

GOVERNMENT OF INDIA

19840/23/6/2016

Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)

FDA Bhawan, Kotla Road, New Delhi-110002

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File No: CT/26/16-DCG (I)

Date: 10/11/16

To,

M/s. Clantha Research Ltd.,
Opp. Pushparaj Towers,
Nr. Judges Bungalows, Bodakdev,
Ahmedabad - 380054.

Subject: Permission for conducting a clinical trial titled "Multicenter, Double Blind, Randomized Parallel-Group Study to Assess the Efficacy and Safety of MYL-14020 compared with Avastin, in the first line treatment of patients with stage IV Non- Squamous Non- Small Cell Lung Cancer"-- regarding.

Reference: Your letter No. CRL.GN.16.104 dated 20/6/2016 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 in your letter and as per the Protocol No: MYL-14020 -3001, Version 1.0, dated 09/Mar/2016 submitted to this Directorate.

1. Dr. Suresh Sudalaiandi, Sri Ramachandra Medical Center, No.1. Ramachandra Nagar, Porur, Chennai- 600116, Tamil Nadu, India.
2. Dr. K. S. Kirushna Kumar, Dept of Radiation Oncology, Meenakshi Mission Hospital & research Centre, Lakearea, Melurroad, Madurai 625107, Tamilnadu, India.
3. Dr. Mahesh Kumar Veeranna Kalloli, KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi- 590010, Karanataka, India.
4. Dr. Karthik ChandraVallam, Mahatma Gandhi Cancer Hospital& Research Institute, 1/7, MVP Colony, Visakhapatanam 530017, Andhra Pradesh, India.
5. Dr. G.Raja, Rajiv Gandhi Government General Hospital and MMC, No. 1 Opposite to Central Railway station, E.V.R periyar Salai, Park Town, Chennai-600003, India.
6. Dr. Manasi Shah, HCG Cancer Center, Sola-Science City Road, Near Sola Bridge, S. G. Highway, Ahmedabad-380060, Gujarat, India.
7. Dr. Loknath Dasappa, Sri.Venkateshwara Hospitals, # 86, hosur Main Road, Madiwala, Bangalore 560068, Karnataka, India.
8. Dr. Asis Mukhopadhyay, Netaji Subhas Chandra Bose Cancer Research Institute 16A, Park Lane, Kolkata-700016, WB, India.
9. Dr. Anil Kumar. N, M.S. Ramaiah Medical College & Hospital, MSRIT Post, MSR Nagar, Bangalore- 560054, Karnataka, India.

10. Dr. Adwaita Gore, Prince Aly Khan Hospital, Aga Hall, Nesbit Road, Mazgaon Mumbai 400010, India.
11. Dr. M.Gopi Chand, City Cancer Center, 33-25 33, Ch.Venkatakrishnayya street, suryarao pet Vijayvada-520002, Andhra Pradesh, India.
12. Dr. Surender kumar beniwal, ATRCTRI (RCC), S. P. Medical College & AG Hospitals, Bikaner - 334003, Rajasthan, India.
13. Dr. Naresh Somani, Bhagwan Mahaveer Cancer, Hospital & Research Center, J. L. Marg, Jaipur-302017, Rajasthan, India.
14. Dr. Pradeep shah, Manibhai Shivabhai Patel Cancer Center Shree Krishna Hospital and Medical Center, Gokal Nagar, Karamsad-388325, Gujarat, India.
15. Dr. Kalyan Kusum Mukherjee, Chittaranjan National Cancer Institute, 37, S.P. Mukherjee road, P.O.Kalighat, Kolkata-700026, West Bengal, India.
16. Dr. Tanveer Mohibbhai Maksud, Unique Hospital- Multi speciality & Research Institute, Opp Kiran Motor, Near Canal, Civil Char rasta, Sosyo Circle Lane, Surat, 395002, Gujarat, India.
17. Dr. Vijay Agarwal, HealthCare Global Enterprises Limited, HCG Towers, No.8, P. Kalinga Rao Road, Sampangiram Nagar, Bangalore-560027, India.
18. Dr. Mukul Goyal, Asian Cancer Research Institute, Apex Hospital Private Limited SP 4 & 6 Malaviya Industrial Area Malaviya Nagar Jaipur-302017, Rajasthan, India.
19. Dr. Dilip Kumar Pardia, Dept. of Radiation Oncology, All India institute of Medical Sciences, Sijua Patrapada, Bhubaneswar -751019, Odisha, India.
20. Dr. Soumya Surath Panda, Dept. of Oncosciences, 4th Floor IMS & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneswar -751003, Odisha, India.
21. Dr. Rakesh Taran, Convenient Hospital Ltd., CHL Hospital & CHL-CBCC Cancer Center, Units of CHL Group of Hospitals, Dept. of Oncology, Near L.I.G. Square, A. B. Road Indore-452008, Madhya Pradesh, India.
22. Dr. Naveen Sharma, Malpani Multispecialty Hospital, SP-6, Road No 1, VKI Area, Sikar Road, Jaipur-302013, Rajasthan, India.
23. Dr. Prashant Kumar Parida, Dept. of Medical Oncology, Acharya Harihar Regional Cancer Center Medical Road, Cuttack-753007, Odisha, India.
24. Dr. Sumit Basu, Ruby Hall Clinic, 40 Sassoon Road, Pune 411001, Maharashtra, India.
25. Dr. Radha madava .K, BGS Global Hospitals, BGS Health & Education City, # 67, Uttarahalli Road, Kengeri, Bangalore- 560060, Karnataka, India.
26. Dr. Sourjya Banerjee, Dept. of Radiotherapy & Oncology, KMC Hospital Attavar, Mangalore-575001, Karnataka, India.
27. Dr. Kartikeya Jain, Kailash Cancer Hospital and Research Center, Muni Seva Ashram, P.O. Goraj, Waghodia, Vadodara-391760, Gujarat, India.
28. Dr. Prabhat Singh Malik, Room no 245, 2nd floor, Dr. B.R. Ambedkar Institute Rotary Cancer Hospital, AIIMS, Ansari Nagar, New Delhi- 110029, India.
29. Dr. Dinesh Kumar Sinha, Regional Cancer Center Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna-800014, Bihar, India.

30. Dr. Aloke Ghosh Dastidar, Department Of Radiotherapy, IPGME&R/SSKM Hospital, 244 AJC Bose Road, Kolkata - 700020, West Bengal, India.
31. Dr. Sushil Meshram, Department of Radiation Therapy and Oncology, Govt. Medical College and Hospital, Nagpur - 440003, Maharashtra, India.
32. Dr. Sameer Gupta, Department of Surgical Oncology, 3rd Floor, Shatabdi Hospital, Phase II, King George's Medical University Lucknow - 226003, Uttar Pradesh, India.
33. Dr. Amit Dhiman, Dayanand Medical College & Hospital, Research & Development Center, Tagore Nagar, Civil Lines, Ludhiana 141001, Punjab, India.
34. Dr. S. H. Advani, Jaslok Hospital and Research Center, 15, Dr. G. Deshmukh Marg, Mumbai 400026, Maharashtra, India.

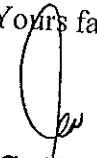
Kindly note that the clinical trial permission is subject to the following condition:

- 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 ten days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.
- f. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.
- g. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.
- h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational

drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

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