

GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Tel No: 01123236965, Fax: 01123236971
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File No: CT/16/000006

To,

M/s Quintiles Research (India) Pvt. Ltd.,
B-101-106, Shapath IV, Opp. Karnavati Club,
Sarkhej- Gandhinagar Road, Ahmedabad-380051

Subject: Permission for conducting a Phase III clinical trial titled “A Randomized, Double-blind, Multi-center, Multi-national Trial to Evaluate the Efficacy, Safety, and Immunogenicity of SAIT101 Versus Rituximab as a First-line Immunotherapy Treatment in Patients with Low Tumor Burden Follicular Lymphoma.”– regarding.

Reference: Your letter No. GCT/Form44/FF/2016/1328 (CT/56/16) dated 19/12/16 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 herein and as per **Protocol No: AGB002, Amendment 01, dated 07/OCT/16** submitted to this Directorate.

1. Dr. Rajib De, Nil Ratan Sircar Medical College & Hospital 138, AJC Bose Road, Kolkata -700014, West Bengal, India.
2. Dr. Chetan Dilip Deshmukh, Lata Mangeshkar Medical Foundation's Deenanath Mangeshkar Hospital and Research Centre, Erandawne, Pune- 411004, Maharashtra, India.
3. Dr. Santhosh Kumar Devadas, M. S. Ramaiah Medical College and Hospital, New BEL Road, MSRIT Post, Bangalore- 560054, Karnataka, India.
4. Dr. Abdul Majeed Kuruvadangal, Department of General Medicine, Government Medical College, Kozhikode- 673008, Kerala, India.
5. Dr. Arun Raja Gopal Warriar, Aster Medcity Aster DM Healthcare. Ltd, Kuttisahib Road, Near Kothad Bridge, South Chittoor P.O, Cheranallur Kochi- 682027, Kerala, India.
6. Dr. Sharat Damodar, Mazumdar Shaw Medical Center, Unit of Narayana Health, Narayana Hrudayalaya Limited, NH Health City, No. 258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore 560 099, Karnataka, India.
7. Dr. Singhal, Mukesh Kumar, Acharya Tulsi Regional Cancer Treatment And Research Institute, Bikaner (Regional Cancer Center) Associated group of Hospitals, S.P. Medical College, Bikaner 334003, Rajasthan, India.
8. Dr. Goyle, Sandeep Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Four Bungalows, Andheri (W), Mumbai - 400053, Maharashtra, India.
9. Dr. Rajnish Vasant Nagarkar, Curie Manavata Cancer Centre Opp. Mahamarg Bus Stand, Mumbai Naka, Nashik - 422004, Maharashtra, India.
10. Dr. Arora Rajendra singh Sujan singh, Sujan Surgical Cancer Hospital And Amravati Cancer Foundation 52/B , Shankar Nagar , Main Road Amravati, 444606. Maharashtra, India.

11. Dr. Sameer Khatri, Max Super Speciality Hospital, Vaishali (A unit of Crosslay Remedies Limited), W-3, Sector-1 Vaishali Ghaziabad UP-201012
12. Dr. Kalyan Kusum Mukherjee, Chittaranjan National Cancer Institute 37, S.P. Mukherjee Road. Kolkata-700026, WB
13. Dr. Badarkhe Girish Vishwanath, Health Care Global Enterprises Limited, HCG Tower #8, P. Kalinga Rao Road, Sampangiram Nagar, Bangalore- 560027, Karnataka, India.
14. Dr. Muzammil Shaikh, P.D. Hinduja National Hospital and Medical Research Centre, Veersavarkar Marg, Mahim (W), Mumbai - 400016, Maharashtra, India.
15. Dr. Amit Trilokinath Bhargava, Fortis Hospital, B-22, Sector - 62, Noida - 201301, UP, India.
16. Dr. Guru Prasad Mohanty, Kailash Cancer Hospital and Research Centre, Muni Seva Ashram, Goraj-391760, Waghodia, Vadodara, Gujarat, India
17. Dr. R. Ranga Rao, Max Super Speciality Hospital, FC 50, C & D Block, Shalimar Bagh, New Delhi
18. Dr. Sadanand Madhav Karandikar, Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon road, Pune.
19. Dr. Kaushal Kumar Babubhai Patel, Apple Hospital, Udhna Darwaja, Ring Road, Surat - 395002, Gujarat, India.
20. Dr. Niti Raizada, Fortis Hospital Ltd. 154/9, Bannerghatta Road, Opp. IIM -B, Bangalore - 560076, 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 14 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,

GYANENDRA
NATH SINGH

Digitally signed by GYANENDRA
NATH SINGH
Date: 2017.07.06 15:15:15 +05'30'

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

