr. Pradeep Venkatesh, Dept. of Vitreo Retinal Diseases & Trauma, Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, Ansari Nagar, New Delhi-29, India.
2. Dr. Pranab Das, The Calcutta Medical Research Institute, No 7/2, Diamond Harbour Road, Kolkata-700027, West Bengal, India.
3. Dr. Shalini Singh, Dr. Shroff's Charity Eye Hospital Vitero- Retina Dept., 5027-Kedarnath Road, Daryaganj, New Delhi-02, India.
4. Dr. Premnath Raman, JSS Hospital, Room No. 1038, Dept. of Ophthalmology, M.G. Road, Mysore - 570 004, Karnataka, India.
5. Dr. Vishal Katiyar, Department of Ophthalmology, Room No. 103 and 104 King George's Medical University, Shah Mina Road, Chowk, Lucknow - 226003, UP, India.
6. Dr. Jignesh Gosai, Oculoplasty Department, A-2 M & J Western Regional Institute of Ophthalmology, Civil Hospital Campus, Asarwa, Ahmedabad, Gujarat- 380016, India.
7. Dr. Girija Devi Paramoo Sreedevi, Regional Institute of Ophthalmology, Red Cross Road, Vanchiyoor P.O, Thiruvananthapuram- 695035, Kerala, India.
8. Dr. Deepa Sharma, Department of Ophthalmology, PGIMER, Dr. Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, Near Gurudwara Bangla Sahib, Connaught Place, New Delhi – 01, India.
9. Dr. Jyotirmay Biswas, Uveitis & Ocular Pathology Dept., Sankara Nethralaya, New No 41, Old No 18, College Road, Chennai-600006, Tamil Nadu, India.
10. Dr. Neha Goel, Retina@ ICARE (Mohni Sabharwal Wing) Room No. 10 to 18 & Research wing, SB Block, ICARE Eye Hospital & Post Graduate Institute ICARE Research Centre, E-3A, Sector-26, Noida - 201301, Uttar Pradesh, India.

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 fourteen 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. 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.

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 (I)

File No CT/15/16 – DCG (I) Clinical Trial NOC No: - GCT/26/16

12998/19.04.16

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/15/16 – DCG (I) Date: 11/08/16

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 "A Clinical Trial Comparing Glycaemic Control and Safety of Insulin Degludec/Liraglutide (IDegLira) versus Insulin Glargine (IGlar) as add-on Therapy to SGLT2i in Subjects with Type 2 Diabetes Mellitus."– regarding.

Reference: - Your letter No. NN/RA/SPTP/091 dated 13 April 2016 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: NN9068-4229 Final Version 2.0, dated 20 November 2015** submitted to this Directorate.

1. Dr. Surya Kumar Singh, Department of Endocrinology & Metabolism, Institute of Medical Sciences, Banaras Hindu University, Varanasi – 221005, UP, India.
2. Dr Jagat Jyoti Mukherjee, Apollo Gleneagles Hospitals, 58 – Canal Circular Road, Kolkata – 700054, West Bengal, India.
3. Dr. Parminder Singh, Dayanand Medical College & Hospital, Research & Development Centre, Tagore Nagar, Civil Lines, Ludhiana – 141001, Punjab, India.
4. Dr Vijayam Balaji, Dr. V. Seshiah Diabetes Research Institute Dr. Balaji Diabetes Care Centre, 729, P.H. Road, Aminjikarai, Chennai – 600029, Tamil Nadu, India.
5. Dr. Sushil Jindal, People's College of Medical Sciences & Research Centre, By Pass Road Bhanpur, Bhopal – 462037, M P, India.
6. Dr Rakesh Kumar Sahay, Department of Endocrinology, 2nd Floor, Golden Jubilee Block Osmania Medical College & General Hospital, Afzalgunj, Hyderabad – 500012, Telangana, India.
7. Dr. Deep Dutta, Dept. of Endocrinology, PGIMER & Dr RML Hospital, 1 Baba Kharak Singh Marg, New Delhi – 110001.

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

a. **OADs should be provided free of cost.**
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 fourteen 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. 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.

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 (I)

File No CT/12/16 – DCG (I)

Clinical Trial NOC No: - GCT/25/16

9508/18.03.16

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/12/16 – DCG (I)

Date: 12/08/16

To,

M/s Novartis Healthcare Pvt. Ltd.,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai-400018

Subject: Permission for conducting a Phase III clinical trial titled "RAINBOW Extension Study: An Extension Study to Evaluate the Long Term Efficacy and Safety of Ranibizumab Compared with Laser Therapy for the Treatment of Infants Born Prematurely with Retinopathy of Prematurity." – regarding.

Reference: - Your letter No. Nil dated 14 March 2016 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: CRFB002H2301E1, Version 00 (Original Protocol), dated 11 Dec 2015** submitted to this Directorate.

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

a. **The safety and efficacy data accrued until Dec 2016 globally should be submitted to CDSCO by 31st January 2017.**
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 fourteen 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 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. 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.

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 (I)

File No CT/10/16 – DCG (I)

Clinical Trial NOC No: - GCT/31/16

7636/02.03.16
24613/09.08.16

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/10/16 – DCG (I)

Date: 23/08/2016

To,

M/s Klinera Corporation India,
401, Hill View Indl. Estate, Amrut Nagar,
L.B.S. Marg, Ghatkopar (W), Mumbai-400086

Subject: Permission for conducting clinical trial titled "A combined phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Induction and Maintenance study evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis." – regarding.

Reference: - Your letter No. Nil dated 29 Feb 2016 and letter No. Nil dated 08 Aug 2016 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: GS-US-326-1100 Amendment 2.0, dated 27 Oct 2015** submitted to this Directorate.

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

a. **Approval is hereby granted for the conduct of the Phase II Portion of study protocol (Protocol No: GS-US-326-1100 Amendment 2.0, dated 27/Oct/2015). The Phase III study portion can be conducted only after obtaining prior approval from this Directorate.**

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 fourteen 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 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. 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.

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 (I)

File No CT/56/15 – DCG (I)

Clinical Trial NOC No: - GCT/30/16

40671/07.12.15

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/56/15 – DCG (I)

Date: 29/08/15

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 IIIa clinical trial titled "Efficacy and Long Term Safety of Oral Semaglutide versus Sitagliptin in Subject with Type 2 Diabetes."** – regarding.

Reference: - Your letter No. NN/RA/SPTP/739 dated 30 Oct 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: NN9924-4222, Version 2.0 (Final), dated 24 August 2015** submitted to this Directorate.

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

a. **OADs should be provided free of cost.**
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 fourteen 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 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. 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.

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 (I)

35210/20/10/15

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/45/15 – DCG (I) Date: 15/09/16

To,
M/s Novartis Healthcare Pvt. Ltd.,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai-400018

Subject: Permission for conducting a Phase III clinical trial titled "A 52-Week, Multicenter, Randomized, Double-blind, Placebo-Controlled Study to Assess the Efficacy and Safety of QAW039 when added to Existing Asthma Therapy in Patients with Uncontrolled Severe Asthma" – regarding.

Reference: - Your letter No. Nil dated 15 October 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: CQAW039A2314, Amended protocol Version 01 clean, dated 19/08/2015** submitted to this Directorate.

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

a. **The carcinogenicity toxicity data should be submitted to support the marketing application/before marketing.**
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 fourteen 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 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. 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.

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 (I)

File No CT/64/15 – DCG (I)

Clinical Trial NOC No: GCT/34/16

51318/21.12.15

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/64/15– DCG (I)

Date: 21/09/16

To,

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

Subject: Permission for conducting a Phase II clinical trial titled "A Randomized, Multinational, Active-Controlled, (Open-Labelled), Dose Finding, (Double-Blinded), Parallel Group Trial Investigating Efficacy and Safety of Once-Weekly NNC0195-0092 Treatment Compared to Daily Growth Hormone Treatment (Norditropin®Flexpro®) in Growth Hormone Treatment naïve Pre-Pubertal Children with Growth Hormone Deficiency." – regarding.

Reference: - Your letter No. NN/RA/SPTP/815 dated 30 Nov 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: NN8640-4172, Version 1.0, dated 02 Sep 2015** submitted to this Directorate.

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

a. **The high dose of glucocorticoids in children should be defined.**
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 fourteen 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 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. 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.

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 (I)

File No CT/57/15 – DCG (I)

Clinical Trial NOC No: - GCT/32/16

50774/16.12.15

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/57/15 – DCG (I)

Date: 21/09/16

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 IV clinical trial titled "LIRA-PRIME: Efficacy in Controlling Glycaemia with Victoza® (Liraglutide) as add-on to Metformin vs. OADs as add-on to Metformin after up to 104 weeks of Treatment in Subjects with Type 2 Diabetes Inadequately Controlled with Metformin Monotherapy and Treated in a Primary Care Setting. – regarding.

Reference: - Your letter No. NN/RA/SPTP/814 dated 14 Dec 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 the supervision of the investigators mentioned in your letter and as per the **Protocol No: NN2211-4232, Version 1.0, dated 04 September 2015** submitted to this Directorate.

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

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 fourteen 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)

File No CT/60/15-DCG (I)

Clinical Trial NOC No: GCT/37/16

50881/17/12/15

GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/60/15-DCG (I)

Date: 21/10/16

To,
M/s. Biocad India Private Limited,
163/C, 3rd Cross, 3rd Phase, IP Nagar,
Bangalore – 560078, Karnataka.

Subject: **Permission for conducting a clinical trial titled "International Comparative Multicenter Double-blind Randomized Clinical Study of Efficacy and Safety of BCD-055 (CJSC BIOCAD, Russia) and Remicade® in Combination with Methotrexate in Patients with Active Rheumatoid Arthiritis"**– regarding.

Reference: Your letter No. nil dated 03/12/15 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 your letter and as per the **Protocol No: BCD-055-3/LIRA Version 1.1, dated 17/Mar/2016** submitted to this Directorate.

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

a. **The investigators must be rheumatologist or qualified physician (i.e MD Medicine).**
b. **More than 50% of the patients recruited should be from the government institution.**
c. **Since the management of the SAE with the molecules may require multispecialty approach only those sites with adequate infrastructure (at least 200 beds) and multispecialty facilities should conduct the clinical trial.**
d. **Some of the important Institutions of the country may also be included as trial sites.**
e. 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.
f. Approval of the Ethics Committee shall be obtained before initiation of the study.
g. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.
h. 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.

i. 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.

j. 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.

k. 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.

l. 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.

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

n. 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.

o. 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.

p. 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)