

Press Release

For Immediate Release

## **Glenmark Pharmaceuticals receives ANDA approval for Calcipotriene and Betamethasone Dipropionate Foam, 0.005%|0.064%**

**Mumbai, India and Mahwah, New Jersey, March 23, 2023:** Glenmark Pharmaceuticals Ltd. (Glenmark), an innovation-driven, global pharmaceuticals company has received final approval by the United States Food & Drug Administration (U.S. FDA) for Calcipotriene and Betamethasone Dipropionate Foam, 0.005%|0.064%, the generic version of Enstilar<sup>®1</sup> Foam, 0.005%|0.064%, of Leo Pharma AS.

With respect to 180-day generic drug exclusivity, the FDA noted that Glenmark was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Calcipotriene and Betamethasone Dipropionate Foam, 0.005%|0.064%. Therefore, with this approval, Glenmark is eligible for 180-days of generic drug exclusivity for Calcipotriene and Betamethasone Dipropionate Foam, 0.005%|0.064%.

According to IQVIA<sup>™</sup> sales data for the 12-month period ending January 2023, the Enstilar<sup>®</sup> Foam, 0.005%|0.064% market<sup>2</sup> achieved annual sales of approximately \$93.6 million\*.

Glenmark's current portfolio consists of 183 products authorized for distribution in the U.S. marketplace and 45 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 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. The company has been Great Place To Work<sup>®</sup> Certified<sup>™</sup> in India, in 2023. Glenmark has impacted over 2.6 million lives over the last decade through its CSR interventions. For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com). Follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark\_pharma).

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**References**

<sup>1</sup>All brand names and trademarks are the property of their respective owners.

<sup>2</sup>Market includes brand and all available therapeutic equivalents

\*IQVIA™ National Sales Perspectives: Retail & Non-Retail, January 2023