सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation(Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/23/000104 Dated 29-12-2023

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 IV clinical trial entitled –"**A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of GolimuRelTM in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate**" vide Protocol No.: RLS/PMS/2023/04 Version:2.0, Date: 30th Oct 2023 - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/39157 dated17-AUG-2023

Sir,

With reference to your application No.BIO/CT04/FF/2023/39157 dated 17-AUG-2023, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8.

(II) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(III) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(IV) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

(V) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial.

(VI) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(VII) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(VIII) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal.

(IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination.

(X) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI.

(XI) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.

(XII) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.

(XIII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial.

(XIV) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority.

(XV) The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

(XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

RAJEEV SINGH RAGHUVANSHI

Yours faithfully

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c2769041015a06564fe67f54b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licensing Authority hereby permits 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 Telephone No.: 022-40678770 FAX: 022- 40678099 to conduct Phase IV clinical trial entitled **"A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of GolimuRelTM in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate"** as per Protocol No.: RLS/PMS/2023/04 Version:2.0, Date: 30th Oct 2023 in the below mentioned clinical trial sites.

2. Details of new drug and clinical trial site [as per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date: 29-Dec-2023

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.01.01 10:56:13 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug:</td><td>Golimumab solution for Injection (50mg/0.5ml) (r-DNA origin)</td></tr>
<tr><td>Dosage form:</td><td>Single use prefilled syringe for subcutaneous injection</td></tr>
<tr><td>Therapeutic Class</td><td>Immunosuppressive</td></tr>
<tr><td>Composition:</td><td>Each Pre-filled syringe contains:
<table>
<tr><th>Name of Ingredients</th><th>Quantity /PFS (50mg/0.5ml)</th></tr>
<tr><td>Golimumab Drug Substance IH</td><td>50 mg</td></tr>
<tr><td>L-Histidine and L-Histidine monohydrochloride monohydrate Ph.Eur.</td><td>0.44 mg</td></tr>
<tr><td>Polysorbate 80 I.P./Ph.Eur./USP</td><td>0.08mg</td></tr>
<tr><td>Sorbitol I.P./Ph.Eur./USP</td><td>20.5 mg</td></tr>
<tr><td>Water for Injection (WFI) I.P./Ph.Eur./USP</td><td>q.s. to 0.5 ml</td></tr>
</table></td></tr>
<tr><td>Indication:</td><td>Golimumab in combination with methotrexate (MTX), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.</td></tr>
</table>

Details of clinical trial site(s):

S.No.	Name and Address of Clinical Trial Site(s)	Ethics Committee Details	Name of Principal Investigator
1.	Medipoint Hospital Pvt. Ltd., 241/1, New D. P. Road, Aundh- 411007, Maharashtra, India	Penta-Med Ethics Committee Medipoint Hospitals Pvt. Ltd Medipoint Hospitals Pvt.Ltd 241/1, New D.P.Road, Near Sai Heritage,Aundh Pune Pune Maharashtra - 411007 India EC Reg. No.: ECR/357/Inst/MH/2013/RR-20	Dr. Girish Kakade
2.	Lifepoint Multispecialty Hospital, 145/1, MumbaiBangalore Highway, Near Hotel Sayaji, Wakad, Pune411 057, Maharashtra, India	Lifepoint Research- Ethics Committee Life Point Mutispe cialty Hospita l Pvt. Ltd. 145/1, Mumbai-Bangalore highwa y Ne ar Hotel Sa yaji Wakad Pune Maha ras htra - 411057 India EC Reg. No.: ECR/751/INST/MH/2015/RR-21	Dr. Nilesh Patil
3.	Oyster and Pearl Hospital, Shivajinagar, Pune 1671-75 Ganesh khind road, Shivajinagar, Pune 411005, Maharashtra India	O and P Ethics Committee, Phadnis Clinic Pvt. Ltd., 1671-75, Behind Hotel Pride Shivajinagar , Pune, Pune Maharashtra – 411005, India EC Reg. No.: ECR/71/Inst/MH/2013-RR19	Dr. Aniruddha Tembhe

4.	Institute of Post Graduate Medical Education & Research (IPGMER) 244 A.J.C. Bose Road, Kolkata700020, West Bengal, India	IPGMEandR Resaerch Oversight Committee IPGMEandR 244 Acharya J. C. Bose Road - Kolkata Kolkata West Bengal - 700020 India EC Reg. No.: ECR/35/Inst/WB/2013/RR-19	Dr. Parasar Gosh
5.	Apollo Gleneagles Hospital Department of Internal Medicine and Rheumatology, 58 Canal Circular Road Kolkata 700054 West Bengal, India	Institutional Ethics Committee Apollo Gleneagles Hospital ,Kolkata Apollo Gleneagles Hospital 58 Canal Circular Road kolkata 700054 Kolkata Kolkata West Bengal - 700054 India EC Reg. No.: ECR/373/Inst/WB/2013/RR-19	Dr Syamasis Bandyopadhyay
6.	Shri Nidan Hospital and Hope Fertility centre, 27- Vidyut Nagar A, Ajmer Road, Jaipur, Rajasthan, - 302021	Institutional Ethics Committee, Radha Krishna Critical Care and General Hospital, 1-C-12 Sheela Chaudhary Road, Talwandi Kota Rajasthan – 324005 India EC Reg. No.: ECR/1094/Inst/RJ/2018	Dr. Avinash Agrawal
7.	Chennai Meenakshi Multispecialty Hospital, Old building no. 149, New no. 72, Luz Church Road, Mylapore, Chennai - 600004, Tamil Nadu, India	CMMHEC, Chennai Meenakshi Multispeciality Hospital Limited, Old 148, new 72, Luz Church Road, Mylapore Chennai Tamilnadu – 600004 India EC Reg. No.: ECR/516/Inst/TN/2014	Dr. V Krishnamurthy
8.	Om Sai Onco Surgery Multispeciality Center, R.S. No. 457/10 C/Dr. Lad Colony, Sugar Mill corner, Main Road, Kasaba Bawada, Kolhapur-416006. Maharashtra, India.	Om Sai Onco Institutional Ethics Committee OM SAI ONCO Surgery Centre 457/10 C, Dr. Lad Colony Surgar Mill Corner main Road Kasaba Bawada Kolhapur Maharashtra - 416006 India EC Reg. No.: ECR/1112/Inst/MH/2018	Dr. Kunal Patil
9.	Assured care plus hospital , 4th& 5th floor, star plus complex , lam road , Muktidham temple, opp, to divisional office, Nashik road, Nashik, Maharashtra ,422101 , India	Institutional Ethics Committee, Assured Care Plus Hospital, 4th and 5th Floor, Star Plus Complex Lam Road, Near Muktidham Temple, Opp. NMC Divisional Office Nskrd, Nashik Maharashtra 422101 EC Reg. No.: ECR/1756/Inst/MH/2022	Dr. Pravin Jadav

10.	ChanRe Rheumatology and Immunology center & Research, Bengaluru, 560010, Karnataka, India	Institutional Ethics Committee – CRICR, ChanRe Rheumatology Immunology Center Research, No. 414/65, 20th Main, West of Chord Road 1st Block, Rajajinagara Bengaluru Karnataka 560010, India EC Reg. No.: ECR/190/Inst/KR/2013/RR-19	Dr. Chandrashekhar Srikantia
11.	Amber Clinic, 401-402, 4th floor, Santorini Square, Opp star Bazzar, Behind Abhishree complex, Near Jodhpur cross road, Satellite Road, Ahmedabad- 380015	Sangini Hospital Ethics Committee, Sangini Hospital, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Nr Jodhpur Cross Roads Satellite Ahmedabad Gujarat – 380015, India EC Reg. No.: ECR/147/Inst/GJ/2013/RR-19	Dr. Vishnu Sharma
12.	North Bengal Medical College & Hospital Sushruta nagar, Siliguri, Darjeeling, West Bengal 734012, India	INSTITUTIONAL ETHICS COMMITTEE North Bengal Medical College And Hospital North Bengal Medical College, Susrutanagar Siliguri, Darjeeling Siliguri Darjeeling West Bengal - 734012 India EC Reg. No.: ECR/1701/Inst/WB/2022	Dr. Araghya Chatopadhyay
13.	Shlok Multispeciality Hospital, Opposite Radhaswami Samyak, Lambhvel Rd, behind Cresent Hotel, Anand, Gujarat 388001	Institutional Ethics Committee Shlok Superspecialty Care 4Th Floor, B/H Cresent Hotel Opp. Radhaswami Samyak, Lambhvel Road Anand Anand Gujarat - 388001 India EC Reg. No.: ECR/1718/Inst/GJ/2022	Dr. Jeet Patel
14.	Kasturi Medicare Pvt. Ltd. Harshniketan, Gaondevi Road, Behind Navrang Hotel, Bhayander (W)	Shah Lifeline Hospital And Heart Institute Ec Shah Lifeline Hospital And Heart Institute Pvt Ltd Geeta Nagar, Phase-7, Mira Bhayander Road Near Fly Over Bridge, Mira Road (East) Thane Maharashtra - 401107 India EC Reg. No.: ECR/1588/Inst/MH/2021	Dr. Dnyaneshwar Halnore
15.	King George Hospital, Maharanipta, Visakhapatnam 530002, Andhra Pradesh, India	IEC King George Hospital, KGH, Maharanipeta, Collector Office Junction, Visakhapatnam, Andhra Pradesh – 530002 India EC Reg. No.: ECR/197/Inst/KGH/2013	Dr. V Satya Prasad

16.	Health1 super speciality hospital EC Health 1 Super Speciality Hospital Block C ,GF To 8 Floor, Shilaj 23/73, On S.P.Ring Road, Near Shilaj Circle, Shilaj. Ahmedabad Ahmedabad Gujarat - 380059 India	Health1 super speciality hospital EC Health 1 Super Speciality Hospital Block C ,GF To 8 Floor, Shilaj 23/73, On S.P.Ring Road, Near Shilaj Circle, Shilaj. Ahmedabad Ahmedabad Gujarat - 380059 India EC Reg. No.: ECR/1666/Inst/GJ/2022	Dr. Nikunj Dadhaniya