

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC)

Mahwah, New Jersey, USA and Mumbai, India, April 29, 2024: Glenmark Pharmaceuticals Ltd. (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC), determined by the FDA to be bioequivalent¹ to Advil^{®2} Dual Action with Acetaminophen Tablets, 250 mg/125 mg (OTC), of Haleon US Holdings, LLC. Glenmark's Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC), will be distributed in the U.S. by Glenmark Therapeutics Inc., USA.

According to Nielsen[®] syndicated data for the latest 52 weeks period ending March 23, 2024, the Advil[®] Dual Action with Acetaminophen Tablets, 250 mg/125 mg (OTC) market³ achieved annual sales of approximately \$84.1 million*.

Glenmark's current portfolio consists of 195 products authorized for distribution in the U.S. marketplace and 52 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 around 3 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).

For more information, please contact

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References:

¹Glenmark's Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC) are only approved for the indications listed in Glenmark's approved drug facts label.

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

³Market includes brand and all available therapeutic equivalents.

*Nielsen[®] NIQ Discover; Syndicated Data for Period Ending March 23, 2024.