



Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/24/000045

Dated 21.03.2025

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 – "An open label, Multicenter, Phase IV study of Teclistamab to evaluate its safety in Indian Participants with Relapsed and Refractory Multiple Myeloma who have previously received at least 3 prior lines of therapy including an Immunomodulatory agent a Proteasome inhibitor and an Anti-CD38 antibody and have demonstrated disease progression on the last therapy" vide Protocol No. 64007957MMY4007, version 1 (Amendment 1) dated 10.12.2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/42660 dated 19.04.2024

Sir,

With reference to your application No.: BIO/CT04/FF/2024/42660 dated 19-APR-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 conduct Phase IV study in minimum of 75 subjects
- (II) You are required to submit Interim report within one year for continuation of the approval.
- (III) You are required to submit the Clinical study report after completion of study to this office.
- (IV) 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
- (V) 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;

- (VI) 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;
- (VII) 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;

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

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

Yours faithfully,

DIGITAL SIGNATURE OF RAJEEV SINGH RAGHUVANSHI
DN: cn=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL
ORGANISATION,
2.5.4.20=42d7189b1c0981b5a263a4a73d025f4b11b680a91108773
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serialNumber=65715e47d940985d8f03bdc902d0e1e73fa12a1a126
ea94a5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2025.03.27 09:45:21 +05'30'

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-REGJMI@ITS.JNJ.COM to conduct Phase IV clinical trial entitled **"An open label, Multicenter, Phase IV study of Teclistamab to evaluate its safety in Indian Participants with Relapsed and Refractory Multiple Myeloma who have previously received at least 3 prior lines of therapy including an Immunomodulatory agent a Proteasome inhibitor and an Anti-CD38 antibody and have demonstrated disease progression on the last therapy"** vide Protocol No. 64007957MMY4007, version 1 (Amendment 1) dated 10.12.2024 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: 21-March-2025

RAJEEV SINGH
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL
ORGANISATION,
2.5.4.20=42d7189b1c0981bb5a263a4a73d025ff4b11b680a9
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serialNumber=657f5e47d940985d8f03bd902d0e1fe73cfa1
2a1a126e994fa5701124a19013, cn=RAJEEV SINGH
RAGHUVANSHI
Date: 2025.03.27 09:45:40 +05'30'

(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:	Teclistamab 10mg/mL solution for injection One 3mL vial contains 30mg of teclistamab (10mg/mL).																										
	Teclistamab 90mg/mL solution for injection One 1.7mL vial contains 153mg of teclistamab (90mg/mL) (r-DNA origin)																										
Therapeutic class	Anti-cancer																										
Dosage form:	Powder for concentrate for solution for infusion																										
Composition:	<table border="1"> <thead> <tr> <th>Name of Ingredients</th> <th>Concentration (30mg /3ml (10mg/ml))</th> <th>Concentration 153mg/1.7 ml (90mg/ml)</th> </tr> </thead> <tbody> <tr> <td>Teclistamab IH</td> <td>10 mg/ml</td> <td>90 mg/ml</td> </tr> <tr> <td>Sodium acetate trihydrate USP/NF/Ph.Eur</td> <td>1.5mg/ml</td> <td>1.5mg/ml</td> </tr> <tr> <td>Glacial acetic acid USP/NF/Ph.Eur/JP</td> <td>0.24mg/mL</td> <td>0.24mg/mL</td> </tr> <tr> <td>Sucrose USP/NF/Ph.Eur/JP</td> <td>80mg/ml</td> <td>80mg/ml</td> </tr> <tr> <td>Polysorbate 20 USP/NF/Ph.Eur/JPE</td> <td>0.40mg/ml</td> <td>0.40mg/ml</td> </tr> <tr> <td>EDTA disodium salt Dihydrate USP NF/Ph.Eur/ JP</td> <td>0.02mg/ml</td> <td>0.02mg/ml</td> </tr> <tr> <td>Water for Injection USP/NF/Ph.Eur/JP</td> <td>q.s to 3.0ml</td> <td>q.s to 1.7ml</td> </tr> </tbody> </table>			Name of Ingredients	Concentration (30mg /3ml (10mg/ml))	Concentration 153mg/1.7 ml (90mg/ml)	Teclistamab IH	10 mg/ml	90 mg/ml	Sodium acetate trihydrate USP/NF/Ph.Eur	1.5mg/ml	1.5mg/ml	Glacial acetic acid USP/NF/Ph.Eur/JP	0.24mg/mL	0.24mg/mL	Sucrose USP/NF/Ph.Eur/JP	80mg/ml	80mg/ml	Polysorbate 20 USP/NF/Ph.Eur/JPE	0.40mg/ml	0.40mg/ml	EDTA disodium salt Dihydrate USP NF/Ph.Eur/ JP	0.02mg/ml	0.02mg/ml	Water for Injection USP/NF/Ph.Eur/JP	q.s to 3.0ml	q.s to 1.7ml
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Sucrose USP/NF/Ph.Eur/JP	80mg/ml	80mg/ml																									
Polysorbate 20 USP/NF/Ph.Eur/JPE	0.40mg/ml	0.40mg/ml																									
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Water for Injection USP/NF/Ph.Eur/JP	q.s to 3.0ml	q.s to 1.7ml																									
Indications:	Teclistamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy																										

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Department of Clinical Hematology and Medical Oncology, Nehru Hospital, Post Graduate Institute of Medical Education & Research, Sector 12, Chandigarh, 160012	Institutional Ethics Committee, Room no 6006, 6th Floor, PN Chuttani block Sector 12, Chandigarh, 160012 India EC Reg. No.: ECR/25/Inst/CH/2013/RR-20	Dr. Pankaj Malhotra
2.	Gauhati Medical College and Hospital, Bhangagarh, Guwahati- 781032, Assam, India	Institutional Ethics Committee, GMCH, 2nd Floor, GMC Main Building, Narakasur Hilltop, Guwahati-781032,	Dr. Damodar Das

		Assam,India EC Reg. No.: ECR/1470/Inst/AS/2020	
3.	Tata Medical Centre, 14 MAR (EW),Newtown, Rajarhat, Kolkata- 700160 0	Institutional Review Board14 MAR (EW),Newtown, Rajarhat, Kolkata-700160, West Bengal, India EC Reg. No. ECR/269/Inst/WB/2013/RR-24	Dr. Jeevan Kumar
4.	M S Ramaiah Medical College and Hospital, M S Ramaiah Nagar, MSRIT Post-560054, Bangalore, Karnataka, Indi	Ethics Committee,M S Ramaiah Medical College &Hospitals,M S Ramaiah Nagar, MSRIT Post-560054, Bangalore, Karnataka, India EC Reg No.: ECR/215/Inst/KA/2013/RR-2	Dr. Santhosh Kumar
5.	Basavatarakam Indo American Cancer Hospital & Research Institute, 10, Banjara Hills, Hyderabad-500034, Telangana -India	Institutional Ethics Committee, Tata Memorial Hospital, IRB office, Main Building, 3rd floor, Tata Memorial Hospital, Parel Mumbai 400 012 EC Reg. No. IEC-I ECR/170/Inst/MH/2013/RR-22 IEC II ECR/414/Inst/MH/2013/RR-24	Dr. Bhausahab Bagal
6.	Room No. 218, 2ndfloor, Dr. B.R.A Institute Rotary Cancer Hospital, All India Institute of Medical Sciences, Ansari Nagar, New Delhi, 110029	Institute Ethics Committee, Room No.102, First Floor, Old O.T. Block AIIMS, Ansari Nagar, New Delhi -110029 EC Reg No ECR/538/Inst/DL/2014/RR-20	Dr. Ranjit Kumar Sahoo
7.	Bhagwan Mahaveer Cancer Hospital & Research Centre, Jawaharlal Nehru Marg, Jaipur -302017	Institutional Ethics Committee BMCHRC, Jaipur EC Reg No ECR/19/Inst/RJ/2013/RR-20	Dr. Upendra Sharma