

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives sANDA approval for Tacrolimus Ointment, 0.03%

Mumbai, India and Mahwah, New Jersey, August 17, 2023: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, integrated, global pharmaceutical company has received final approval by the United States Food & Drug Administration (U.S. FDA) Tacrolimus Ointment, 0.03%, the generic version of Protopic¹ Ointment, 0.03%, of Leo Pharma AS. Glenmark's Tacrolimus Ointment, 0.03%, will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA.

According to IQVIATM sales data for the 12-month period ending June 2023, the Protopic[®] Ointment, 0.03% market² achieved annual sales of approximately \$15.4 million*.

Glenmark's current portfolio consists of 184 products authorized for distribution in the U.S. marketplace and 51 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 Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an integrated, research-led, 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. The company has also been Great Place To Work[®] CertifiedTM 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

*IQVIATM National Sales Perspectives: Retail & Non-Retail, June 2023