

## Glenmark Pharmaceuticals receives ANDA approval for Topiramate Capsules USP, 15 mg and 25 mg

**Mahwah, New Jersey, USA and Mumbai, India, July 17, 2024:** Glenmark Pharmaceuticals Ltd. (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Topiramate Capsules USP, 15 mg and 25 mg. Glenmark's Topiramate Capsules USP, 15 mg and 25 mg has been determined by the FDA to be bioequivalent and therapeutically equivalent<sup>1</sup> to Topamax<sup>®2</sup> Capsules, 15 mg and 25 mg of Janssen Pharmaceuticals, Inc., and will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA.

According to IQVIA<sup>™</sup> sales data for the 12-month period ending May 2024, the Topamax<sup>®</sup> Capsules, 15 mg and 25 mg market<sup>3</sup> achieved annual sales of approximately \$21.9 million\*.

Glenmark's current portfolio consists of 198 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 Ltd.**

Glenmark Pharmaceuticals Ltd. (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 11 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, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2022. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted more than 3 million lives over the last decade through its CSR interventions. For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com). You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram ([glenmark\\_pharma](https://www.instagram.com/glenmark_pharma)).

### **For more information, please contact**

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### **References:**

<sup>1</sup>Glenmark's Topiramate Capsules USP, 15 mg and 25 mg is only approved for the indication(s) listed in Glenmark's approved label.

<sup>2</sup>All brand names and trademarks are the property of their respective owners.

<sup>3</sup>Market includes brand and all available therapeutic equivalents. Note: IQVIA data obtained by Glenmark is only available for all approved RLD indications. Glenmark's product is only approved for the indications listed in Glenmark's approved label and is not marketed for all RLD indications.

\*IQVIA<sup>™</sup> National Sales Perspectives: Retail & Non-Retail, May 2024