

Glenmark Specialty SA Receives U.S. FDA Approval for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation, with 180-Day Competitive Generic Therapy Exclusivity

Elmwood Park, New Jersey, March 04, 2026 – Glenmark Specialty SA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation.

Glenmark's Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation has been determined by the FDA to be bioequivalent and therapeutically equivalent¹ to the reference listed drug (RLD), FloVent^{®2} HFA Inhalation Aerosol, 44 mcg of GlaxoSmithKline Intellectual Property Ltd. England (NDA – 021433).

Glenmark has been granted a Competitive Generic Therapy (CGT) designation for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation and is the "first approved applicant" as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Glenmark is eligible for 180 days of CGT exclusivity upon commercialization.

Glenmark's Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA starting in March 2026. The approval further strengthens Glenmark's respiratory portfolio in the U.S. and underscores its commitment to expanding access to quality inhalation therapies.

According to IQVIA[™] sales data for the 12-month period ending January 2026, the FloVent[®] HFA Inhalation Aerosol, 44 mcg market³ achieved annual sales of approximately \$520.1 million*.

Commenting on the launch, Marc Kikuchi, President & Business Head, North America said, "Receiving approval for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation marks an important milestone in strengthening our respiratory portfolio in the U.S. The CGT designation and first approved applicant status reflect the technical expertise and dedication of our teams in bringing complex inhalation therapies to market. We remain committed to improving access to quality and affordable respiratory treatments for patients and healthcare providers."

¹Glenmark's Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation is only approved for the indication(s) listed in Glenmark's approved label.

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

³Market 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™ National Sales Perspectives: Retail & Non-Retail, January 2026

About Glenmark Pharmaceuticals Limited

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a global, research-led pharmaceutical company with a unique focus on innovation and accessibility. We pioneer transformative breakthrough therapies that aim to redefine treatment while expanding access to high-quality and affordable medicines for patients around the world. With 11 world-class manufacturing facilities across four continents, supported by six cutting-edge R&D centres, and a commercial footprint in 80+ countries, we deliver a diversified portfolio across branded, specialty, generics, and consumer health products, with a focus on respiratory, dermatology, and oncology. Scrip 100 positions Glenmark among the Top 100 biopharmaceutical companies globally by pharmaceutical sales for 2024. For more information, visit www.glenmarkpharma.com

For more information, please contact

Akhila Natarajan | mediarelations@glenmarkpharma.com | +91 98216 89525
Adfactors PR | glenmark@adfactorspr.com | +91 88502 91322