File No CT/32/16-DCG(I)

Clinical Trial NOC No: GCT/48/16

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
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24231/05/08/16

File No: CT/32/16-DCG (I)

Date: 03/01/17

To,

M/s. Cipla BioTec Private Limited,
Plot No. L-147/B, Verna Industrial Estate,
Verna, Salcette - Goa – 403722.

Subject: **Permission for conducting a clinical trial titled "A randomized, double-blind, multicentric, parallel-group study comparing efficacy, safety and immunogenicity of CBT124, a candidate biosimilar Bevacizumab in combination with Carboplatin and Paclitaxel with EU-sourced Avastin® in combination with Carboplatin and Paclitaxel in first-line treatment for subjects with stage IV (unresectable recurrent disease or metastatic) Non-squamous Non-Small Cell Lung Cancer (NSCLC)"**– regarding.

Reference: Your letter No. BMAB/RA/26/2016 dated 01/08/2016 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 investigators mentioned below and as per the **Protocol No: CBT124/CT/002 Version 2.0/Amendment 1.0, dated 21 July 2016** submitted to this Directorate.

1. Dr. Amit Kumar Dhiman, Dept. Of Oncology, Dayanand Medical College and Hospital (DMCH), Ludhiana – 141001, Punjab.
2. Dr. C.D. Sivanandan, Dept. of Radiation Oncology, Regional Cancer Centre P.O Box No. 2417, Medical College Campus, Thiruvananthapuram – 695011, Kerala.
3. Dr. Chetan Deshmukh, Deenanath Mangeshkar Hospital and Research Center, Off Karve Road Erandwane, Pune-411004, Maharashtra.
4. Dr. Chirag Jyotiker Desai, Hemato Oncology Clinic Ahmadabad Pvt. Ltd., 1st Floor, Vedanta Institute of Medical Sciences, Near Samved Hospital, Stadium-Commerce College Road, Navrangpura, Ahmedabad-380009.
5. Dr. Ganesha, St. Johns Medical College Hospital, Sarjapur Road, Bengaluru, Karnataka-560034.
6. Dr. Kakali Choudhury, Health Point Hospital #21 PrannathPandit Street (Opp. Lansdowne Padmapukur) Kolkata - 700025, West Bengal.
7. Dr. KiranKumar Puna Jadhav, Dept. of Surgery, Sassoon General Hospital, Jay Prakash Narayan Road, Station Road, Sassoon Road, Pune-411001.
8. Dr. Krishna Prasad, Kasturba Medical College Hospital, Dept. of Medical Oncology, Attavar, Mangalore-575001, Karnataka.
9. Dr. K. C. Lakshmaiah, Srinivasan CancerCare Hospital, 236/1, Vijayashree Layout, Bannerghatta Road, Omkar Nagar, Arekere, Bangalore, Karnataka-560072.
10. Dr. Lalit Kumar, All India Institute of Medical Sciences, Ansari Nagar New Delhi-110029.

11. Dr. Mahesh V. Pawar, KEM Hospital Research Centre, 3rd Floor, Day Care Centre, Banoo Koyaji Building, Rasta Peth, Sardar Moodliar Road, Pune – 411011.
12. Dr. Rajnish Vasant Nagarkar, Curie Manavata Cancer Centre, Opp. Mahamarg Bus Stand, Mumbai Naka, Nashik-422004, Maharashtra.
13. Dr. Mukesh S, Room No 22, Dept, of Radiation Oncology, MMCRI-K R Hospital, Mysore-570001.
14. Dr. Randeep Singh, HCG-SMH-Curie Cancer Centre, Shanti Mukand Hospital, #2, Institutional Area, Vikas Marg Extension, Karkardooma, Delhi-110092.
15. Dr. Sandeep Kumar Jasuja, R.K. Birla Cancer Center, SMS Hospital, JLN Marg, Jaipur – 302004.
16. Dr. Satyanarayan, Dept. of Radiation Oncology, ATRCTRI (RCC) S.P. Medical College and AG of Hospitals, Bikaner-334003.
17. Dr. Tanveer Mohibbhai Maksud, Unique Hospital, Multispecialty and Research Institute, Opp. Kiran Motor, Near Canal Road, Civil Char Rasta, Sosyo Circle lane, Surat-395002.
18. Dr. M. Vikranth, City Cancer Centre, 33-25-33, Ch Venkata Krishnayya Street, Suryarao Pet, Vijayawada-520002, Andhra Pradesh.
19. Dr. Wesley M Jose, Amrita Institute of Medical Sciences and Research Centre, Ponekkara P O, Cochin-682041, Kerala.
20. Dr. Siddhartha Nanda, All India Institute of Medical Sciences, Raipur Tatibandh, G E Road, Raipur, Chattisagarh-492099.
21. Dr. Hari Goyal, Dept. of Medical Oncology and Haematology , Artemis Hospital, sector 51, Gurgaon, Haryana-122001.

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 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 (India)