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Glenmark inks licensing agreement with Chinese firms for oncology drug Envafolimab

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Registering, and commercialising Envafolimab in India, Asia Pacific, Middle East and Africa, Russia, CIS, and Latin America

Glenmark Specialty S.A. (GSSA), a subsidiary of India-based Glenmark Pharmaceuticals Ltd. (Glenmark), has announced the signing of a license agreement with China-based Jiangsu Alphamab and 3DMed (together as the Licensors), for KN035 (Envafolimab) 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, commercialise, Envafolimab 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 dollar amount up to launch, additional triple digit million 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.

Envafolimab, under the brand name ENWEIDA 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 tumour.

Over 30,000 patients have already 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.

Furthermore, Envafolimab is currently being developed in the US by Tracon Pharma in a pivotal trial in soft tissue sarcoma (STS) subtypes including Undifferentiated Pleomorphic Sarcoma (UPS) and the genetically related myxofibrosarcoma (MFS). Envafolimab has obtained two orphan drug designation from the US FDA for advanced biliary tract cancer and 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.