

Press Release

For Immediate Release

Glenmark, Jiangsu Alphamab Biopharmaceuticals and 3D Medicines announce the signing of a License Agreement for KN035 (Envafohimab) for Multiple Geographies around the World

- *Glenmark will be responsible for further developing, registering, and commercializing Envafohimab in India, Asia Pacific, Middle East and Africa, Russia, CIS, and Latin America.*
- *Jiangsu Alphamab (on behalf of the Licensors) will receive a low double digit Million US Dollar amount up to launch, additional triple digit Million US Dollar milestone payments based on sales performance across the length of the agreement, and a royalty fee of single-to-double-digits percentage according to the level of net sales.*
- *Jiangsu Alphamab will be responsible of manufacturing KN035 within and outside the Territory.*

Mumbai, India, January 25, 2024: Glenmark Specialty S.A. (GSSA), a subsidiary of Glenmark Pharmaceuticals Ltd. (Glenmark), today announced the signing of a license agreement with JIANGSU ALPHAMAB BIOPHARMACEUTICALS CO., LTD (Jiangsu Alphamab) and 3D MEDICINES (BEIJING) CO., LTD. (3DMed), (together as the Licensors), for KN035 (Envafohimab) for India, Asia Pacific, Middle East and Africa, Russia, CIS, and Latin America (the Territory).

Under the terms of the agreement, GSSA will receive from Jiangsu Alphamab and 3DMed, an exclusive license to develop, register, commercialize, Envafohimab for the oncology indication in the Territory. Jiangsu Alphamab will be the exclusive supplier of the product. Jiangsu Alphamab (on behalf of the Licensors) will receive a low double digit Million US Dollar amount up to launch, additional triple digit Million US Dollar milestone payments based on sales performance across the length of the agreement, and a royalty fee of single-to-double-digits percentage according to the level of net sales.

"This is an important milestone for Glenmark, as through this transformational deal, we gain access to the first recombinant humanized single domain antibody against PD-L1 in a Sub-Q formulation for a wide territory globally. We are excited at the opportunity to take this innovative immuno-oncology product to cancer patients across the emerging markets and meaningfully contribute towards improving their access to potentially life-saving treatments." remarked Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd.

Envafohimab, under the brand name ENWEIDA (恩維達®) has been approved in China by the National Medical Products Administration (Chinese NMPA) in November 2021 as the global-first subcutaneous injection PD-L1 inhibitor for the treatment of adult patients with previously treated microsatellite instability-high (MSI-H) or deficient Mismatch repair (dMMR) advanced solid tumor. Over 30,000 patients have already greatly benefited from this innovative treatment in China where, in December 2023, it has also been officially included in the "List of Breakthrough Therapies" by the NMPA.*

Overall, dMMR prevalence across 13 tumor types (based on 54 papers and 20,383 patients) was estimated at 16% (11%–22%)**, which makes it quite a widespread genetic signature among cancer patients. Envafohimab has the potential to provide an effective treatment for such population across Emerging Markets and beyond.

Furthermore, Envafohimab is currently being developed in the USA by Traccon Pharma in a pivotal trial in soft tissue sarcoma (STS) subtypes including Undifferentiated Pleomorphic Sarcoma (UPS) and the genetically related myxofibrosarcoma (MFS). Envafohimab has obtained two orphan drug designation from the U.S. FDA for advanced biliary tract cancer and soft tissue sarcoma (STS) and a Fast Track designation for STS. Additional indications such as Biliary Tract cancer and non-small cell lung cancer are currently in development.

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ABOUT KN035 (Envafohimab Injectable) (brand name: ENWEIDA, 恩維達®)

KN035 (Envafohimab Injectable) is a recombinant single domain antibody against PD-L1 fused with human Fc, a drug independently invented by Alphamab Oncology and co-developed with 3D Med Beijing since 2016. On December 20, 2019, TRACON Pharmaceuticals, Inc., the shares of which are listed on the Nasdaq Global Select Market (ticker symbol: TCON), was granted the exclusive and nontransferable license in the U.S., Canada, Mexico and each of their dependent territories for KN035 in the field of human therapeutic applications for sarcoma. On March 30, 2020, Jiangsu Alphamab, a wholly-owned subsidiary of Alphamab Oncology, Jiangsu Simcere Pharmaceutical Co., Ltd.* (江蘇先聲藥業有限公司) ("Jiangsu Simcere"), a subsidiary of Simcere Pharmaceutical Group Limited, the shares of which are listed on the Stock Exchange (stock code: 2096), and 3D Med Beijing entered into a cooperation agreement (the "Simcere Agreement"). Pursuant to the Simcere Agreement, Jiangsu Simcere has been granted an exclusive marketing right in respect of oncology indications of KN035 and the rights of first refusal for in-licenses or transfers in mainland China. And it has been approved by the National Medical Products Administration of China (國家藥品監督管理局) as the global-first subcutaneous injection PD-L1 inhibitor in November 2021.

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 10 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2022. The company has also been Great Place To Work® Certified™ in India for FY 2023. 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 2.9 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).

About Alphamab Oncology

Alphamab Oncology is a leading biopharmaceutical company committed to the discovery, development, manufacturing, and commercialization of cutting-edge biotherapeutics for the treatment of cancer. On December 12, 2019, the company was successfully listed on the Main Board of the Hong Kong Stock Exchange, trading under the stock code 9966.

Our integrated platform seamlessly combines research, development, and manufacturing capabilities for biologics. We take pride in our extensive intellectual property portfolio, encompassing protein/antibody engineering, antibody screening, and multi-module/multi-functional antibody modification.

Distinguished by a globally competitive pipeline, Alphamab Oncology specializes in antibody-drug conjugation, single domain antibody/monoclonal antibodies, and multi-functional antibodies. Notably, Envafohimab, the world's first subcutaneously injectable PD-L1 inhibitor, received approval from Chinese authorities in 2021, offering widespread accessibility to cancer patients. Three additional products are currently in the advanced stages of clinical development, with KN026 having earned Breakthrough Designation from the China National Medical Products Administration. Furthermore, we have cultivated a series of early-stage assets, including two in Phase I development.

Our overarching mission is to enhance the manageability and curability of cancer by addressing unmet medical needs in oncology. Alphamab Oncology is dedicated to the development of safe and affordable drugs, leveraging a global competitive edge.

About 3D Medicines, Inc.

3D Medicines, Inc. is a commercial-stage biopharmaceutical company with a mission to help people with cancer live longer and better. Envisioning a future when cancer is managed as a chronic disease, 3D Medicines focuses on the development of differentiated immuno-oncology drugs, helping cancer patients live with prolonged survival time and a better quality of life. 3D Medicines has established a pipeline with both biological macromolecule and chemotherapeutic small-molecule drugs, as well as a professional team capable of global development, registration and commercialization operation.

References:

* Data on file

***Epidemiology of Microsatellite Instability High (MSI-H) and Deficient Mismatch Repair (dMMR) in Solid Tumors: A Structured Literature Review (Maria Lorenzi et al.)*

Contacts

Glenmark Pharmaceuticals Ltd. Udaykumar Murthy Corporate Communications +91 9960377617 corpcomm@glenmarkpharma.com	Alphamab Oncology Media@alphamabonc.com
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