September 05, 2025

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.
Phiroze Jeejeebhoy Towers
Dalal Street, Fort, Mumbai – 400 001

Ref: Scrip Code: 532296

To,
The Manager – Listing,
The National Stock Exchange of India Ltd.,
Plot No. C/1, G Block
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051

Ref: Scrip Name: GLENMARK

Dear Sir,

Sub: Glenmark Initiates a Multi-Country Phase 3 Clinical Trial for Envafolimab in Resectable Stage III Non-Small Cell Lung Cancer

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Limited

HARISH VINAYAK KUBER
Digitally signed by HARISH VINAYAK KUBER
Date: 2025.09.05 09:40:28 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Encl: As above

Press Release
For Immediate Distribution

glenmark
A new way for a new world

Glenmark Initiates a Multi-Country Phase 3 Clinical Trial for Envafolimab in Resectable Stage III Non-Small Cell Lung Cancer

DCGI grants No Objection Certificate to commence enrollment in India

Clinical Trial Applications underway in Russia, Brazil, and Mexico

Mumbai, India, 05, September 2025 – Glenmark Pharmaceuticals Ltd., a research-led, global pharmaceutical company, today announced the initiation of a multi-country (ex-China) Phase 3 Clinical Trial for Envafolimab, a novel subcutaneous PD-L1 inhibitor, in patients with resectable Stage III Non-Small Cell Lung Cancer (NSCLC) in the neoadjuvant/adjuvant setting. The Company has received approval from the Drugs Controller General of India (DCGI) to begin patient enrollment and dosing in the country.

In parallel, Glenmark has submitted a Clinical Trial Application (CTA) in Russia and is preparing to open additional clinical trial sites in Brazil and Mexico, further expanding the global footprint of this pivotal study.

The randomized, multi-center, Phase 3 trial will assess the efficacy, safety, pharmacokinetics, and immunogenicity of Envafolimab in patients with resectable Stage IIIA and IIIB (N2) NSCLC, while a parallel Phase 3 study of Envafolimab sponsored by 3D Medicines Inc., was initiated in December 2023 and is actively recruiting in China.

Lung cancer remains the leading cause of cancer-related deaths worldwide, with NSCLC comprising approximately 80-85%[1] of cases, and 20-30% diagnosed at Stage III[2]. Despite surgical options for a subset of Stage III patients, five-year survival remains poor, ranging from 36% and 26% at Stage IIIA and IIIB[3] respectively. These outcomes highlight the urgent need for innovative, accessible immunotherapy options like Envafolimab to improve prognosis in resectable Stage III NSCLC.

Commenting on the announcement, Dr. Monika Tandon, Global Head of Clinical Development, Glenmark Pharmaceuticals Limited, said, "The initiation of this pivotal Phase 3 study for Envafolimab marks an important milestone in Glenmark's journey to reimagine possibilities in oncology. With its novel subcutaneous administration, Envafolimab has the potential to make cutting-edge immunotherapy more accessible and convenient for patients worldwide, especially in regions where healthcare resources are constrained. By advancing this trial across multiple geographies, we are reinforcing our commitment to transforming the standard of care in Stage III NSCLC and addressing one of the greatest unmet needs in cancer treatment today."

[1&2] PubMed Central
[3] PubMed

Glenmark
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About Envafolimab

Envafolimab is a novel anti-PD-L1 inhibitor (recombinant single domain anti-PD-L1 fused with Fc portion of human IgG1) administered subcutaneously, invented by Alphamab Oncology, and co-developed with 3D Medicines Inc. since 2016. Envafolimab Injection is approved by National Medical Products Agency (NMPA) in China in November 2021, as a global-first subcutaneous anti-PD-L1, for the treatment of advanced unresectable or metastatic solid tumors with MSI-H/dMMR. More than 40,000 cancer patients have already benefited in China from this innovative drug. The product has also been included in the 'List of breakthrough therapies' by the NMPA. In 2024, Alphamab Oncology and 3D Medicines Inc. entered into a licensing agreement with Glenmark Pharmaceuticals for Envafolimab, pursuant to which Glenmark was granted an exclusive license for development, registration and commercialization of oncology indications of Envafolimab in India, Asia Pacific (except Singapore, Thailand, Malaysia), the Middle East and Africa, Russia, Commonwealth of Independent States and Latin America. Currently, Envafolimab is also undergoing clinical development in multiple Phase 2 and Phase 3 trials for the treatment of various tumors e.g., resectable non-small cell cancer, advanced/metastatic biliary tract cancer, metastatic endometrial cancer, renal cell cancer, etc. Availability of this novel immune-oncology therapy will help reduce the burden on patients, caregivers and health care system because of its unique subcutaneous administration (faster administration within 30 seconds, like a regular subcutaneous injection).

About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. Scrip 100 positions Glenmark amongst the Top 100 biopharmaceutical companies ranked by Pharmaceutical Sales in 2023; while Generics Bulletin places it in the Top 50 Generics and biosimilar companies ranked by sales in 2024. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted over 3.3 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (Glenmark_pharma).

For more information, please contact

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