File No. CT/43/19-DCG(I)

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
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

सत्यमेव जयते

File No. CT/19/000045

To,

M/s. Eli Lilly and Company (India) Pvt. Ltd.,
Plot No. 92, Sector 32,
Gurugram – 122001, Haryana.

Sir,

With reference to your application No GCT/Form44/FF/2019/13607 (GCT/43/19) dated 10-06-2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Phase 3, Multicenter, Open-Label Extension Study to Evaluate the Long-Term Efficacy and Safety of Mirikizumab in Patients with Moderately to Severely Active Ulcerative Colitis ", Protocol number I6T-MC-AMAP, dated 15/03/2018** 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) 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;

(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 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;

(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 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;

(viii) 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;

(ix) 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;

(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 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;

(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 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;

(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 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

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

(xviii) 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,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION , 2.5.4.20=cec9e6dd3ecf4caa36d3ae0e432d59a6f4c3a02cb467e76d5edcdb3a751ee144, ou=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.08.13 14:55:22 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licensing Authority
Stamp

File No. CT/43/19-DCG(I)

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. Eli Lilly and Company (India) Pvt. Ltd., Plot No. 92,Sector 32, Gurugram – 122001, Haryana** to conduct clinical trial of the new drug or investigational new drug as per protocol number **I6T-MC-AMAP, dated 15/03/2018** 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 _____

S ESWARA REDDY
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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59af4fc3d02c0467e7fd3edcdb3a751ee144, ou=DGHS,CID-6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.08.13 14:50:32 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licensing 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	Mirikizumab
Therapeutic class:	Anti-Ulcerative Colitis
Dosage form:	Injection
Composition:	Water for Injection = 1.000ml U.S.P. Inactive Polysorbate 80 =0.300 milligram (mg) U.S.P. Inactive Sodium Chloride = 8.770 milligram (mg) U.S.P. Inactive Citric Acid Anhydrous = 0.385 milligram (mg) U.S.P. Inactive Sodium Citrate Dihydrate = 2.350 milligram (mg) U.S.P. Inactive LY3074828 =100.000 Milligram (mg) In House Specification Active
Indications:	Ulcerative Colitis

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Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
King George's Medical University, Lucknow-226003, Uttar Pradesh, India	Institutional Ethics Committee, King George's Medical University, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow-226003, Uttar Pradesh, India ECR/262/INST/UP/2013/RR-16	Dr. Abhijit Chandra
Fortis Hospital Noida, B-22, Sector-62, Gautam Buddh Nagar, Noida, Uttar Pradesh, India-201301	Fortis Hospital Institutional Ethics Committee, Room No. 1341, 3rd Floor, IPD, Fortis Hospital, B-22, Sector-62, Noida-201301 (U.P) ECR/69/INST/UP/2013/RR-16	Dr. Ajay Bhalla
Dayanand Medical College and Hospital, Department of Gastroenterology, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab-141001, India	Drug Trial Ethics Committee, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab-141001, India ECR/101/Inst/PB/2013/RR-16	Dr. Ajit Sood
Lokmanya Tilak Municipal General Hospital & Medical College, Sion, Mumbai – 400022, India	Institutional Ethics Committee – Human Research – Lokmanya Tilak Municipal Medical College, Sion, Mumbai – 400022, India. ECR/266/Lokmanya/Inst/MH/2013	Dr. Akash Shukla
M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post , Bangalore,-560054, Karnataka	Ethics Committee, M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post , Bangalore,-560054, Karnataka ECR/215/INST/KA/2013/RR-16	Dr. Avinash Balekuduru
Institute of Digestive & Liver Diseases, Dispur Hospitals Pvt Ltd, Ganeshguri, Guwahati-781006, Assam	Ethics Committee, Dispur Hospitals Pvt. Ltd, Ganeshguri, Guwahati-781006, Assam ECR/622/Inst/AS/2013/RR-17	Dr. Bhabadev Goswami
KEM Hospital Research Centre, Pune, Sardar Moodlikar Road, Rasta Peth, Pune-411011, Maharashtra, India	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, Pune, Sardar Moodlikar Road, Rasta Peth, Pune-411011, Maharashtra, India ECR/272/INST/MH/2013/RR-16	Dr. Bharat Kalambe

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Shree Giriraj Multispeciality Hospital, 27-Navjyot Park Corner, 150 feet Ring Road, Rajkot-360005, Gujarat, India	Shree Giriraj Hospital Research Ethics Committee, 150 feet Ring Road, 27-Navjyot Park Main Road, Amin Marg Cross Road, Rajkot-360005, Gujarat, India IEC/74/GJ/2013/RR-16	Dr, Mehta Chetan Nalin
Centre for Liver Research & Diagnostics, Dept. Of Gastroenterology & Hepatology, Deccan College of Medical Science, Owaisi Hospital & Research Centre, Kanchanbagh, Hyderabad-500058, Telangana	Institutional Ethics Committee, Deccan College of Medical Science, Owaisi Hospital & Research Centre, Kanchanbagh, Hyderabad-500058, Telangana ECR/133/Inst/AP/2013/RR-16	Dr. Mohd.Aejaz Habeeb
S. R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar patel Marg, C-Scheme, Jaipur-30200 I Rajasthan India	S. R. Kalla Memorial Ethical Committee for Human Research, S. R. Kalla Memorial Gastro & General Hospital,78-79 Dhuleshwar Garden Behind HSBC Bank Sardar Patel Marg, C-Scheme Jaipur-30200 1 Rajasthan India ECR/8/INST/RAJ/2013/RR-16	Dr. Mukesh Kalla
Fortis Escorts Heart Institute, Okhla Road, New Delhi-110025, India	Institutional Ethics Committee, Room No. 23A, IInd Floor, Residential Tower, Fortis Escorts Heart Institute, Okhla Road New Delhi-110025 ECR/261/Inst/DL/2013/RR-16	Dr. Mukul Rastogi
Sir Ganga Ram Hospital SGRH Marg, Rajinder Nagar, New Delhi-110060, India	Ethics Committee Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, India ECR/20/INST/DL/2013/RR-16	Dr. Naresh Kumar Bansal
Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra, India	Institutional Ethics Committee Poona Medical Research Foundation, E4-C to E4-F, 4th Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-16	Dr. Pai Nitin Vikas
Fortis Hospitals Limited, Mulund Goregaon Link Road, Bhandup (West), Mumbai-400078, India, Maharashtra	Institutional Ethics Committee Fortis Hospitals Limited, Mulund Goregaon Link Road, Bhandup (West), Mumbai-400078, India, Maharashtra ECR/531/Inst/MH/2014/RR-17	Dr. Nutan D. Desai
Victoria Hospital, Bangalore Medical College and Research Institute, K R. Road, Fort, Bangalore-560002, India	Ethics Committee of Bangalore Medical College and Research Institute, K R. Road, Fort, Bangalore-560002, India ECR/302/INST/KA/2013/RR-16	Dr. Parevsh Kumar Jain

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Gandhi Hospital, In-patient Block, 5th Floor, Department of Gastroenterology, Gandhi Hospital, Musheerabad, Secunderabad, Telangana, India-500003	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad, Telangana, India-500003 ECR/180/Inst/AP/2013	Dr. P. Shravan Kumar
Department of Gastroenterology, Osmania General Hospital, Afzalgunj, Hyderabad-500012, Telangana, India	Ethics Committee Osmania Medical College Koti, Hyderabad-500095, Telangana, India ECR/300/INST/AP/2013/RR-16	Dr. B. Ramesh Kumar
Sunshine Hospitals Sunstiine Hospitals, Paradise, PG Road, Secunderbad-500003, Tetangana, India	Institutional Ethics Committee, sunshine Hospitals, paradise, PG Road, Secunderbad-500003, Telangana, India ECR/171/Inst/AP/2013/RR-16	Dr. B. Ravi Shankar
Asian Institute of Gastroenterology Hospitals Plot No. 2/3/4/5, Survey No. 136, 1, Mindspace Rd, Gachibowli, Hyderabad, Telangana-500032	Institutional Ethics Committee, Asian Institute of Gastroenterology, 6-3-661, Somajiguda, Hyderabad-500082, India ECR/346/INST/AP/2013/RR-16	Dr. Rupa Banerjee
Dept. of Gastroenterology, PGIMER, Sector-12, Chandigarh-160012, India	Institute Ethics Committee, PGIMER, Sector-12, Chandigarh-160012, India ECR/25/Inst/CH/2013/RR-16	Dr. Saroj Kant Sinha
Nirmal Hospital Pvt. Ltd, Ring Road, Surat-395002, Gujarat, India	Nirmal Hospital Private Limited Ethics Committee, Nirmal Hospital Pvt. Ltd, Ring Road, Surat-395002, Gujrat, India ECR/390/Inst/GJ/2013/RR-16	Dr. Saumin Prakashbhai Shah
Apollo Hospitals International Ltd, Plot no. 1a, GIDC estate, Bhat, Gandhinagar, Gujarat, India-382428	Institutional Ethics Committee – Clinical Studies, Office of Institutional Ethics Committee, Site office Building, Apollo Hospital, Gandhinagar, Gujarat - 382428, India. ECR/30/INST/GJ/2013/RR-16	Dr. Shravan Bohra
Midas Multispeciality Hospital Pvt. Ltd., Midas Heights, 07, Central Bazaar Road, Ramdas Peth, Nagpur - 440010, Maharashtra.	Institutional Ethics Committee Midas Multispeciality Hospital Pvt. Ltd., Midas Heights, 07, Central Bazaar Road, Ramdas Peth, Nagpur - 440010, Maharashtra. ECR/494/Inst/MH/2014/RR-17	Dr. Shrikant Mukewar
Acharya Vinoba Bhave Rural Hospital Jawharlal Nehru Medical College, Datta Meghe Institute of	Institutional Ethics Committee, Datta Meghe Institute of Medical Sciences (DU), Research House, Near Food Court, Datta Meghe Institute of Medical Sciences (DU), Sawangi –	Dr. Kirnake VijendraVasantrao

Medical Sciences Sawangi, (Meghe) Wardha – 442004, Maharashtra, India	442004, Maharashtra, India. ECR/440/Inst/MH/2013/RR-16	