

GOVERNMENT OF INDIA

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
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Tel No: 01123236965, Fax: 01123236971
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File No: CT/95/13 - DCG (I)

Dated: 01/05/2015

To,

M/s Cliantha Research Ltd.
Sigma 1 Corporate, B/h Rajpath Club,
Opp. Mann Party Plot, Off S.G. Highway,
Bodakdev, Ahemdabad - 380054.

Subject: Permission for conducting a clinical trial entitled "A Randomized, Double-blind, Multi-center, Parallel-group, Active and Placebo Controlled, Three arm Clinical study to Compare the Efficacy and Safety of Clindamycin 1% / Benzoyl Peroxide 5% Topical Gel (of Cadila Healthcare Limited, India) versus BenzaClin® Topical Gel (of Valeant Pharmaceuticals International, Inc.) versus Placebo Topical Gel in the ratio of 2:2:1 respectively in Patients with Acne Vulgaris"- regarding.

Clinical Trial NOC No.:- GCT/15/15

Reference: -Your letter No. CRL.CT.GN.99 dated 13 Nov 2013 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: CRL/CT/05/12-13 version 3.0 dated 22 Aug 2014** submitted to this Directorate.

1. Dr. Abhishek De, Dept. of Dermatology, Institute of Post Graduate Medical Education & Research (IPGMER), 224 AJC Bose Road, Kolkata-700020, West Bengal.
2. Dr. Geeta Kiran, Dept. of Dermatology, 5th floor, Gandhi Medical college and Hospital, Musheerabad, Secunderabad, Hyderabad-500003, Andhra Pradesh.
3. Dr. P. Guruprasad, Dept. of Dermatology, King George Hospital, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh.
4. Dr. Bela J. Shah, Dept. of Dermatology, Room No. 139, Leprosy and STI, OPD Building, 1st Floor, Wing No. 3, B J Medical college, Civil Hospital, Ahmedabad-380016, Gujarat.

5. Dr. Chitra Nayak, Dept. of Dermatology, T N Medical College and BYL Nair Hospital, Dr. AL Nair Road, Mumbai-400008, Maharashtra
6. Dr. Hemangi Jerajani, MGM Medical College and Hospital, Sector 18, Kamothe, Navi Mumbai-410209, Maharashtra
7. Dr. Jayadev B. Betkerur, Dept. of Skin and STD, JSS Hospital, Ramanuja Road, Mysore, Karnataka-570004.
8. Dr. Rajesh Pratap Singh, Skin, VD & Leprology Department, Government Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra
9. Dr. Ranjan Raval, Dept. of Dermatology, Seth V S General Hospital, Ellisebridge, Ahmedabad-380006, Gujarat.
10. Dr. Rachita Dhurat, Department of Dermatology (Skin & VD), OPD16, New OPD Building, 2nd Floor, LTM Medical College & LTMG Hospital, Sion, Mumbai-400022, Maharashtra.
11. Dr. Grandhi Sudhakarao Venkata, Medipoint Hospital Pvt. Ltd., 241/1, New D P Road, Aundh, Pune-411007, Maharashtra.
12. Dr. Sushil Pande, Dept. of Dermatology, OPD No. 07, NKP Salve Institute of Medical Sciences and Lata Mangeshkar Hospital, Digdoh, Hingna, Nagpur-440019, Maharashtra.
13. Dr. Yogesh Marfatia, OPD-1, Dept. of Skin and VD, Baroda Medical College, Vadodara-390001, Gujarat.
14. Dr. Sharmila Patil, Dept. of Dermatology, OPD No. 54, 1st floor, Dr. D Y Patil Medical College & Hospital and Research Centre Plot No. 2, Sector-5, Nerul, Navi Mumbai-400 706, Maharashtra.

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

- a. Rescue medication (including score going from 1 to 2, score worsens or crosses 3) for placebo group is required after two weeks.
- b. **The storage condition of the IMP should be recorded.**
- 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

requirement of audio-visual recording of informed consent process of trial subjects.

- o. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

Yours faithfully,



(Dr. V.G. Somani)
Joint Drugs Controller (India)

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 ten 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. In addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials. All the Sponsors /Investigators /Institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are required to adhere to this