

Press Release

For immediate distribution

Glenmark Pharmaceuticals receives ANDA approval for Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg and 200 mg

Mumbai, India, March 21, 2022: Glenmark Pharmaceuticals Inc., USA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for its Lacosamide Tablets¹ USP, 50 mg, 100 mg, 150 mg and 200 mg, the generic version of Vimpat^{®2} Tablets, 50 mg, 100 mg, 150 mg and 200 mg of UCB, Inc. The company plans to launch the product immediately.

Commenting on the development, Robert Crockart, Chief Commercial Officer, Glenmark Pharmaceuticals Ltd, said, “The FDA approval for generic Lacosamide Tablets USP reiterates our ongoing commitment to make treatment options more accessible for patients. We look forward to quickly launching this product in the U.S. market.”

According to IQVIA™ sales data for the 12 month period ending January 2022, the Vimpat[®] Tablets, 50 mg, 100 mg, 150 mg and 200 mg market³ achieved annual sales of approximately \$1.7 billion*.

Glenmark’s current portfolio consists of 174 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. (Glenmark) is a global innovation-driven pharmaceutical company with presence across Specialty, Generics and OTC businesses. Globally, Glenmark focuses on the following key therapy areas: respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents and operations in over 80 countries. It was ranked among the world's top 50 Generics and Biosimilars companies (Top 50 Company Rankings, 2020, from Informa's Generics Bulletin). The company has been listed on the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for the fourth consecutive year in a row, most recently in 2021. DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally with only the top ranked companies in terms of Corporate Sustainability within each industry are featured in the index. www.glenmarkpharma.com

For more information, please contact:

Udaykumar Murthy

Deputy General Manager, Corporate Communications

+91 9960377617 | corpcomm@glenmarkpharma.com

References:

¹Glenmark's Lacosamide Tablets are only approved for their FDA-approved indication.

²All brand names and trademarks are the property of their respective owners.

³Market includes brand and all available therapeutic equivalents.

*IQVIA™ National Sales Perspectives: Retail & Non-Retail, January 2022