F. No. BIO/CT/19/000001
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002

To,

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Center (DALC),
R-282, TTC area of MIDC,
Thane-Belapur Road, Rabale,
Navi Mumbai – 400 701

Subject - Permission for conducting a Phase 3 clinical trial entitled "Prospective, multi-center, randomized, double-blind, two arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of Ustekinumab (R-TPR-046)/Stelara® in patients with moderate to severe plaque psoriasis" as per Protocol No.: RLS/DRM/2018/04; Version 2.0, Dated: 26-Jul-2019 – Reg.

Ref : Your application No. BIO/Form44/FF/2019/12964 dated 11-Jan-2019 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting subject mentioned study under the provisions of Drugs and Cosmetics Rules 122-DA and 122-DAC, under the supervision of the investigators mentioned below as per Protocol No.: RLS/DRM/2018/04; Version No: 2.0 Date: 26-Jul-2019 submitted to this Directorate.

Name of Investigator	Clinical Trial Site address	Name and Address of the Ethics Committee
Dr. Shekhar N. Pradhan	B. J. Govt. Medical College and Sassoon General Hospital, Pune Station Road, Agarkar Nagar, Pune, Maharashtra – 411 001	Institutional Ethics Committee of B. J. Govt. Medical College and Sassoon General Hospital, Pune Station Road, Agarkar Nagar, Pune, Maharashtra – 411 001 EC Reg. No.: ECR/280/Inst/MH/2013/RR-16
Dr. Dilip Jogaikar	Shree Hospital Siddharth Mansion, Nagar Road Pune -411 006, India	Shree Hospital, 5th Floor, Siddharth Mansion, Nagar Road Pune - 411 014 EC Reg. No.: ECR/93/Inst/MH/2013/RR-16
Dr. Hari Kishan Kumar. Y	Rajarajaeswari Medical college and Hospital, No.202, Kambipura, Mysore Road, Bengaluru - 560 074, Karnataka, India	Institutional Ethics Committee, Rajarajaeswari Medical college and Hospital, No.202, Kambipura, Mysore Road, Bengaluru - 560 074, Karnataka EC Reg. No.: ECR/56/Inst/KA/2013/RR-16
Dr. Madan Mohan	Dr. B. R. Ambedkar Medical College, Gandhi Nagar, Kadugondanahalli, Bengaluru, Karnataka 560 045, India	Institutional Ethics Committee, Dr. B. R. Ambedkar Medical College, Gandhi Nagar, Kadugondanahalli, Bengaluru, Karnataka 560 045

		EC Reg. No.: ECR/508/Inst/KA/2014/RR-17
Dr. A.M Jayaraman	Chennai Meenakshi Multispecialty Hospital, Old#149, New# 72, Luz Church Road, Mylapore, Chennai - 600 004, Tamil Nadu, India	Chennai Meenakshi Multispecialty Hospital Ethics Committee, Old# 149, New# 72, Luz church Road, Mylapore, Chennai-600 004, Tamil Nadu EC Reg. No.: ECR/516/Inst/TN/2014/RR-17
Dr. Savitha A. S	Sapthagiri Institute of Medical Science and Research Center, #15 Chikkasandra, Hesaraghatta Main Road, Bangalore – 560 090	Institutional Ethics Committee, Sapthagiri Institute of Medical Science and Research Center, #15 Chikkasandra, Hesaraghatta Main Road, Bangalore – 560 090 EC Reg. No.: ECR/583/Inst/KA/2014/RR-17
Dr. Shivakumar Patil	KLES Dr Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi – 590 010, Karnataka, India	Institutional Ethics Committee, KAHER, JNMC Campus, Nehru Nagar, Belagavi – 590 010 EC Reg. No.: ECR/211/Inst/KA/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 122 DAA, inclusion of Rule 122 DAB, 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 S ESWARA REDDY
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Date: 2019.08.13 18:10:26 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)