



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
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File No. CT/25/000187

To

M/S Glenmark Pharmaceuticals LTD.,
B/2, Mahalaxmi Chambers 22,
Bhula Bhai Desai Road,
Mumbai (India) - 400026.

Sir,

With reference to your application no. GCT/CT04/FF/2025/53864 dated 26-Dec-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"AN OPEN-LABEL, RANDOMIZED, MULTICENTER PHASE III CLINICAL TRIAL OF SHR-A1811 VERSUS INVESTIGATOR-SELECTED CHEMOTHERAPY FOR PLATINUM-RESISTANT RELAPSED EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER"** Protocol No. GSP 402-301 (SHR-A1811-315_Extension) version 3.0 dated 18-Dec-2025 with a total of up-to apporx 35 to 50 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, specifically:-

- (i) **PI shall be Medical Oncologist only.**
- (ii) **Day care center should not be a part of clinical trial.**
- (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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

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SINGH RAGHUVANSHI
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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 Glenmark Pharmaceuticals Ltd., B/2, Mahalaxmi Chambers 22, Bhula Bhai Desai Road, Mumbai (India) – 400026** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. GSP 402-301 (SHR-A1811-315_Extension) version 3.0 dated 18-Dec-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

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SINGH RAGHUVANSHI
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(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	Trastuzumab Rezetecan for Injection 100mg/vial
Therapeutic class:	Anticancer
Dosage form:	Injection (Lyophilized Powder)
Composition:	Trastuzumab Rezetecan (SHR-A1811 ADC) =100.0000mg/vial Manufacturer Specification Active Sodium Hydroxide C.P. Inactive Water for Injection C.P. Inactive Polysorbate 80 C.P. Inactive Succinic Acid C.P. Inactive Sucrose C.P. Inactive
Indications:	Platinum-Resistant Relapsed Epithelial Ovarian, Fallopian Tube, Or Primary Peritoneal Cancer

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Bhagwan Mahaveer Cancer Hospital and Research Centre, Jawahar Lal Nehru Marg Jaipur Rajasthan - 302017	Institutional Ethics Committee, Bhagwan Mahaveer Cancer Hospital & Research center, Jawaharlal Nehru Marg, Jaipur-302017 ECR/19/Inst/RJ/2013/RR-20	Dr Deepak Gupta
2.	Regional Cancer Centre, PO Box No. 2417, Medical College Campus Thiruvananthapuram Kerala - 695011	Human Ethics Committee, RCC-Regional Cancer Centre, Medical College Campus, Thiruvananthapuram - 695011, Kerala ECR/21/Inst/Ker/2013/RR-24	Dr Lakshmi Haridas
3.	TATA Memorial Hospital, Main Building, 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai Maharashtra - 400012	Institutional Ethics Committee 3rd floor, Main building, Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India. IEC I: ECR/170/Inst/MH/2013/RR-22,	Dr Sudeep Gupta
4.	TATA Memorial Hospital, Main Building, 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai Maharashtra - 400012	Institutional Ethics Committee 3rd floor, Main building, Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India. IEC II: ECR/414/Inst/MH/2013/ RR-24	Dr Sudeep Gupta
5.	Rajiv Gandhi Cancer Institute and Research Centre, Sector-5 Rohini Delhi Delhi - 110085	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Sector V, Rohini, West Metro station Delhi, South West Delhi - 110085 India ECR/10/Inst/DC/2013/RR-24	Dr Sumit Goyal
6.	The Gujarat Cancer and Research Institute Civil Hospital, Asarwa Ahmedabad Gujarat	GCRI/GCS Ethics Committee The Gujarat Cancer & Research Institute, M.P. Shah Cancer Hospital, Civil Hospital Campus, Asarwa, Ahmedabad -380 016, Gujarat, India	Dr Rajan Yadav

		ECR/41/Inst/GJ/2013/RR-24	
7.	Tata medical center, Tata medical center 14 Major Arterial Road (EW) New Town, rajarhat kolkata West Bengal - 700156	Institutional Review Board, Tata Medical Centre, 14- Major arterial Road (E-W) Rajrhat, New Town, , Kolkata, 700160 ECR/269/Inst/WB/2013/RR-24	Dr Arnab Bhattacharjee
8.	All India Institute of Medical Sciences, Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1 st Floor, Old O.T. Block, Ansari Nagar, New Delhi Delhi - 110029	AIIMS Ethics Committee, Room no- 710-711, 7th floor- NCA Building, Ansari Nagar, New Delhi - 110029, India ECR/538/Inst/DL/2014/RR-25	Dr Sachin Khurana
9.	Aster CMI Hospital, Aster CMI Hospital 43 2, New Airport Road, NH 7, Sahakara Nagar Hebbal Karnataka - 560092	Aster CMI Hospital Institutional Ethics Committee Aster CMI Hospital, 43/2, New Airport Road, NH-7, Sahakara Nagar, Hebbal Bengaluru Bengaluru (Bangalore) Urban Karnataka - 560092 India ECR/1084/Inst/KA/2018/RR-21	Dr Velukuru Sai Vivek
10.	M. S. Ramaiah Medical College and Hospital, M. S. Ramaiah Medical College and Hospital, M S Ramaiah Nagar Mathikere Karnataka - 560054	Ethics Committee M S Ramaiah Medical College & Hospitals, M S Ramaiah Nagar, MSRIT Post-560054, Bangalore, Karnataka, India. ECR/215/Inst/KA/2013/RR-22	Dr Santhosh Kumar Devadas
11.	Omega Hospital, Omega Hospital, CHR Lane, Road Number 1, Seven Hills Colony Hyderabad Telangana - 500032	Institutional Ethics Committee, Omega Hospital, MLA colony, Road no.12, Banjara Hills, Hyderabad, Telangana, 500034 ECR/596/Inst/AP/2014/RR-22	Dr Vindhya Vasini
12.	Sir H N Reliance Foundation Hospital and Research Hospital, Sir H N Reliance Foundation Hospital and Research Hospital, 3rd Floor Tower building, Medical Oncology department, Prarthana Samaj, Raja Rammohan Roy Rd, Girgaon Mumbai Maharashtra - 400004	IEC of Sir H N Reliance Foundation Hospital and Research Centre, Raja Ram Mohan Roy Road, Prarthana Samaj, Mumbai City, Maharashtra- 400004 India ECR/1389/Inst/MH/2020/RR-25	Dr Sewanti Limaye
13.	R.K. Birla Cancer Centre, Sawai Man Singh Medical College and Attached Hospitals, Department of Medical Oncology, R.K. Birla Cancer Centre, Sawai Man Singh Medical College and attached Hospitals, JLN Marg,	Ethics Committee of SMS Medical College & Attached Hospital Office of Ethics Committee, Second Floor, New Academic Block, S.M.S. Medical College & Attached Hospital, J.L.N. Marg, Jaipur-302004, Rajasthan, India.	Dr Sandeep Kumar Jasuja

	Rajasthan, India. Jaipur Rajasthan - 302004	ECR/26/INST/RJ/2013/RR-24	
14.	KIMS-Kingsway Hospitals, KIMS-Kingsway Hospitals, 44,Parwana Bhawan, Kingsway Nagpur Maharashtra - 440001	KIMS KINGSWAY HOSPITALS ETHICS COMMITTEE KIMS Kingsway Hospitals, 44, Parwana Bhawan, Kingsway, Nagpur- 440001, Maharashtra, India ECR/1269/Inst/MH/2025	Dr Saurabh Prasad
15.	Homi Bhabha Cancer Hospital and Research Centre, Plot no. 1, Medicity, New Chandigarh Mullanpur New Chandigarh Punjab - 140901	Institutional Ethics Committee Homi Bhabha Cancer Hospital And Research Centre, Department Of Radiodiagnosis, First Floor B Block, Medcity, New Chandigarh Mullanpur, SAS Nagar, Punjab - 140901 India ECR/1988/Inst/PB/2024	Dr Seema Gulia
16.	Mahamana Pandit Madan Mohan Malviya Cancer Centre, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus Varanasi Uttar Pradesh - 221005	IEC, MPMMCC and HBCH Varanasi Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi, Uttar Pradesh, 221005 India ECR/1501/Inst/UP/2021	Dr Bipinesh Sansar
17.	Vardhman Mahavir Medical College and Safdarjung Hospital, Old Sports injury Centre, Medical oncology Block, VMMC and Safdarjung Hospital, Ansari Nagar West New Delhi Delhi - 110024	Institutional Ethics Committee, VMMC and SJH, Ring Road, Ansari Nagar, New Delhi, South Delhi – 110024 ECR/593/Inst/DL/2014/RR-25	Dr Kaushal kalra
18.	Sahyadri Super Specialty Hospital, Pune, Sahyadri Superspeciality Hospital, 163 Bhosale nagar, Hadapsar Pune Maharashtra - 411028	Sahyadri Hospitals Private Limited Ethics Committee Sahyadri Hospitals Private Limited Survey No 89 And 90 Plot No 54 Lokmanya Colony Kothrud, Pune, Maharashtra -411038 India ECR/493/Inst/MH/2013/RR-24	Dr Shona Milon Nag
19.	Chittaranjan National Cancer Institute, Chittaranjan National Cancer Institute, Street Number 299, DJ Block, Action Area 1 D, Newtown Kolkata West Bengal - 700160	Institutional Ethics Committee, Chittaranjan National Cancer Institute, 37, S.P. Mukherjee Road, Kolkata 700026, West Bengal, India ECR/241/Inst/WB/2013/RR-25	Dr Chandrani Mallik

20.	Sankalp Speciality Hospital, Sankalp Speciality Hospital, Dhanvantari Marg, Vallabh Nagar, Behind Chhan Hotel, Mumbai Agra Highway, Mumbai Naka Nashik Maharashtra -422009	Sankalp Speciality Hospital Ethics Committee Sankalp Speciality Hospital, Dhanvantari Marg, Behind Chhan Hotel, Mumbai Agra Highway, Mumbai Naka, Nashik-422009, Maharashtra, India ECR/2221/Inst/MH/2026	Dr Bhushan Tapiram Nemade
21.	Indrayani Hospital and Cancer Institute, Alandi-Chakan Road, -412105, Maharashtra, India Pune Maharashtra - 412105	Narsimha Saraswati Medical Foundation Ethics Committee Indrayani Hospital And Cancer Institute, Alandi-Chakan Road Alandi Devachi Pune Maharashtra – 412105 ECR/1121/Inst/MH/2018/RR-21	Dr Asma Sadique Pathan
22.	Max Super Speciality Hospital A unit of Crosslay Remedies Ltd, Max Super Speciality Hospital A unit of Crosslay Remedies Ltd. W-3, Sector-1, Vaishali Ghaziabad Uttar Pradesh - 201012	Intuitional Ethics Committee Max Super Speciality Hospital, Vaishali (A Unit of Crosslay Remedies Ltd.), W-3, Sector-1, Vaishali, Ghaziabad, UP-201012 ECR/360/Inst/UP/2013/RR-24	Dr Gopal Sharma
23.	Malabar Cancer Centre Post Graduate Institute of Oncology Sciences and Research-PGIOSR, Moozhikkara P.O, Thalassery Kannur Kerala - 670103	Institutional Ethics Committee Malabar Cancer Centre, Moozhikkara P.O Kodyeri Thalassery Kannur Kerala - 670103 India. ECR/780/Inst/KL/2015/RR-21	Dr Nandini Devi R
24.	MNJ Institute of Oncology and Regional Cancer Centre, Red Hills, Lakdikapul Hyderabad Telangana - 500004	MNJ Institute of Oncology and Regional Cancer Centre Ethics Committee MNJ Institute Of Oncology And RCC Lakdikapul Red Hills, Hyderabad Telangana - 500004 India ECR/227/Inst/AP/2013/RR-24	Dr Parimkayala Radhika
