

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 /17/000067

To,

M/s. Excel Life Sciences Pvt. Ltd.,
D-62, 1st Floor, Sector-2,
Noida - 201301, UP.

Subject: Clinical Trial Titled “A Phase 2b Open-label Study of Selinexor (KPT-330) in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)”– regarding.

Reference: Your online application reference No. GCT/Form44/FF/2017/4559 (GCT/69/17) dated 24/08/2017.

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: KCP-330-009 Version 7.0, dated 29 March 2017**, submitted to this Directorate.

1. Dr. Adwaita A Gore, Prince Aly Khan Hospital, Aga Hall, Nesbit Road, Mazagaon, Mumbai-400010, India.
2. Dr. Nirmal Raut, Bhakti Vedanta Hospital and Research Institute, Srishti Complex, Bhakti Vedanta Swami Marg, Mira Road (East), Thane-401107, Maharashtra, India.
3. Dr. Dinesh Kumar Sinha, Department of Oncology, Regional Cancer Centre, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna-800014, Bihar, India.
4. Dr. Akshay Dilip Shah, S.L. Raheja (A Fortis Associate) Hospital, Raheja Rugnalaya Marg, Mahim West, Mumbai-400016, Maharashtra, India.
5. Dr. Prasanth Ganesan, Cancer Institute (WIA), Sardar Patel Road, Adyar Chennai-600020, Tamil Nadu, India.
6. Dr. Sreejith G. Nair, Department of Medical Oncology, Regional Cancer Centre, Medical College Campus, Post Box No. 2417, Thiruvananthapuram-695011, Kerala, India.
7. Dr. Vivek S Radhakrishnan, Tata Medical Center Department of Hematology 14 MAR (E-W), New Town, Rajarhat, Kolkata-700160, West Bengal, India.
8. Dr. Shailendra Prasad Verma, King George’s Medical University, Shah Mina Road, Chowk Lucknow, Uttar Pradesh-226003, India.
9. Dr. Sourav Kumar Mishra, Institute of Medical Sciences and SUM Hospital, K-8 Kalinga Nagar, Ghatikla, Bhubaneswar-751003, Odisha, India.
10. Dr. Sameer Bakhshi, Dr. B.R.A Institute Rotary Cancer Hospital All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029, India.

11. Dr. Asis Mukhopadhyay, Netaji Subhas Chandra Bose Cancer Research Institute 16-A, Park Lane Kolkata-700016, West Bengal, India.
12. Dr. Pankaj Malhotra, Post Graduate Institute of Medical Education and Research (PGIMER), Sector-12, Chandigarh-160012, India.
13. Dr. Tuphan Kanti Dolai, Department of Hematology, Nil Ratan Sircar Medical College and Hospital, 138, Acharya Jagadish Chandra Bose Road, Sealdah, Kolkata, West Bengal-700014, India.
14. Dr. Amit Kumar Dhiman, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab, India.
15. Dr. Sonali Mohapatra, Department of Medical Oncology All India Institute of Medical Sciences, Sijua, Patrapada, PO-Dumduma, Bhubaneswar, Odisha-751019, India.
16. Dr. Chetan Dilip Deshmukh, Deenanath Mangeshkar Hospital and Research Centre, Off Karve Road Near Mhatre Bridge, Erandawne, Pune, Maharashtra-411004, India.
17. Dr. Sivanesan Balasubramanian, G. Kuppaswamy Naidu Memorial Hospital, P.B. No. 6327, Nethaji Road, Pappanaickenpalayam, Coimbatore-641037, TamilNadu, India.
18. Dr. Advani Suresh Hariram, Department of Medical Oncology Jaslok Hospital and Research Centre, 15- Dr. G. Deshmukh Marg, Mumbai-400026, Maharashtra, India.
19. Dr. Praveen Kumar Bansal, Department of Medical Oncology, Asian Institute of Medical Sciences, Badkal Flyover Road, Sector 21 A, Faridabad-121001, Haryana, India.
20. Dr. Bhavin Shah, Sterling Hospital, Sterling Hospital Road, Memnagar, Ahmedabad-380052, Gujarat, India.
21. Dinesh Bhurani, Rajiv Gandhi Cancer Institute and Research Centre Sector-5, Rohini, Delhi-110085, India.
22. Dr. Krishna Kumar Rathnam, Department of Oncology, Meenakshi Mission Hospital and Research Centre, Lake Area, Melor Road, Madurai-625107, TamilNadu, India.
23. Dr. Anitha Ramesh, Saveetha Medical College and Hospital Saveetha Nagar, Thandalam, Chennai-602105, India.
24. Dr. Ganesh Shivlingrao Jaishetwar, Yashoda Hospital, Block-B, Rajbhavan Road, Somajiguda, Hyderabad-500082, Telangana, India.

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.
- m. Informed Consent Documents (ICD) including patient information sheet (PIS) and informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

Yours faithfully,

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