Press Release
For Immediate Distribution

Glenmark receives ANDA approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC)

Mahwah, New Jersey, March 20, 2025: Glenmark Pharmaceuticals Inc., USA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC), determined by the FDA to be bioequivalent[1] to Pataday®[2] Once Daily Relief Ophthalmic Solution, 0.2% (OTC), of Alcon Laboratories, Inc. Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (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 February 22, 2025, the Pataday® Once Daily Relief Ophthalmic Solution, 0.2% (OTC) market[3] achieved annual sales of approximately $50.7 million*.

Commenting on the launch, Marc Kikuchi, President & Business Head, North America said, "We are pleased to continue to expand our OTC ophthalmic portfolio. The addition of Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% highlights our commitment to meeting market needs and providing quality over-the-counter solutions for our customers."

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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 cardio-metabolic, respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. Scrip 100 positions Glenmark amongst the Top 100 biopharmaceutical companies ranked by Pharmaceutical Sales in 2023; while Generics Bulletin places it in the Top 50 Generics and biosimilar companies ranked by sales in 2024. 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 over 3.3 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).

Glenmark
A new way for a new world

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References:

[1]Glenmark's Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC) is only marketed for the indications listed in Glenmark's approved drug facts label.

[2] This product is not manufactured or distributed by Alcon Laboratories, Inc., distributor of Pataday® Once Daily Relief, and/or Novartis AG, owner of the registered trademark Pataday®, respectively. [Neither Alcon nor Novartis make or license Glenmark's product.]

[3]Market includes brand and all available therapeutic equivalents. Note: Nielsen syndicated 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.

*Nielsen® NIQ Discover; Syndicated Data for Period Ending February 22, 2025