



File No. BIO/CT/24/000133

Dated 30.05.2025

To,

M/s Johnson and Johnson Private Limited
LBS Marg Mulund West ,
Maharashtra (India) – 400080

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled – "A Phase-IV, Multicenter, Non-Comparative, Open-Label Study Evaluating the Safety and Efficacy of Guselkumab Administered Subcutaneously in the Treatment of Indian Patients with Psoriatic Arthritis" vide Protocol CNTO1959PSA4018, Version No. 1, dated 26 August 2024 - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/45903 dated 14.10.2024

Sir,

With reference to your application No.:BIO/CT04/FF/2024/45903 dated 14.10.2024, 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) You are required to submit the Clinical study report after completion of study to this office.
- (II) 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
- (III) 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;
- (IV) 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;
- (V) 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;
- (VI) 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.
- (VII) 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.

- (VIII) 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;
- (IX) 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.
- (X) 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.
- (XI) 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.
- (XII) 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.
- (XIII) 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.
- (XIV) 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 authorized 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.
- (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 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.
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

Yours faithfully,
Digitally signed by RAJEEV
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RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

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 Licensing Authority hereby permits M/s Johnson & Johnson Pvt. Ltd., HIGI House, L.B.S. Marg, Mulund Mulund West (India) - 400080 Telephone No.: 0124-4647000 FAX: 0124-4647000 E-Mail : RA-JNJIN-REGJJMI@ITS.JNJ.COM to conduct Phase IV clinical trial entitled **"A Phase-IV, Multicenter, Non-Comparative, Open-Label Study Evaluating the Safety and Efficacy of Guselkumab Administered Subcutaneously in the Treatment of Indian Patients with Psoriatic Arthritis"** vide Protocol CNTO1959PSA4018, Version No. 1, dated 26 August 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: 30-May-2025

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:	Guselkumab Solution for Injection 100 mg/ml (r-DNA origin)		
Dosage form:	Single-use pre-filled syringe for subcutaneous administration		
Composition:	Name of Ingredients	Unit Formula per dose	Pharmacopoeial specification
	Guselkumab	100 mg	In-house
	Sucrose	1.5mg/ml	NF/Ph. Eur./JP
	L-Histidine	0.24mg/mL	USP/Ph. Eur./JP
	L-Histidine monohydrochloride monohydrate	80mg/ml	Ph. Eur./JP
	Polysorbate 80	0.40mg/ml	NF/Ph. Eur./JP
	Water for Injection	0.02mg/ml	USP/Ph. Eur./JP
Indications:	Guselkumab is indicated for the treatment of adult patients with active psoriatic arthritis.		

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	M/s Jehangir Clinical Development Centre Pvt. Ltd., Jehangir Hospital Premises 32, Sassoon Road, Pune Maharashtra -411001	Jehangir Clinical Development Centre Pvt. Ltd., Jehangir Hospital Premises, 32 Sassoon Road, Pune, Maharashtra – 411001 EC Reg. No.: ECR/352/Inst/MH/2013/RR-19	Dr Nachiket Kulkarni
2.	M/s Chennai Meenakshi Multispeciality Hospital Ltd., New No.70, Old No.149, Luz Church Road, Mylapore, Chennai Tamil Nadu - 600004	CMMHEC, Chennai Meenakshi Multispeciality Hospital Limited, Old No 148, New 72, Luz Church Road, Mylapore, Chennai, Tamil Nadu - 600004 EC Reg. No.: ECR/516/Inst/TN/2014/RR-20	Dr. Krishnamurthy Venkataraman
3.	M/s All India Institute of Medical Sciences, Department of Rheumatology, Room No.4076, 4th floor, Teaching Block, AIIMS, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee, All India Institute of Medical Sciences situated at Room No. 102, 1st Floor, Old O.T.Block, Ansari Nagar, New Delhi- 110029, India EC Reg. No. ECR/538/Inst/DL/2014/RR-20	Dr. Uma Kuma

4.	M/s Apollo Multispeciality Hospitals Limited, 58, Canal Circular Rd, Kadapara, Kolkata West Bengal - 700054	Institutional Ethics Committee, Apollo Gleneagles Hospitals, 58 Canal Circular Road, Kolkata, West Bengal – 700054. EC Reg No.: ECR/373/Inst/WB/2013/RR-19	Dr. Syamasis Bandyopadhyay
5.	M/s Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, India	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi, Delhi – 110060 EC Reg No.: ECR/20/Inst/DL/2013/RR-24	Dr. Atul Kakar
6.	M/s Marengo CIMS Hospital, Ahmedabad, plot no 67/1, Opp Panchamrut Bunglows, Near Shukan Mall, Off. Science city Road, Sola, Ahemdabad, Gujarat, India, 380060	Ethics Committee of CIMS, Care Institute of Medical Sciences, Near Shukan Mall, Off. Science city Road, Sola, Ahemdabad, Gujarat, India, 380060 EC Reg No.: ECR/206/Inst/GJ/2013/RR-24	Dr. Reena Sharma
7.	M/s ESIC Medical College and Superspeciality Hospital, OPD Block, 4thFloor, Room No. 407, Sanathnagar, Hyderabad - 500038	Institutional Ethics Committee, ESIC Medical College and Hospital and ESIC SSH ESIC Medical College, Sanath Nagar, Hyderabad, Telangana - 500038 EC Reg No.: ECR/1303/Inst/TG/2019/RR-22	Dr. Vijaya Prasanna
8.	M/s P D Hinduja Hospital & Medical Research Centre, Veer Savarkar Marg, Mahim - 400016, Maharashtra, India.	Institutinal Ethics Committee, P. D. Hinduja Hospital and Medical Research Centre, 913, 9th floor, Research Dept., Lalita Girdhar (S1) bldg., T H Katariya Marg, Mahim Mumbai, Mumbai City, Maharashtra - 400016 EC Reg No.: ECR/61/Inst/MH/2013/RR-19	Dr. Sandeep Yadav
9.	M/s Nizam's Institute of Medical Sciences Department of Clinical Immunology & Rheumatology Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad-500082	NIMS Institutional Ethics Committee, Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad , Telanagana - 500082 EC Reg No.: ECR/303/Inst/AP/2013/RR-24	Dr. Meghna Gavali