File No. CT/55/23-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/23/000055

To,

M/s InVentiv International Pharma Services Private Limited,
3rd Floor, Tower B, Presidency Towers, 46/4, M G Road,
Gurgaon, Haryana (India) – 122001.

Sir,

With reference to your application No. GCT/CT04/FF/2023/37579 (GCT/55/23) dated 19-05-2023, please find enclosed herewith the permission in Form CT-06 for conduct of phase II b clinical trial titled, "**A Phase 2, Multicenter, Multinational, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Efficacy, and Pharmacokinetics of Multiple Dose Levels of ESK-001 in Adult Patients with Systemic Lupus Erythematosus" Protocol number: ESK-001-010, Original Version 3, dated 08/February/ 2023 with a total of up-to 40 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) 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) 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;

(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.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c276904 1015a06564fe67f54b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1F E73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV RAGHUVANSHI
Date: 2023.11.17 17:09:51 +05'30'

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

File No. CT/55/23-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 to **M/s**. **Inventiv International Pharma Services Private Limited, 3rd Floor, Tower B, Presidency Tower, 46/4, M. G. Road, Sector 14, Gurugram, Haryana-122001** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number: ESK-001-010, Original Version 3, dated 08/February/2023** 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 _____

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c276904 1015a06564fe67f54b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1F [illegible] RAJEEV SINGH RAGHUVANSHI
Date: 2023.11.17 09:51:32 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
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	ESK-001
Therapeutic class:	Immunosuppressive Medicines
Dosage form:	Tablets
Composition:	ESK-001 =21.7000 mg/tablets Other than the above mentioned types Active Microcrystalline Cellulosea = 88.2000 mg/tablet U.S.P. Inactive Silicified Microcrystalline Cellulose= 88.1000 mg/tablet U.S.P. Inactive Magnesium Stearate = 2.0000mg/tablet U.S.P. Inactive Opadry II White = 6.0000 mg/tablet In House Specification Inactive Purified Water = 1.0000 U.S.P. Inactive
Indications:	Systemic Lupus Erythematosus

File No. CT/55/23-DCG(I)

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
St. John's Medical College Hospital, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India	Institutional Ethics Committee, St. John's Medical College Hospital, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India ECR/238/Inst/KA/2013/RR-19	Dr. Vineeta Shobha
Unity Trauma Center and ICU (Unity Hospital), Nr. D. R. World, Opp. Raghuvir Business Empire, Aai Mata Road, Parvat Patiya, Surat-395010, Gujarat, India	Unity Hospital Ethics Committee, Unity Trauma Center and ICU, N-4 Janki park Society, Aai Mata Road, Parvat Patiya, Surat-395010, Gujarat, India ECR/1226/Inst/GJ/2019	Dr. Romi Kirankumar Shah
Nirmal Hospital Pvt. Ltd., Ring Road. Surat, Gujarat-395002, India	Nirmal Hospital Pvt. Ltd Ethics Committee, Nirmal Hospital Pvt. Ltd., Ring Road. Surat, Gujarat-395002, India ECR/390/Inst/GJ/2016/RR-19	Dr. Bankimchandra Nanubhai Desai
Medanta The Medicity, Sector 38, Gurgaon Haryana, 122001	Medanta Institutional Ethics Committee (MIEC) 10th Floor, A-wing (POCU), Medanta The Medicity, Sector-38, Gurgaon, Haryana 122001 ECR/282/Inst/HR/2013/RR-20	Dr. Rajiva Gupta
Panchshil Hospital, Highway, Ramnagar, Sabarmati, Ahmedabad-380005, Gujarat, India	Panchshil Institutional Ethics Committee, Office of Ethics Committee, First Floor, Panchshil Hospital, Highway, Ramnagar, Sabarmati, Ahmedabad-380005, Gujarat, India ECR/833/Inst/GJ/2016/RR-19	Dr. Puja Srivastava
Shalby Hospital, Opp. Kamavati Club, S.G. Highway, Ahmedabad-380015, Gujarat, India	Ethics Committee -Shalby Ltd, Shalby Hospital, Opp. Kamavati Club, S.G. Highway, Ahmedabad-380015, Gujarat, India ECR/711/Inst/GJ/2015/RR-21	Dr. Reena Shanna
Lifepoint Multi-speciality Hospital, 3rd Floor, Clinical Research Department, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad,	Lifepoint Research Ethics Committee, Lifepoint Multi-speciality Hospital, 3rd Floor, Clinical Research Department, 145/1, Mumbai Bangalore Highway, Near Hotel	Dr. Patil Nilesh Jayavant

Pune-411057, Maharashtra, India	Sayaji, Wakad, Pune-411057, Maharashtra, India ECR/751/INST/MH/2015/RR-21	
Jasleen Hospital, 1st Floor, Opposite to Big Bazar, Panchasheel Square, Dhantoli, Nagpur-440012	Jasleen Hospital Ethics Committee, Opp, Big Bazar, Panchasheel Square, Dhantoli, Nagpur-440012 ECR/264/Inst/MH/2013/RR-20	Dr. Smruti Sanjay Ramteke
CHANRE RHEUMATOLOGY AND IMMLINOLOGY CENTER AND RESEARCH No. 414/65, 20th Main Road, West of Chord Road, 1st Block Rajajinagara, Bengaluru - 560010, Karnataka, India	Institutional Ethics Committee, CHANRE RHEUMATOLOGY AND IMMLINOLOGY CENTER AND RESEARCH No. 414/65, 20th Main Road, West of Chord Road, 1st Block Rajajinagara, Bengaluru - 560010, Karnataka, India ECR/190/Inst/KR/2013/RR-19	Dr. Chandrashekara Srikantiah
V.S. General Hospital, Nr. Ellisbridge, Paldi, Ahmedabad-380006, Gujarat, India	Riddhi Medical Nursing Home IEC Riddhi Medical Nursing Home, A/101 Jalaram Plaza Jawahar Chowk, Maninagar, Ahmedabad, Gujarat -380008, India ECR/886/Inst/GJ/2016/RR-19	Dr. Dhaiwat Shukla
Sanjay Postgraduate Institute of Medical Sciences, Department of Clinical Immunology & Rheumatology, Rae Bareli Road, Lucknow, Uttar Pradesh-226014	Institutional Ethics Committee, Sanjay Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh-226014 ECR/16/Inst/UP/2013/RR-20	Dr. Amita Aggarwal
Post Graduate Institute of Medical Education & Research Chandigarh, Madhya Marg, Sector-12, Chandigarh,160012, India	Institutional Ethics Committee, PGIMER, Room no. 6006, 6th Floor, PN Chuttani Block, Research Block B, PGIMER, Chandigarh, U.T. India-160012 ECR/25/Inst/CH/2013/RR-20	Dr. Manish Rathi
SMS Medical College & Hospital, Jawahar Lal Nehru Marg, Ashok Nagar, Jaipur, rajasthan-302001	SMS Medical College & Attached Hospitals ECR/26/Inst/RJ/2013/RR-19	Dr. Avinash Jain
Medipoint Hospital Pvt. Ltd., 241/1, New D.P. Road, Aundh, Pune-411007, Maharashtra, India	Pentamed Ethics Committee, Medipoint Hospital Pvt. Ltd., 241/1, New D.P. Road, Aundh, Pune-411007, Maharashtra, India ECR/357/Inst/MH/2013/RR-20	Dr. Kakade Girish Vitthalrao

****