

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 mg

Mahwah, New Jersey, USA and Mumbai, India, November 7, 2023: Glenmark Pharmaceuticals Ltd. (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 mg, the generic version of Prolixin^{®1} Tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, of Apothecon Inc. Glenmark's Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 mg, will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA.

According to IQVIA[™] sales data for the 12-month period ending September 2023, the Prolixin[®] Tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg market² achieved annual sales of approximately \$18.1 million*.

Glenmark's current portfolio consists of 189 products authorized for distribution in the U.S. marketplace and 50 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 Limited

Glenmark Pharmaceuticals Limited (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, 2021; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2021. The company has also been Great Place To Work[®] Certified[™] in India. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), becoming the second Indian Pharmaceuticals company to achieve this approval. 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).

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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, September 2023