सत्यमेव जयते

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
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File No. CT/26/000040

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/2026/55559 dated 15-Mar-2026, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIlogy-5)" Protocol No. 79635322MMY3002 Amendment 1 dated 19 February 2026 with a total of up-to 44 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. Serum, urine and Bone Marrow Aspirate 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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.06.30 16:19:37 +05'30'

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. 79635322MMY3002 Amendment 1 dated 19 February 2026** 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
Date: 2026.06.30 16:20:07 +05'30'

(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	Ramantamig (JNJ-79635322) Ramantamig (JNJ-79635322)
Therapeutic class:	Trispecific T cell engaging antibody Trispecific T cell engaging antibody
Dosage form:	Solution for injection Solution for injection
Composition:	JNJ-79635322 5.0000 mg/ml In House Specification Active JNJ-79635322 50.0000 mg/ml In House Specification Active
Indications:	Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1	N. R.S. Medical College And Hospital, Centernary building, 138, 4th floor, A.J.C Bose Road Kolkata West Bengal - 700014	Ethics Committee, N.R.S. Medical College, Kolkata West Bengal – 700014 ECR/609/Inst/WB/2014/RR-25	Dr Tuphan Kanti Dolai
2	LMMFs Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune Maharashtra - 411004	Institutional Ethicscommittee of Deenanath Mangeshkar Hospital And Research Centre, Pune, Maharashtra – 411004 ECR/15/Inst/Maha/2013/RR-22	Dr Sameer R Melinkeri
3	M S Ramaiah Medical College And Hospitals, M S Ramaiah Nagar, MSRIT Post Bengaluru Bengaluru Karnataka - 560054	Ethics Committee, MS Ramaiah Medical College And Hospitals, Bengaluru (Bangalore) Urban. Karnataka – 560054 ECR/215/Inst/KA/2013/RR-22	Dr Santhosh Kumar Devadas
4	Fortis Memorial Research Institute, Sector-44, Opp. Millenium city center Gurugram Haryana - 122002	IEC, Fortis Memorial Research Institute, Gurugram Haryana – 122002 ECR/223/Inst/HR/2013/RR-22	Dr Rahul Bhargava
5	TATA Medical Center, 14 Major Arterial Road EW, Rajarhat, New Town. Kolkata West Bengal - 700160	INSTITUTIONAL REVIEW BOARD, TATA MEDICAL CENTER, Kolkata West Bengal - 700160 India ECR/269/Inst/WB/2013/RR-24	Dr Jeevan Kumar
6	Dr B.R.A. Institute Rotary Cancer Hospital, Room 218, second floor, All India Institute of Medical Science, Ansari Nagar, New Delhi Delhi - 110029	Institute Ethics Committee All India Institute of Medical Sciences, New Delhi, Delhi - 110029 India ECR/538/Inst/DL/2014/RR-25	Dr Ranjit Kumar Sahoo
7	Bhagwan Mahaveer Cancer Hospital and Research Center, Jawahar Lal Nehru Marg Jaipur Rajasthan - 302017	Institutional Ethics Committee Bhagwan Mahaveer Cancer Hospital and Research Center Jaipur Rajasthan - 302017 India ECR/19/Inst/RJ/2013/RR-25	Dr Prakash Singh Shekhawat
8	Rajiv Gandhi Cancer Institute and Research, D-18, Sector 5, Rohini Delhi Delhi - 110085	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre Delhi - 110085 India ECR/10/Inst/DC/2013/RR-24	Dr Dinesh Bhurani

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