



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
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File No. CT/24/000077

To,

M/s. AstraZeneca Pharma India Limited,
Block N1, 12th Floor Manyata Embassy,
Business Park, Rachenahalli Outer Ring Road,
Bangalore, Karnataka (India) – 560045.

Sir,

With reference to your application No. GCT/CT04/FF/2024/43742 dated 07.06.2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Multicenter, Parallel-group, Double-blind, 2-Arm, Phase III Study to Investigate the Efficacy and Safety of Anifrolumab Administered as Subcutaneous Injection and Added to Standard of Care Compared with Placebo Added to Standard of Care in Adult Participants with Idiopathic Inflammatory Myopathies (Polymyositis and Dermatomyositis)”** Protocol No.: D3463C00003, Version 3.0 dated 06 Mar 2024 with a total of up-to 25 subjects from India under the provisions of New Drugs and Clinical Trial Rules, 2019

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

- (i) That the CT Scan for tuberculosis screening shall not be mandatory and depend on discretion of investigator.
- (ii) Human biological samples i.e. Blood sample, Plasma sample and Urine sample related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.
- (iii) 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 Licencing Authority under rule 8;
- (iv) 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;

- (v) 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;

- (vi) the Central Licencing 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;
- (vii) 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;
- (viii) 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;
- (ix) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (x) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;
- (xi) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
- (xii) 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 Licencing 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;
- (xiii) 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xiv) 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xv) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) the Central Licencing 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;
- (xix) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

- (xx) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- (xxi) 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.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

FORM CT-06
(See rules 22,25,26,29 and 30)
**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

1. The Central Licensing Authority hereby permits **M/s. AstraZeneca Pharma India Limited, Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore, Karnataka (India) - 560045** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: D3463C00003, Version 3.0 dated 06 Mar 2024** in the below mentioned clinical trial sites [As per Annexure].

2. Details of new drug or investigational 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 _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Anifrolumab (MEDI-546) Solution for injection, 150mg/mL (in 0.8mL pre-filled syringe) or Placebo
Therapeutic class:	Type I IFN Receptor antagonist
Dosage form:	Solution for injection
Composition:	Anifrolumab =120.0000 milligram (mg) In House Specification Active L-Histidine =1.0000 milligram (mg) U.S.P.,J.P.,Ph.Eur Inactive L-Histidine hydrochloride monohydrate =3.0000 milligram (mg) J.P.,Ph.Eur Inactive L-lysine hydrochloride =7.0000 milligram(mg) U.S.P.,J.P.,Ph.Eur Inactive α,α trehalose dihydrate=39.0000 milligram (mg) J.P.,Ph.Eur Inactive Polysorbate 80 =0.4000 milligram(mg) J.P.,Ph.Eur Inactive Water for injection =0.7000 gram(g)U.S.P.,Ph.Eur Inactive
Indications:	Adult Participants with Idiopathic Inflammatory Myopathies (Polymyositis and Dermatomyositis)

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Fortis Hospitals Limited, Mulund Goregaon Link Road, Bhandup (W), Mumbai -400078, Maharashtra	Institutional Ethics Committee, Fortis Hospitals Limited, Bhandup West, 101, Mulund Goregaon Link Road, Bhandup West, Mumbai Suburban, Maharashtra -400078 ECR/531/Inst/MH/2014/RR-19	Dr Bhojani Kuashik Shashikant
2.	Nizam's Institute of Medical Sciences (NIMS), Department of Clinical Immunology and Rheumatology, Millenium block, 4th Floor, Punjagutta, Hyderabad-500082, Telangana	NIMS Institutional Ethics Committee, NIZAMs Institute of Medical Science, Punjagutta, Hyderabad, Telangana, 500082 ECR/303/Inst/AP/2013/RR-19	Dr Liza Rajasekhar
3.	IPGME&R and SSKM Hospital, 244, AJC Bose Road, Bhowanipore, Kolkata, 700020, West Bengal	IPGME and Research Oversight Committee, Institute of Postgraduate Medical Education & Research, 244 Acharya J. C. Bose Road, Kolkata, West Bengal -700020 ECR/35/Inst/WB/2013/RR-19	Dr Geetabali Sircar
4.	Medanta-The Medicity, Sector-38, Gurugram-122001, Haryana	Medanta Institutional Ethics Committee, Medanta-The Medicity, Sector 38, Gurugram, Haryana -122001 ECR/282/Inst/HR/2013/RR-20	Dr Rajiva Gupta
5.	Krishna Institute of Medical Sciences Limited, 1-8-31/1, Minister Road, Secunderabad-500003, Telangana	KIMS Ethics Committee, Krishna Institute of Medical Sciences Limited, 1-8-31/1, Minister Road, Secunderabad, Hyderabad, Telangana -500003 ECR/142/Inst/AP/2013/RR-19	Dr Veeravalli Sarathchandra Mouli
6.	Sheth Vadilal Sarabhai General Hospital, Madalpur Gam, Paldi Road, Ellisbridge, Ahmedabad-380006, Gujarat	Sangini Hospital Ethics Committee, Sangini Hospital, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar, Nr Jodhpur Crossroads, Satellite, Ahmedabad, Gujarat, 380015 ECR/147/Inst/GJ/2013/RR-19	Dr Dhaiwat Mrugeshbhai Shukla

7.	JSS Hospital, Sri Shivarathreeshwara Nagara, MG Road, Mysore -570004, Karnataka	Institutional Ethics Committee, JSS Hospital, JSS Medical college, Shivarathreeshwara Nagara, MG Road, Mysuru-570015, Karnataka ECR/387/Inst/KA/2013/RR-22	Dr Subramanian Ramaswamy
8.	Medanta Hospital, Sector-A, Pocket-1, Sushant Golf City, Amar Shaheed Path, Lucknow, Uttar Pradesh - 226030	Institutional Ethics Committee, Medanta Hospital Lucknow, Sector A, Pocket 1, Sushant Golf City, Shaheed Path, Lucknow, Uttar Pradesh, 226030 ECR/1529/Inst/UP/2021	Dr Shahzeene Dhuria
9.	Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Four Bungalows, Andheri West, Mumbai - 400053	Institutional Ethics Committee, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao saheb Achutrao Patwardhan Marg, Four Bungalows, Andheri West, Mumbai, Maharashtra -400053 ECR/141/Inst/MH/2013/RR-19	Dr Jyotsna Laxmikant Oak
