

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives 2nd ANDA tentative approval for Saxagliptin Tablets, 2.5 mg and 5 mg

Mahwah, New Jersey, Mumbai, India; February 17, 2023 – Glenmark Pharmaceuticals Inc., USA (Glenmark) has received a 2nd tentative approval by the United States Food & Drug Administration (U.S. FDA) for Saxagliptin Tablets, 2.5 mg and 5 mg, the generic version of Onglyza^{®1} Tablets, 2.5 mg and 5 mg, of AstraZeneca AB. Glenmark's first tentative approval letter for Saxagliptin Tablets, 2.5 mg and 5 mg was received on June 12, 2017.

According to IQVIA[™] sales data for the 12-month period ending December 2022, the Onglyza[®] Tablets, 2.5 mg and 5 mg market² achieved annual sales of approximately \$122.3 million*.

Glenmark's current portfolio consists of 179 products authorized for distribution in the U.S. marketplace and 46 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

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About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an innovation-driven, global pharmaceutical company with 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, 2021; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2021. Glenmark has impacted over 2.6 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).

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References:

¹All brand names and trademarks are the property of their respective owners.

²Market includes brand and all available therapeutic equivalents

*IQVIA[™] National Sales Perspectives: Retail & Non-Retail, December 2022