

F. No. BIO/CT/18/000055
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi – 110002

To,

M/s Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Center,
R-282 TTC Area of MIDC, Thane -Belapur Road,
Rabale, Navi Mumbai, Maharashtra (India) - 400701

Subject: Permission for conducting a Phase 3 clinical trial titled "Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of Panitumumab (R-TPR-048) / Vectibix in patients with metastatic colorectal cancer", Protocol No. RLS/ONC/2018/01, version 2.0, dated 11 Dec 2018-regarding

Reference: Your Application No. BIO/Form44/FF/2018/9090, dated 30-JUL-2018 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 and Cosmetics Rules 122DA and 122DAC, under the supervision of the following investigators mentioned below as per Protocol No.: RLS/ONC/2018/01, version 2.0, dated 11 Dec 2018 submitted to this Directorate.

S. No.	Name of Investigator	Clinical Trial Site Address	Name and Address of the Ethics Committee
1	Dr. Kaushik Chatterjee	Institute of Post Graduate Medical Education and Research, 244 AJC Bose Road, Kolkata, West Bengal - 700020	IPGME & R Research Oversight Committee, Office of the Dean, Institute of Post Graduate Medical Education & Research, 244 AJC Bose Road, Kolkata-700020, West Bengal, India. EC Reg. No. ECR/35/Inst/WB/2013/RR-16
2	Dr. Rajnish Nagarkar	HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka and Manavata Cancer Centre, Opposite Mahamarg Bus Stand, Mumbai Naka, Nashik, Maharashtra - 422001	Manavata Clinical Research Institute Ethics Committee, Curie Manavata Cancer Centre, opposite Mahamarg Bus Stand, Mumbai Naka, Nashik-422004. EC Reg. No. ECR/500/Inst/MH/2013/RR-16
3	Dr. Ashok Diwan	Department of Radiology	Institutional Ethics committee,

		and Oncology, Government Medical College and Hospital, Medical College Square, Nagpur, Maharashtra - 440003	Department of Pharmacology, Govt. Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India EC Reg. No. ECR/43/Inst/MH/2013/RR-16
4	Dr. Viraj Borgaonkar	Seth Nandlal Dhoot Hospital, Marathwada Medical Research and Rural Development Institution, A-1, MIDC, Chikalthana, Jalna Road, Aurangabad Maharashtra - 431210	Seth Nandlal Dhoot Hospital Institutional Ethics Committee, A- 1, MIDC, Chikalthana, Airport Road, Aurangabad-431210, Maharashtra, India EC Reg. No. ECR/39/Inst/MH/2013/RR-16
5	Dr. Ravikumar Wategaonkar	Lokmanya Holistic Cancer Care and Research Center, 314-B TelcoRoad, Chinchwad, Pune Maharashtra - 411033	Ethics Committee, Lokmanya Medical research Center, Lokmanya Hospital, 314/B, Chinchwad, Pune-411033, Maharashtra, India EC Reg. No. ECR/175/Inst/MH/2013/RR-16
6	Dr. Kishore Singh	Maulana Azad Medical College and Associated Lok Nayak Hospital, New Delhi- 110002	Institutional Ethics Committee, 3 rd Floor, Room No. 306, Maulana Azad Medical College and Associated Lok Nayak Hospital, New Delhi- 110002 EC Reg. No. ECR/329/Inst/DL/2013/RR-16
7	Dr. Lokesh K N	Sri Venkateswara Hospital,, No. 86, Hosur Road, Madiwala, Bangalore, Karnataka - 500068	Sri Venkateswara Hospital Ethics Committee, #86, Hosur Main Road, Madiwala, Bangalore- 560068 EC Reg. No. ECR/298/Inst/KA/2013/RR-16
8	Dr. Minish Jain	Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune Maharashtra - 411001	Institutional Ethics Committee, Poona Medical Research Foundation, E4-C to 4-F, 4th Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India EC Reg. No. ECR/24/Inst/MH/2013/RR-16

9	Dr. Rajesh Makadia	Shree Giriraj Multispecialty Hospital, Navjot Park Corner, 50 Feet ring road, Rajkot Gujarat - 360005	Shree Giriraj Hospital Research Ethics Committee, 27-Navjot Park Corner, 150 feet Ring Road, Rajkot-360005, Gujarat, India EC Reg. No. ECR/74/Inst/GJ/2013/RR-16
10	Dr. Rohan Bhise	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belagavi, Karnataka - 590010	Institutional Ethics Committee, KAHER, JMNC Campus, Nehru Nagar, Belgaum-590010, Karnataka, India EC Reg. No. ECR/211/Inst/KA/2013/RR-16
11	Dr. Kirankumar Jadhav	B. J. Govt. Medical College and Sassoon General Hospital, Department of Surgery, Sassoon Road, Pune Maharashtra - 411001	Institutional Ethics Committee, B. J. Govt. Medical College and Sassoon General Hospital, Department of Pharmacology, BJ Govt Medical College, Sassoon Road, Pune-411001, Maharashtra, India EC Reg. No. ECR/280/Inst/MH/2013/RR-16

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

- (a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y annexed to these Rules, 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 to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with procedures prescribed in Schedule Y.
- (f) In case of an injury or death during the clinical trial to the subjects of the Clinical Trial, 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) Submit complete report of clinical trials as per the approved protocol from the individual Investigator duly signed by him along with his observations/remarks on the drug.
- (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. Indicate the date of commencement and conclusion of the clinical trial at each center (in case the study is multicentric)
- (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 bulk drug to be used in the manufacturing of finished formulation intended to be used in the clinical trial and clinical trial batches of finished formulation shall be manufactured under GMP conditions using validated procedure and shall have ongoing stability programme.
- (m) If the clinical trial batches are different from that of the primary batches for which data have been submitted, stability report for clinical trial batches are to be submitted as per Appendix IX of Schedule Y of Drugs and Cosmetic Rules for Drug substance and formulation along with Clinical study report.
- (n) 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.

It is informed that all the amendments to Rule 122DAA, inclusion of Rule 122DAB, compensation matters etc. that are appended to the Drugs & Cosmetics Act & Rules, vide GSR 53 (E) dated 30.01.2013 and in Part X-A, after Rule 122DAB, Rule 122 DAC vide GSR 63 (E) dated 01.02.2013 are mandatory and binding.

Yours faithfully

**S ESWARA
REDDY** Digitally signed by
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Date: 2019.01.11
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(Dr. S. Eswara Reddy)
Drugs Controller General (India)