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
E-Mail : dci@nic.in

File No. CT/25/000141

To,

M/s MSD Pharmaceuticals Private Limited,
6th Floor, Tower-B, Vatika Tower, Sector 54,
Haryana (India) – 122001.

Sir,

With reference to your application No. GCT/CT04/FF/2025/52162 dated 22-Sep-2025; please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Phase 3, Randomized, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of Sacituzumab Tirumotecan (MK-2870) in Combination With Pembrolizumab With or Without Bevacizumab Compared With Standard of Care as First-line Maintenance Treatment for Participants With Persistent, Recurrent, or Newly Diagnosed Metastatic Cervical Cancer With PD-L1 CPS Greater Than or Equal to 1 (TroFuse-036/GOG-3123/ENGOT-cx22)" Protocol no.: MK-2870-036 Version No. 00 dated 22-JUL-2025 with a total of up-to 55 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) The firm shall submit safety data for completed Induction phase.
(ii) Increase the number of subjects in India;
(iii) 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;
(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(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 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;

(xix) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xx) 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;

(xxi) 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
Date: 2026.03.09 16:22:15 +05'30'

(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 MSD Pharmaceuticals Private Limited, 6th Floor, Tower B, Vatika Tower, Sector-54, Gurgaon (India) - 122001 Telephone No.: null FAX: null E-Mail: SUGAM_MSDINDIA1@MERCK.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: MK-2870-036 Version No. 00 dated 22-JUL-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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.03.09 16:22:22 +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	Sacituzumab tirumotecan
Therapeutic class:	Anticancer
Dosage form:	Lyophilized Powder for solution for injection
Composition:	MK-2870 =20.0000 mg/ml In House Specification Active Histidine Hydrochloride Monohydrate Ph.Eur Inactive Histidine Ph.Eur Inactive Sucrose Ph.Eur Inactive
Indications:	Metastatic Cervical Cancer

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	TATA Memorial Hospital, Main Building, 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai Maharashtra - 400012	Institutional Ethics Committee (IEC)-I 3rd floor, Main building, IRB Department, Tata Memorial Hospital, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India. Institutional Ethics Committee (IEC)-II 3rd floor, Main building, IRB Department, Tata Memorial Hospital, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India. Institutional Ethics Committee (IEC)-III Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), Tata Memorial Centre, Paymaster	Dr Sudeep Gupta

		Shodhika, First Floor, Sector -22, Ove Village Kharghar, Navi Mumbai- 410210, Maharashtra, India. IEC – I: ECR/170/Inst/MH/2013/RR-22 IEC – II: ECR/414/Inst/MH/2013/RR-2 4 IEC – III: ECR/149/Inst/MH/2013/RR-24	
2.	Basvatarakam Indo-American Cancer Hospital & Research Institute, Road No. 14, Banjara Hills Hyderabad Andhra Pradesh - 500034	Institutional Ethics Committee Basavatarakam Indo American Cancer Hospital, RI Road No. 10, Banjara Hills, Hyderabad Telangana - 500034 India ECR/7/Inst/AP/2013/RR-20	Dr Senthil Rajappa
3.	Deenanath Mangeshkar Hospital and Research Centre, Department of Research, 6th Floor C Wing, Deenanat Mangeshkar Hospital and Research Centre, Off Karve Road. Erandawane Pune Maharashtra - 411004	Institutional Ethics committee Deenanath Mangeshkar Hospital And Research Centre, Off Karve Road, Erandawane, Pune, Maharashtra –411004, India ECR/15/Inst/Maha/2013/RR-22	Dr Chetan Deshmukh
4.	Mahatma Gandhi Cancer Hospital & Research Institute, Ethics Committee, Mahatma Gandhi Cancer Hospital & Research Institute, Institutional Review Board, 1/7 MVP Colony, Visakhapatnam Andhra Pradesh - 530017	Institutional Review Board, Mahatma Gandhi Cancer Hospital Research Institute, 1/7 MVP Colony, Visakhapatnam, Andhra Pradesh –530017, India ECR/529/Inst/AP/2014/RR-25	Dr Rajani Priya Yedla

5.	All India Institute of Medical Sciences, Ethics Committee, AllIndia Institute of Medical Sciences, Room No. 102, 1st Floor, Old O.T. Block, Ansari Nagar, New Delhi Delhi -110029	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, Delhi - 110029 India ECR/538/Inst/DL/2014/RR-25	Dr Raja Pramanik
6.	KLE University KLE Dr. PK Hospital and MRC, Nehru Nagar Belagavi Belagavi Karnataka - 590010	Institutional Ethics Committee, KLE university KLE University KLE Dr. PK hospital and MRC, Nehru Nagar, Belagavi, Belgaum, Karnataka-590010, India ECR/211/Inst/KA/2013/RR-24	Dr Rohan Bhise
7.	Apollo Speciality Hospital, New No.467, old No. 320, Padma Complex, Anna Salai, Nandanam, Chennai TamilNadu - 600035	Institutional Ethics Committee-Clinical Studies Apollo Hospitals Enterprises Limited, No-21 Greams Lane off, Greams road , Tamil Nadu -600006 India ECR/37/Inst/TN/2013/RR-24	Dr S G Raman
8.	Apollo Hospitals Enterprise Limited, Plot 13, Parsik Hill Road, Sector 23, CBD Belapur, Navi Mumbai Maharashtra -400614	Institutional Ethics Committee- Clinical Studies Apollo Hospitals Enterprise Limited Plot No -13, Parsik Hill Road, Off Uran Road Sector23, CBD Belapur, Opp Nerul Wonders Park Navi Mumbai Thane Maharashtra - 400614 India ECR/1108/Inst/MH/2018/RR-21	Dr Jyoti Bajpai
9.	Tata Memorial Centre, Mahamana Pandit Madan Mohan Malaviya Cancer Centre and Homi Bhabha Cancer Hospital, Sundar Bagiya Near Nariya Gate Banaras Hindu University Campus Varanasi Uttar	IEC, MPMMCC and HBCH Varanasi Mahamana Pandit Madan Mohan Malaviya Cancer CentreSundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus Varanasi, Uttar Pradesh - 221005 India ECR/1501/Inst/UP/2021	Dr Bipinesh Sansar

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