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/25/000046

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/2025/49192 dated 30-Apr-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Randomized, Controlled, Double-blind, Multicenter Phase III Clinical Study to Assess Efficacy and Safety of Envafolimab Plus Platinum-based Doublet Chemotherapy Versus Placebo Plus Platinum-based Doublet Chemotherapy as Neoadjuvant/Adjuvant Therapy in Subjects with Resectable Stage III Non-small Cell Lung Cancer" Protocol No. GSP 401-302 version 1.0 dated 21 April 2025 with a total of up-to 80 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) Firm should submit global data US and Japan with pooled analysis and sub-group analysis to CDSCO.

(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 Licencing 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 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;

(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 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;

(ix) 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;

(x) 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;

(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 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;

(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 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;

(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 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xix) 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;

(xx) 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: 2025.09.02 11:22:00 +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 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 401-302 version 1.0 dated 21 April 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: 2025.09.02 11:22:10 +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	Envafolimab injection 200mg/1ml.
Therapeutic class:	Antineoplastic agents, PD-1/PDL-1 (Programmed cell death protein 1/death Ligand 1) inhibitors
Dosage form:	Solution for Sub cutaneous Injection
Composition:	Each vial contains Envafolimab 200mg/ml Sodium acetate....2.72 mg/ml (Ph Eur, BP, JP, ChP, USP) L-Proline.... 25.3 mg/ml (Ph Eur, USP) Polysorbate 20....0.2 mg/ml (Ph Eur, JP, NF) Glacial acetic acid.... q.s.(Adjust pH to 6.30-6.50) (Ph Eur, BP, JP, USP) Water for Injection q.s.to 1 ml (USP)
Indications:	Resectable Stage III non-small cell lung cancer

Annexure:

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics Committee Details	Name of Investigator
1.	Malabar Cancer Centre (PGIOSR), Medical Oncology Ward, Department of Clinical Hematology and Medical Oncology, Ground floor Malabar Cancer Centre, (Post Graduate Institute of Oncology Sciences & Research), Moozhikkara P.O, Kodiyeri Thalassery, Kannur, Kerala India 670103.	Institutional Ethics Committee-Malabar Cancer Centre, Malabar Cancer Centre (PGIOSR), Moozhikkara P.O Kodiyeri Thalassery Kannur Kerala - 670103 India. ECCR/780/Inst/KL/2015/RR-21	Dr. Praveen Shenoy
2.	Apollo Cancer Hospitals, Apollo Hospitals, Jubilee Hills, Rd Number 72, Opposite Bharatiya Vidya Bhavan School, Film Nagar, Hyderabad, Telangana 500096, India	Institutional Ethics Committee-Clinical Studies Apollo Hospitals Enterprises and Limited Research and Innovations, Auditorium Ground Floor Medical College Building, Apollo Health City, Hyderabad, Telangana 500033, India ECR/38/Inst/AP/2013/RR-24	Dr. SVSS Prasad
3.	SMS Medical College & Attached Hospital, R. K. Birla Cancer Centre, SMS Hmedical College & Attached Hospitals, J.L.N. Marg, Jaipur 302004, Rajasthan, India	Ethics Committee of SMS Medical College & Attached Hospital., Office of Ethics Committee, Second Floor, New Academic Block, S.M.S. Medical College, J.L.N. Marg, Jaipur-302004, Rajasthan, India. ECR/26/Inst/RJ/2013/RR-24	Dr. Sandeep Kumar Jasuja
4.	SunAct Cancer Institute Pvt Ltd, 4th Floor, Tieten Medicity Hospital, Kasarvadavali, Ghodbunder Road, Thane West, Maharashtra - 400615, India	Vedant Hospital Institutional Ethics Committee, Tieten Hospital, Kasarvadavli, Ghodbunder Road, Thane West, Maharashtra - 400615, India ECR/1154/Inst/MH/2018/RR-22	Dr. Vijay M. Patil
5.	HCG Cancer Centre, Shipra Path 52/36, Ward 27, Sector 5, Mansarovar, Jaipur-302020, Rajasthan, India	HCGEL Jaipur Institutional Ethics Committee, Shipra Path 52/36, Ward 27, Sector 5, Mansarovar, Jaipur-302020, Rajasthan, India ECR/1625/INSt/RJ/2021	Dr. Jitendra Kumar Pehalajani
6.	Fortis Flt Lt. Rajan Dhall Hospital, Sector-B, Pocket 1, Aruna Asaj Ali Marg, Vasant Kunj, New Delhi 110070, India	Ethics Committee for Research, Fortis Flt Lt Rajan Dhall Hospital, Sector-B, Pocket-1, Aruna Asif Ali Marg, Vasant Kunj, New Delhi-110070, Delhi ECR/57/Inst/DL/2013/RR-24	Dr. Amit Bhargava

7.	Regional Cancer Centre, Medical College Campus, Medical College P.O, Thiruvananthapuram, Kerala - 695011, India	Human Ethics Committee, Regional Cancer Centre, Medical College Campus, Thiruvananthapuram - 695011, Kerala ECR/21/Inst/Ker/2013/RR-24	Dr. Anoop TM
8.	Max Super Speciality Hospital, Dwarka (A Unit of Muthoot Hospitals Pvt Ltd), Plot No. 1, Sector 10, Dwarka, New Delhi - 110075, India	Max Healthcare Ethics Committee (MHEC), Ground Floor, Office of Ethics Committee, West Block, Near MS office, Max Super Speciality Hospital, Saket (West Vlock), (A Unit of Max Healthcare Institute Limited) 1, Press Enclave Road, Saket. New Delhi- 110017, India ECR/118/Inst/DL/2013/RR-24	Dr. Hari Goyal
9.	Sir H N Reliance Foundation Hospital and Research Hospital, 3rd Floor Tower building, Medical Oncology department, Prarthana Samaj, Raja Rammohan Roy Rd, Girgaon, Mumbai 400004, Maharashtra, India	IEC of Sir H N Reliance Foundation Hospital And Research Centre Sir H N Reliance Foundation Hospital and Research Centre, Raja Ram Mohan Roy Road, Prarthana Samaj, Girgaum Mumbai (India) - 400004 India ECR/1389/Inst/MH/2020	Dr. Sewanti Limaye
10.	Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune 411001, Maharashtra, India	Institutional Ethics Committee Poona Medical Research Foundation, E 4-C to E 4-F, 4th Floor, 5th Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India ECR/24/INST/MH/2013/RR-22	Dr. Minish Jain
11.	Dept. of Medical Oncology, MVR Cancer Centre and Research Institute, CP 13/516 B.C, Vellalasseri, NIT (Via) , Poolacode, Kozhikode, 673601, Kerala, India	Institute of Ethics Committee MVR Cancer Centre and Research Institute, Vellalasseri, NIT (Via), Poolacode, Kozhikode, 673601, Kerala, India ECR/1259/Inst/KL/2019/RR-24	Dr. Narayanankutty Warrier
12.	MOC Cancer Care & Research Centre, 1st Floor, SS House, Nehru Road, Vile Parle, Mumbai 400057, Maharashtra, India	Mumbai Oncocare Centre Institutional Ethics Committee (MOC IEC) 1 To 4 floor -1st shreepati Arcade, August kranti Marg, Nana Chowk, Mumbai 400036, Maharashtra, India ECR/1277/Inst/MH/2019/RR-24	Dr. Ashish Joshi
13.	Sir Ganga Ram Hospital, Medical Oncology Department, Sir Ganga Ram Marg, Old Rajinder Nagar, New Delhi-110060, India	Sir Ganga Ram Hospital, Ethics Committee, Sir Ganga Ram Hospital Old, Rajinder Nagar, New Delhi, Delhi – 110060, India ECR/20/INST/DL/2013/RR-24	Dr. Shyam Aggarwal

14.	Department of Medical Oncology, HCG-City Cancer Centre, 35-25-33, CH Venkata Krishnayya Street, Suryarao Pet, Vijayawada 520002, Andhra Pradesh, India	Institutional Ethics committee-HCG Curie City Cancer centre 44-1-1/3, Machavaram, Gunadala, Vijayawada-520004, Andhra Pradesh, India ECR/869/Inst/Ap/2016/RR-24	Dr. Lakshmi Priyadarshini K.
15.	Healthcare Global Enterprises Limited #8, HCG Towers, P. Kalinga Rao road, Sampangi Rama Nagar, Bengaluru, Karnataka- 560027 India	HCG Central Ethics Committee HCG Bangalore Institute of Oncology, HCG Towers, Tower-I P, Kalinga Rao Road, Sampangiram Nagar, Bangalore Bengaluru (Bangalore), Urban Karnataka 560027, India ECR/386/Inst/KA/2013/RR-24	Dr. Govind Babu K.
16.	Unique Hospital Multispeciality and Research Institute, Nr. Kiran Motors, Opp Unique hospital B.R.T.S Junction, Civil Char rasta - Sosyo Circle Lane, Off ring road, Surat 395002, Gujarat, India	Ethics Committee, Unique Hospital - Multispecialty & Research Institute Near Kiran Motors, Opp Unique Hospital B.R.T.S Junction, Civil Char rasta - Sosyo Circle Lane, Off ring road, Surat 395002, Gujarat, India ECR/595/Inst/GJ/2014/RR-20	Dr. Tanveer Maksud
17.	Sankalp Speciality Hospital, Dhanvantari Marg, Vallabh Nagar, Behind Chhan Hotel, Mumbai Agra Highway, Mumbai Naka, Nashik-422009, Maharashtra, India	Navsanjeevani Hospital Ethics Committee, Navsanjeevani Hospitals, Plot no 8, Motkari Nagar, Tidke Colony, Mumbai Naka, Nashik Maharashtra - 422002 India. ECR/1036/Inst/MH/2018/RR-21	Dr. Bhushan Tapiram Nemade
18.	The Gujarat Cancer & Research Institute, M.P. Shah Cancer Hospital, Civil Hospital Campus, Asarwa, Ahmedabad -380016, Gujarat, India	GCRI/GCS Ethics Committee The Gujarat Cancer & Research Institute, M.P. Shah Cancer Hospital, Civil Hospital Campus, Asarwa, Ahmedabad -380 016, Gujarat, India ECR/41/Inst/GJ/2013/RR-24	Dr. Rajan Yadav
19.	Chittaranjan National Cancer Institute, Street Number 299, DJ Block, Action Area 1D, Newtown, Kolkata 700160, West Bengal, India	Institutional Ethics Committee, Chittaranjan National Cancer Institute 37, S.P. Mukherjee Road, Kolkata 700026, West Bengal, India ECR/241/Inst/WB/2013/RR-20	Dr. Chandrani Mallik
20.	LMMF's Deenanath Mangeshkar Hospital & Research Center, Erandawane, Pune 411004, Maharashtra, India	Institutional Ethics committee Deenanath Mangeshkar Hospital & Research Centre Off Karve Road, Erandawane, Pune, Maharashtra - 411004, India ECR/15/Inst/Maha/2013/RR-22	Dr. Chetan Dilip Deshmukh

21.	Department of Medical Oncology, Vardhman Mahavir Medical College and Safdarjung Hospital, H693+H6W, NH 48, near AIIMS Hospital, Ansari Nagar West, New Delhi, Delhi 110029, India.	Institutional Ethics Committee VMMC and SJH VMMC and Safdrajung Hospital, Ring Road Ansari Nagar, New Delhi, South Delhi, Delhi 110029, India ECR/593/Inst/DL/2014/RR-20	Dr. Kaushal Kalra
22.	Fortis Memorial Research Institute, Gurgaon, Sector - 44, Opposite HUDA City Centre, Gurugram, Haryana 122002, India	Institutional Ethics Committee, Fortis Memorial Research Institute, Sector - 44, Gurugram, Haryana 122002 ECR/223/Inst/HR/2013/RR-22	Dr. Ankur Bahl
23.	All India Institute of Medical Science, Dept. of Medical Oncology, 1st Floor, Dr. B. R. A. Institute Rotary Cancer Hospital, Ansari Nagar, New Delhi 110029, India.	AIIMS ETHICS COMMITTEE IEC, AIIMS, Room no- 102, First floor, Old O.T. Block, Ansari Nagar, New Delhi - 110029, India ECR/538/Inst/DL/2014/RR-20	Dr. Sachin Khuarana
24.	Asian Cancer Institute-ACI Hospitals, August Kranti Marg Road, Kemp's Corner, Cumballa Hill, Mumbai 400036, Maharashtra, India	Asian Institute of Oncology Private Limited Institutional Ethics Committee Asian Cancer Institute Cumballa Hill Hospital, 93/95, Cumballa Hill Hospital, August Kranti Marg, Kemps Corner, Mumbai City, Maharashtra 400036, IndiaE ECR/1624/Inst/MH/2021	Dr. Ramakant Deshpande
25.	Sahyadri Super Speciality Hospital, Department of Medical Oncology, Plot No. 30 C, Erandawane, Karve Road, Pune 411004, Maharashtra, India	Sahyadri Hospitals Pvt Ltd. Ethics Committee Sahyadri Hospitals Pvt. Ltd., Survey No. 89 and 90, Plot No. 54, Lokmanya Colony, Kothrud, Pune 411038, Maharashtra, India ECR/493/Inst/MH/2013/RR-24	Dr. Tushar Patil

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