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/CT04/FF/2024/43390 Dated 18-11-2024

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 randomised, double-blind, multicentre study to compare the immunogenicity and safety of proposed abatacept biosimilar (DRL_AB) with Reference abatacept (Orencia®) administered subcutaneously as an add-on to methotrexate in patients with moderately to severely active rheumatoid arthritis" vide Protocol number: AB-01-005 Version: 3.0 Dated: 26 Sep 2024– regarding

Ref.: Your Application No BIO/CT04/FF/2024/43390 dated 16-05-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2024/43390 dated 16-05-2024, 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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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File. No. BIO/CT04/FF/2024/43390

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 randomised, double-blind, multicentre study to compare the immunogenicity and safety of proposed abatacept biosimilar (DRL_AB) with Reference abatacept (Orencia®) administered subcutaneously as an add-on to methotrexate in patients with moderately to severely active rheumatoid arthritis" vide Protocol number: AB-01-005 Version: 3.0 Dated: 26 Sep 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: 18.11.2024

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	Abatacept (rDNA origin) solution for injection in prefilled syringe
Therapeutic class	Antirheumatic
Dosage form:	Solution for injection in Pre-filled syringe
Composition:	

Name of Ingredient	Amount per ml	Function
Abatacept (rDNA origin) IH	125mg	Active ingredient
Sodium phosphate monobasic Monohydrate USP/BP	0.585mg	Buffer
Sodium phosphate dibasic Monohydrate USP/BP/Ph.Eur	0.535mg	Buffer
Sucrose EP/JP/CP	150mg	Stabilizing agent
L-Histidine USP/JP/Ph.Eur	7.4mg	Stabilizing agent
Sodium chloride USP/EP/BP/JP	1.17mg	Tonicity
Poloxamer 188 Ph.Eur/NF	8.0mg	Surfactant
Water for injection IH	q.s to 1ml	Solvent

Indications:	rheumatoid arthritis

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Sushruta Multi speciality Hospital & Research Centre Pvt Ltd, Vidyanagar, Hubballi - Dharwad Road, Hubballi-580021, Karnataka, India	Sushruta Hospital Ethics Committee, P.B Road, Vidyanagar, Hubbal-580021, Karnataka, India. ECR/372/Inst/KA/2013/RR-19	Dr Vikram Muralidar Haridas
2	Vijaya Ortho and Trauma Center Opp. BIMS, Vijaya Road, Ayodhya Nagar, Belagavi, Karnataka-590001, India.	Independent Ethics Committee, Zest Ethics LLP, P NO. 132 206/5, Sadashiv Nagar, Belagavi, Karnataka-590001, India ECR/350/Indt/KA/2021	Dr. Archana Uppin

3	Chennai meenakshi multi speciality hospital, Old no 149 new no 70, Luz church road, Mylapore, Chennai-600 004.	Chennai meenakshi multi speciality hospital ethics committee, Chennai meenakshi multi speciality hospital, Old no 149 new no 70, Luz church road, Mylapore, Chennai-600 004. ECR/516/Inst/TN/2014/RR-20	Dr. Krishnamurthy Venkataraman
4	Medical College P.O, Kozhikode-673008, Kerala,India	Institutional Ethics Committee Room No.1 & 2, Ground Floor, Lecture Theatre Complex, Medical college campus, P.O, Calicut-673008, Kerala. ECR/395/Inst/KL/2013/RR-20	Dr. Neeraj Manikath
5	Assure Care Plus Hospital, 4th & 5th floor, Star plus complex, Lam Road, Near Muktidham Temple, Opp-NMC Divisional Office, Nashik Road , Nashik , Maharashtra , India - 422101	EC- Assure Care Plus Hospital, 4th & 5th floor, Star plus complex, Lam Road, Near Muktidham Temple, Opp-NMC Divisional Office, Nashik Road, Nashik, Maharashtra, India – 422101 ECR/1756/Inst/MH/2022	Dr. Praveen Jadhav
6	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
7	Avron Hospitals PVT LTD, 4-Shantiniketan Park, Near Sardar Patel statue, Naranpura, Ahmedabad, Gujarat 380013	Avron Multi speciality Hospitals Ethics Committee, 4-Shantiniketan Park, Nr. Sardar Patel, Naranpura, Ahmedabad, Gujarat 380013 ECR/1136/Inst/GJ/2018/RR-22	Dr. Vishnu Sharma
8	JSS hospital, MG Road, Mysore-570004, Karnataka, India.	Institutional Ethics Committee,JSS Medical College, 3rd floor, JSS Hospital, Mysore ECR/387/Inst/KA/2013/RR-22	Dr. Ramaswamy Subramanian
9	Shri Nidaan Hospital and Hope Fertility Centre" 27-Vidhut Nagar-A, Ajmer Road, jaipur-302021,	"Swastic Ethics Committee Shri Nidaan Hospital and Hope Fertility Centre" 27-Vidhut Nagar-A, Ajmer	Dr. Avinash Agarwal

	Rajasthan, India	Road, jaipur-302021, Rajasthan,India. ECR/434/Inst/RJ/2013/RR-19	
10	S R Kalla Memorial Gastro & General Hospital, Jaipur Dept.: Research Department 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.	S R Kalla Memorial Gastro & General Hospital 78-79 ,Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme,Jaipur,Rajasthan,India,302001. ECR/8/Inst/Raj/2013/RR-19	Dr Rahul Katta
11	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
12	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 Committe, SMS Medical College and attached hospitals J.L.N Marg, Jaipur,Rajasthan,India,302004 . ECR/26/Inst/RJ/2013/RR-19	Dr. Aradhana Singh
13	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
14	Charm Healthcare Private Limited (formely known as SHENOY'S CARE PRIVATE LIMITED, Near Toyata Showroom, NH 66, Nettoor , Cochin- 682040, Kerala, India	Institutional Ethics Committee, Sree Sudheendra Medical Mission, Kacheripady, Chittoor road,Kochi, Ernakulam, Kerala- 682018, India ECR/884/Inst/KL/2016/RR-20	Dr. Padmanabha Shenoy
15	Yashoda Hospital Raj Bhavan Road, Matha	Yashoda Academy of Medical Education and Research	Dr Rajendra V Prasad

	Nagar, Somajiguda, Hyderabad, Telangana-500082	Address:Yashoda Hospital, Behind Harihara Kala Bhavan SP Road, Secunderabad-500003 ECR/49/Inst/AP/2013/RR-22	
16	Jasleen Hospital 1st floor, Opp.big Bazar, Panchashil Square, Dhantoli Nagpur, Maharashtra - 440012 India	Jasleen Hospital Ethics Committee Jasleen Hospital Opp.big Bazar, Panchashil Square, Dhantoli, Maharashtra - 440012 India ECR/264/Inst/MH/2013/RR-20	Dr Smruti Ramteke
17	chanRe Rheumatology and lmmunology centre and Research, Address: No. 414/65, 2oth Main, West of Chord Road, 1st Block, Rajajinagar, Bangalore - 560010, Karnataka' India	Institutional Ethics Committee - CRICR Address: ChanRe Rheumatology and Immunology Centre and Research, No.414l65, 20th Main, West of Chord Road, lst Block, Rajajinagar, Bangalore5600l0, Karnataka,India ECR/190/lnst/KR/2013/RR-19	Dr Chandrashekara S