File No: BIO/CT/19/000009
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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 (India) – 400701

Subject: Application for grant of permission to conduct Phase III clinical trial of the new drug Golimumab Solution for Injection to compare the efficacy, pharmacokinetics, pharmacodynamics, safety and immunogenicity of R-TPR-044 / Simponi® in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate as per Protocol No.: RLS/RA/2018/05 Version 2.0, Dated 15 May 2019 under the D&C Act and Rules thereunder-Regarding

Ref: Your application no. BIO/Form44/FF/2019/13273 dated 05-FEB-2019

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/RA/2018/05 Version 2.0, Dated 15 May 2019 submitted to this Directorate.

S.No	Name of Investigator	Clinical Trial Site address	Name and Address of the Ethics Committee
1	Dr. Alakendu Ghosh	Institute of Post Graduate Medical Education & Research (IPGMER), 244 A.J.C. Bose Road, Kolkata- 700020, Kolkata, West Bengal, India	IPGME&R Research Oversight Committee, C/o Office of the Dean college Buidling , 5Th Floor Institute of Postgraduate Medical Education & Research 244 Acharya J.C. Bose Road West Bengal – 700020 Regist.No.ECR/35/Inst/WB/2013-RR-16
2	Dr. Liza Rajasekhar	Nizam's Institute of Medical Science, Punjagutta, Hyderabad-500082,Hyderabad, Telangana, India	Institutional Ethics Committee, Nizams Institute of Medical Sciences, Panjagutta, Hyderabad Telangana - 500082 Regist.No.ECR/303/Inst/AP/2013-RR-16
3	Dr Vijay Goni	Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Sector 12, Chandigarh - 160012	Institutional Ethics Committee, Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Sector 12, Chandigarh Chandigarh – 160012 Regist.No.ECR/25/Inst/CH/2013-RR-16
4	Dr. Arun Kumar Sharma	SMS Medical College and Attached Hospitals, Ground Floor,Dhanwantari OPD Block, Jaipur-302016, Rajasthan, India	Ethics Committee, SMS Medical College and Attached Hospitals, Ground Floor, Dhanwantari OPD Block, Jaipur-302016, Rajasthan, India Regist.No.ECR/26/Inst/RJ/2013-RR-16
5	Dr. Liyakat Ali Gauri	S. P. Medical College & Associated Group (AG) of Hospitals Bikaner - 334003, Rajasthan, India	Ethics Committee , S.P Medical College & A.G Hospitals, HRMC Cardiovascular Sciences & Research Centre Bikaner Rajasthan–334001 Regist.No.ECR/27/SP/Inst/Raj/2013-RR-16
6	Dr. Sanjay Kumar	G.S.V.M Medical College,Swaroop Nagar, Kanpur Uttar Pradesh- 208002	Ethics Committee, G.S.V.M Medical College,Swaroop Nagar, Kanpur Uttar Pradesh- 208002

			Regist.No.ECR/680/Inst/UP/2014-RR-17
7	Dr. Sajal R Mitra	Dept of Orthopedics , Govt Medical College & Hospital, Medical College Square Road, Nagpur, Maharashtra - 440003	Institutional Ethics Committee, Govt Medical, Nagpur, Maharashtra – 440003 Regist.No.ECR/43/Inst/MH/2013-RR-16
8	Dr Vikram M Haridas	Sushruta Multispecialty Hospital & Research Centre Pvt. Ltd., P.B. Road, Vidyanagar,Hubli Karnataka - 580021	Sushruta Hospital Ethics Committee, Sushruta Multispecialty Hospital & Research Centre Pvt. Ltd., P.B. Road, Vidyanagar, Hubli Karnataka - 580021 Regist .No.ECR/372/Inst/KA/2013/RR-16
9	Dr. Lalit Duggal	Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi - 110060, India	Ethics Committee ,Sir Ganga Ram Hospital, Old Rajinder Nagar New Delhi Delhi-110060 Regist.No.ECR/20/Inst/DL/2013-RR-16
10	Dr. Srikantiah Chandrashekara	ChanRe Rheumatology & Immunology Center & Research, West of Chord Road, 1st Block, Rajajinagar, Bengaluru - 560010, Karnataka, India	Institutional Ethics Committee, ChanRe Rheumatology & Immunology Centre and Research ,414/65, 20th Main, west of Chord raod,1st block, Rajajinagar, Bangalore Karnataka-560010 Regist.No.ECR/190/Inst/KA/2013-RR-16
11	Dr.Krishnamurthy Venkataraman	Chennai Meenakshi Multispecialty Hospital, Old no. 149, New no. 72, Luz Church Road, Mylapore, Chennai - 600004, Tamil Nadu	Chennai Meenakshi Multispeciality Hospital Ethics Committee, Chennai Meenakshi Multispeciality Hospital situated at New No.72, Old No. 148, Luz Church Road, Mylapore, Chennai Tamil Nadu Regist.No.ECR/516/Inst/TN/2014-RR-17
12	Dr. Girish Gokuldas Bhatia	Medipoint Hospital Pvt. Ltd, 241/1, New D.P Road, Aundh, Pune – 411007, Pune, Maharashtra, India	Penta-Med Ethics Committee, Medipoint Hospital Pvt. Ltd., 241/1, New DP Road, neas Sai Heritage, Aundh, Pune Maharashtra Regist.No.ECR/357/Inst/MH/2013-RR-16
13	Dr. Deepak Rai	Vinaya Hospital, Vinaya Hospital,P. O. BOX: 717, Karangalpady,Mangalore,Karnataka	Ethics Committee,Vinaya Hospital,P. O. BOX: 717, Karangalpady, Mangalore,Karnataka Regist.No.ECR/664/Inst/KA/2014
14	Dr. Nilesh Patil	Lifepoint Multispeciality Hospital, 3rd floor, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057,Maharashtra	LPR Ethics Committee, Lifepoint Multispeciality Hospital, 3rd floor, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune - 411057, Maharashtra Regist.No.ECR/751/Inst/MH/2015-RR-18
15	Dr. Praveen Jadhav	Sujata Birla Hospital & Medical Research Centre, Opposite to Bytco College, Nashik, Pune Highway, Nashik Road, Nashik - 422101, Maharashtra	Sujata Birla Ethics Committee, Sujata Birla Hospital & Medical Research center, Opposite to Bytco College , Nashik Road, Nahsik Maharashtra – 422101 Regist.No.ECR/98/Inst/MH/2013/RR-16
16	Dr Pankaj Patni	Aman Hospital and Research Centre, 15 Shashwat, Opp, E.S.I Hospital Sarabhai, Gotri Road Gujarat - 390021	Institutional Ethics Committee, Aman Hospital and Research Centre, 15/Shashwat, Opp, E.S.I Hospital Sarabhai, Gotri Road Gujarat - 390021 Regist.No.ECR/857/Inst/GJ/2016

Licensing Authority as defined in clause (b) of Rule 21, issue permission for conduct of clinical trial, subject to the following conditions further, 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 for conduct of clinical trials in India and other applicable regulations;

(b) Approval of the Ethics Committee shall be obtained before initiation of the study;

(c) Clinical trial 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 the procedures prescribed in Schedule Y;

(f) In case of an injury or death during the clinical trial to the subject 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 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 trials in India and other applicable regulations;

(h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites and the investigator shall allow officers authorized by the Central Drug 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 trials 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) Indicating the date of commencement and conclusion of the clinical trial at each center (in case the study is multicentric).

(k) The bulk drug to be used in the manufacturing of finished formulation intended to be used in the clinical trial and clinical trail batches of finished formulation shall be manufactured under GMP conditions using validated procedure and shall have ongoing stability programme.

(l) 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.

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 & Rule, 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: 2019.07.02 17:35:06 +05'30'

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