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
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File No. BIO/CT/23/000084 Dated 01-05-2024

To,

M/s Dr. Reddys Laboratories Limited,
Biologics, Survey no 47 & 44 (Part), Bachupally Village,
Bachupally Mandal , Medchal-Malkajgiri District, , Telangana(India) - 500090.

Subject: Application for grant of permission to conduct Phase III clinical trial titled – "A Phase III,multicentre,single arm,clinical trial to evaluate the efficacy and safety of olokizumab in moderate to severe rheumatoid arthritis patients with inadequate response to methotrexate" vide Protocol number: OKZ-01-002 Version: 3.0 Dated: 23 FEB 2024– regarding

Ref.: Your Application No BIO/CT04/FF/2023/38250 dated 23-06-2023.

Sir,

With reference to your Application No. BIO/CT04/FF/2023/38250 dated 23-06-2023, 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 authorised 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.

(XVII) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified.

(XVIII) It may kindly be noted that merely granting permission to conduct clinical trial 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.

(XIX) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of two years from the date of its issue, unless extended by the Central Licencing Authority.

(XX) The firm should submit Clinical study report (CSR) to this office after completion of trial.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.05.02 17:18:23 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File. No. BIO/CT/23/000084

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 Licencing Authority hereby permits **M/s Dr. Reddys Laboratories Limited, Biologics, Survey no 47 & 44 (Part), Bachupally Village, Bachupally Mandal , Medchal-Malkajgiri District, , Telangana(India) - 500090** to conduct clinical trial of the new drug or investigational new drug study titled "A phase III,multicentre,single arm,clinical trial to evaluate the efficacy and safety of olokizumab in moderate to severe rheumatoid arthritis patients with inadequate response to methotrexate" vide Protocol number: OKZ-01-002 Version: 3.0 Dated: 23 FEB 2024 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: 01.05.2024

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Olokizumab(rDNA origin) 160mg/ml-2ml vial
Therapeutic class	Antirheumatic
Dosage form:	solution for subcutaneous injection
Composition:	

Name of Ingredient	Amount per ml	Function
Olokizumab(rDNA origin) IH	160mg	Active ingredient
Sodium chloride USP/EP	3.510mg	Tonicity
Polysorbate 80 USP/EP	0.300mg	Stabilizer
L-Histidine hydrochloride monohydrate USP/EP	6.290mg	Buffer
Sorbitol USP/EP	36.434mg	Stabilizer
Water for injection USP/EP	q.s to 1ml	Solvent

Indications:	Moderate to severe active rheumatoid arthritis

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	SMS Medical College and attached hospitals, Jaipur Department of Rheumatology and Clinical immunology), Dhanvantri OPD Block, S.M.S Medical college & Attached Hospital, Jaipur-302004	Ethics Committee, SMS Medical College and attached hospitals J.L.N Marg,Jaipur,Rajasthan,India,302004. ECR/26/Inst/RJ/2013/RR-19	Dr. Aradhana Singh
2	Shree Hospital and Critical Care Centre 799, Om Nagar, Opp Tajshree Building,Sakkardara square, Nagpur- 440009, Maharashtra Nagpur MAHARASHTRA	Shree Hospital Ethics Committee 786A, Om Nagar, Opp Tajshree Building,Sakkardara square, Nagpur- 440009, Maharashtra Nagpur MAHARASHTRA. ECR/553/Inst/MH/2014/RR-20	Dr Ashish Pongade
3	Government Medical College & Government General Hospital, Vizianagaram	Institutional Ethics Committee,Government General College,	Dr. A Ramakrishnam Naidu

	Department of Emergency and Internal Medicine, Government Medical college, Government General hospital, Cantonment, vizianagaram-535003, Andhra Pradesh, India,	Government General College, Cantonment, vizianagaram-535003, Andhra Pradesh, India, ECR/1829/Inst/AP/2023	
4	Omkar Heart institute and Nursing Home, Nashik Omkar Heart institute and Nursing Home, B/H Regimental Plazza, Bytco point, Nashik Road, Nashik-422101, Maharashtra, India	Leelavati Institutional Ethics Committee Leelavati care hospital,Near College road,Nashik, 422005,Maharashtra, India. ECR/1653/Inst/MH/2022	Dr. Chaudhari Suraj Laxman
5	Lala Lajpat Rai Hospital, GSVM Medical College, Kanpur Swaroop Nagar, Kanpur, Uttar Pradesh 208002	Ethics Committee GSVM Medical College Swaroop Nagar, Kanpur, Uttar Pradesh 208002. ECR/680/Inst/UP/2014/RR-20	Dr Mahendra Pal Singh
6	Shree Giriraj Multispeciality Hospital 27 Navjyot Park, 150 Ft Ring Road, Rajkot, Gujarat-360005	Shree Giriraj Hospital Research Ethics Committee, Shree Giriraj Multispeciality Hospital 27-Navjyot Park Main Road, Amin Marg Cross Road rajkot Rajkot Gujarat - 360005 India ECR/74/Inst/GJ/2013/RR-19	Dr Myank thakker
7	Chopda Medicare and Research Centre Pvt. Ltd. Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik- 422005, Maharashtra	Magna-care Ethics Committee, Chopda Medicare and Research Centre Pvt. Ltd. Canada Corner, Nashik-422005, Maharashtra. ECR/79/Inst/MH/2013/RR-19	Dr Naisar Dilip Nahar
8	King George Hospital, Visakhapatnam Department of Orthopaedics, King George Hospital, Andhra Medical College, Visakhapatnam- 530002 , Andhra Pradesh, India.	Institutional Ethics Committee, King George Hospital King George Hospital, Andhra Medical College, Maharanipeta,Visakhapatnam-530002 , Andhra Pradesh, India. ECR/197/Inst/KGH/2013/RR-20	Dr. P Sivananda
9	S R Kalla Memorial Gastro & General Hospital, Jaipur Dept.: Research Department	S R Kalla Memorial Gastro & General Hospital 78-79 ,Dhuleshwar Garden,	Dr Rahul Katta

	Floor name – 1st floor Room No: Clinical research department, 78-79 ,Dhuleshwar Garden, Behind HSBC Bank Sardar Patel Marg C-Scheme,Jaipur,Rajasthan,India, 302001.	Behind HSBC Bank, Sardar Patel Marg, C-Scheme,Jaipur,Rajasthan,India,302001. ECR/8/Inst/Raj/2013/RR-19	
10	Unity Hospital, Surat Nr Dr world Opp Raghuvir Business Empire, Aai Mata Road, Parvat Patiya, Surat, Gujrat- 395010	Unity Hospital Ethics Committee Unity Trauma hospital & ICU, N-4,Janki park society,Aai Mata road,Parvat Patiya, Surat, Gujarat- 395010,India. ECR/1226/Inst/GJ/2019	Dr Romi K Shah
11	Sahyadri Asthirog Balrog Dental Nursing Home & Maternity Centre, Aurangabad Sahyadri Hospital, Ram Nagar N-2 Cidco, Aurangabad Maharshtra 431007, India,	Ethics Committee Ajanta Superspeciality Hospital, Ajanta Superspeciality Hospital Plot no15.N-13/C,HUDCO Corner,Beside yash hotel,Ajanta Road,Aurangabad Maharshtra 431003, India. ECR/1499/Inst/MH/2021	Dr Sachin Bedmutha
12	Dr Prabhakar Kore Hospital and MRC, Belagavi KLE's Dr. Prabhakar Kore Hospital and MRC, Department of Orthopeadics, Nehru Nagar, Belagavi-590010, Karnataka India.	Institutional Ethics Committee, KLE University, KLE University KLE Dr. PK Hospital and MRC JNMC Campus,Nehru Nagar, Belagavi-590010, Karnataka India. ECR/211/Inst/KA/2013/RR-19	Dr Sameer Haveri
13	Bharati Hospital and Research Centre, Bharati Hospital and Research Centre, Bharati Vidyapeeth University Campus, Pune-Satara Road, Pune 411043, Maharastra.	Institutional Ethics Committee BVDU 4th floor, Bharati Hospital and Research Centre Pune-Satara Road, Dhankawadi,Pune 411043, Maharastra ECR/313/Inst/MH/2013/RR-19	Dr Sandeep Kansurkar
14	Shri Guru Ram Rai Medical College & Shri Mahant Indiresh Hospital,Dehradun, Kargi - Patel Nagar Bypass, Industrial Area, Govt.Industrial Estate, Patel Nagar, Dehradun, Uttarakhand 248001	SGRR Institute of Medical Health Sciences IEC IEC,Administrative Building, Patel Nagar, Dehradun, Uttarakhand 248001 ECR/710/Inst/UK/2015/RR-21	Dr Subodh Gururani
15	Kauveri Hospitals, Chennai	Kauvery Institutional Ethics	Dr. S Sham

	Kauvery Hospitals, 81 TTK Road Junction, CIT Colony Alwarpet Chennai 600018	Committee Kauveri Hospital,No.199,Luz Church Road,Mylapore, chennai,600018,Tamil nadu ,India. ECR/966/Inst/TN/2017/RR-21	
16	Maharaja Agrasen Superspeciality Hospital Department of General Medicine, Agrasen Aspatal Marg, Sec. 7, Central Spine, Vidyadhar Nagar, Jaipur-302039, Rajasthan	SKCC Institutional Ethcis Committee, SS Multispecialty Hospital Plot No 13 New Sneh Nagar Near Universal Mansion Wardha Road Nagpur Nagpur Maharashtra – 440015 ECR/1222/Inst/RJ/2019/RR-22	Dr Rahul Jain
17	Saraswati Kidney Centre Nagpur, 13, Jaitala road, near Jaiprakash Nagar Metro Station, New Sneh Nagar, Nagpur, Maharashtra 440015	Drug Trial Ethics Committee, Dayanand Medical College and Hospital, Ludhiana ECR/1725/Inst/MH/2022	Dr Sachin V Dhote
18	Dayanand Medicalc College & Hospital, Research & Development Centre, civil line ,Tagore nagar,Ludhiana,Punjab,141001	Unity Hospital Ethics Committee, UNITY TRAUMA CENTER AND ICU N-4 Janki Park Society Aai Mata Road, Paravat Patiya Surat Surat Gujarat - 395010 India ECR/101/Inst/PB/2013/RR-19	Dr Dinesh Jain