



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health
Services) Ministry of Health & Family
Welfare
FDA Bhavan
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File No. CT/25/000115

To,

M/s Johnson and Johnson Private Limited,
HIGI House, L. B. S. Marg, Mulund (West),
Maharashtra (India) - 400080

Sir,

With reference to your application No. GCT/CT04/FF/2025/51359 dated 13-Aug-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3 Randomized, Double-blind, Placebo-Controlled, Parallel Group, Multicenter Protocol in Adults with an Open Label Study in Adolescents to Evaluate the Efficacy and Safety of Induction and Maintenance Therapy with Icotrokinra in Participants With Moderately to Severely Active Ulcerative Colitis (ICONIC-UC)”**. **Protocol No. 77242113UCO3001 Amendment 1 dated 24 July 2025 with a total of up-to 94 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:-

- 1) **Human biological samples i.e. Whole blood, serum, plasma, urine, EDTA blood samples and stool samples related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
- 2) 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;
- 3) 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;

- 4) 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;
- 5) 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;
- 6) 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;
- 7) 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;
- 8) 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;
- 9) 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;
- 10) 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;
- 11) 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;
- 12) 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;
- 13) 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;
- 14) 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;
- 15) 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;
- 16) 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;
- 17) 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;
- 18) the sponsor and the investigator shall maintain the data integrity of the data generated

during clinical trial.

- 19) 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;
- 20) 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 Johnson and Johnson Private Limited, HIGI House, L. B. S. Marg, Mulund (West), Maharashtra (India) - 400080** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. 77242113UCO3001 Amendment 1 dated 24 July 2025** 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	icotrokinra (JNJ-77242113)
Therapeutic class:	IL 23R antagonist peptide
Dosage form:	Tablets
Composition:	JNJ- 77242113- AAC =320.0000 milligram (mg) In House Specification Active
Indications:	Moderately to Severely Active Ulcerative Colitis

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1	Gandhi Hospital, In-Patient Block, 5th Floor, Department of Gastroenterology, Musheerabad Secunderabad Telangana - 500003	INSTITUTIONAL ETHICS COMMITTEE ECR/180/AP/2013/RR-24	Dr P Shравan Kumar
2	G.B. Pant Hospital, Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, Dept. of Gastroenterology ,Academic Block, 2nd Floor, JLN Marg New Delhi Delhi - 110002	INSTITUTIONAL ETHICS COMMITTEE MAMC ECR/329/Inst/DL/2013/RR-24	Dr Ashok Dalal
3	All India Institute of Medical Sciences, Ansari Nagar New Delhi New Delhi Delhi - 110029	Institute Ethics Committee All India institute of Medical Sciences, ECR/538/Inst/DL/2014/RR-20	Dr Vineet Ahuja
4	All India Institute of Medical Sciences, Aurangabad road, Phulwari sharif, Patna, Bihar Patna Bihar - 801507	IEC-AIIMS-Patna ECR/1387 /Inst/BR/2020	Dr Sudhir Kumar
5	SUM ultimate medicare, K-8 Kalinga Nagar, Ghatikia, Bhuwaneshwar Orissa	Institutional Ethics Committee-Clinical Research & Studies, ECR/1604/INST/OD/2021	Dr Ayaskanta Singh

6	Yashoda Hospitals, Behind Hari Hara Kala Bhavan, SP Road Secunderabad Telangana - 500003	Institutional Ethics Committee Yashoda Academy of Medical Education and Research ECR/49/Inst/AP/2013/RR-22	Dr B Ravi Shankar
7	P. D. Hinduja National Hospital and Medical Research Center., first floor, OPD wing, Veer Savarkar Road, Mahim, Mumbai Maharashtra-400016	Institutional Ethics Committee ECR/61/Inst/MH/2013/RR-24	Dr Devendra Desai
8	Fortis Memorial research institute, Sector - 44, Opposite Millennium city center metro station, Gurugram Haryana - 122002	IEC, Fortis Memorial Research Institute ECR/223/Inst/HR/2013/RR-22	Dr Gourdas Choudhuri
9	ASTER CMI Hospital, 43-2, NH7, New Airport Road, Sahakar Nagar, Hebbal, Bengaluru Karnataka - 560092	Aster CMI Hospital Institutional Ethics Committee ECR/1084/Inst/KA/2018/RR-21	Dr Kayal Vizhi N
10	Yashoda Healthcare services pvt limited, Raj bhavan Road, Somajiguda, Hyderabad Hyderabad Telangana - 500082	Institutional Ethics Committee Yashoda Academy of Medical Education and Research ECR/49/Inst/AP/2013/RR-22	Dr Kiran Kumar Peddi
11	Lisie Hospital, P.B No. 3053, Kochi, Ernakulam Kochi Kerala - 682018	Institutional Ethics Committee, ECR/40/Inst/KL/2013/RR-25	Dr Mathew Philip
12	S. R. Kalla Memorial Gastoand General Hospital, 8-79, Dhuleshwar Garden, Sardar Patel Marg, C-Scheme, Jaipur Rajasthan - 302006	S.R. Kalla Memorial Ethical Committee For Human Research ECR/8/Inst/Raj/2013/RR-24	Dr Mukesh Kalla
13	Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi Delhi - 110060	Sir Ganga Ram Hospital Ethics Committee ECR/20/Inst/DL/2013/RR-24	Dr Naresh Kumar Bansal
14	Fortis Hospitals, Chandigarh Road, near Radha Swami Satsang Bhavan, village Mundian Kalan, Ludhiana Punjab - 141123	Institutional Ethics Committee ECR/746/Inst/PB/2015/RR-22	Dr Nitin Shanker Behl

15	SIDS Hospital and Research Centre, A unit of SIDS Healthcare Private Limited, Off Ring Road, Near Shell Petrol Pump, Ring Road-Sosyo Circle Lane, Surat, Gujarat, Surat Gujarat - 395002	Surat Institute of digestive sciences ECECR/813/Inst/GJ/2016/RR-24	Dr Kabrawala Mayank Vasantla
16	AIG Hospitals, Plot No 2-3-4-5, Survey No 136, 1, Mindspace Road, Gachibowli Hyderabad Telangana - 500032	Institutional Ethics Committee ECR/346/Inst/AP/2013/RR-22	Dr Rupa Banerjee
17	Gujarat Gastro and Vascular Hospital, Hospital, Opp. Shree Ram Petrol Pump, Anandmahal Road, Adajan, Surat Gujarat -395009	UNITY HOSPITAL ETHICS COMMITTEE ECR/1226/Inst/GJ/2019/RR-24	Dr Saumin Shah
18	Mazumdar Shaw Medical Centre - a unit of Narayana Hrudayala limited, No. 258-A Bommasandra Industrial Area Anekal Taluk, Benaluru Karnataka - 560099	Narayana Health Medical Ethics Committee, ECR/390/Inst/KA/2013/RR-24	Dr Uday Nagesh Shivaji
19	Dayanand Medical College and Hospital, Tagore nagar, CIVIL LINES, Ludhiana Ludhiana Punjab - 141001	Drug Trial Ethics Committee ECR/101/Inst/PB/2013/RR-24	Dr Vandana Midha
20	Indraprastha Apollo Hospital, Sarita Vihar, Delhi Mathura Road, New Delhi, New Delhi Delhi - 110076	Institutional Ethics Committee-Clinical Studies ECR/5/INST/DL/2013/RR-24	Dr Yogesh Batra
