Press Release **For Immediate Distribution**

Glenmark Specialty S.A. (Switzerland) receives NDA Approval by the United States Food and Drug Administration (FDA) for Ryaltris™ Nasal Spray for the Treatment of Symptoms of Seasonal Allergic Rhinitis in Adults and Pediatric Patients 12 Years of Age and Older

- *Ryaltris™ is a metered, fixed-dose, aqueous suspension, prescription drug product nasal spray approved by the FDA for the treatment of symptoms of Seasonal Allergic Rhinitis in adults and pediatric patients 12 years of age and older.*
- *Ryaltris™ will be marketed and distributed in the United States through our partner Hikma Specialty U.S.A. Inc., Columbus, OH.*

Mumbai, India; New Jersey; USA; January 14, 2022: Glenmark Pharmaceuticals Limited, a research-led, global integrated pharmaceutical company announced that its fully owned subsidiary Glenmark Specialty S.A. (Switzerland), received FDA approval on its New Drug Application (NDA) for Ryaltris™, an innovative, fixed-dose (metered), prescription, combination drug product nasal spray for the treatment of symptoms of Seasonal Allergic Rhinitis in adults and pediatric patients 12 years of age and older in the United States.

"The FDA's approval of Ryaltris™ represents a major milestone for Glenmark and clearly supports our efforts to bring innovative treatment options in our key therapeutic areas." said Mr. Robert Crockart Chief Commercial Officer of Glenmark Pharmaceuticals Limited. "With this NDA approval, we look forward to bringing this new medicine to physicians and their patients for the treatment of symptoms of seasonal allergic rhinitis, including nasal and ocular symptoms."

Ryaltris™ will be marketed and distributed in the United States (US) by *Hikma Specialty U.S.A., Inc.,* as part of its exclusive licensing agreement with Glenmark Specialty S.A (Switzerland).

About Ryaltris™

Ryaltris™ is a metered, fixed-dose, aqueous suspension, prescription drug product nasal spray approved by the FDA for the treatment of symptoms associated with Seasonal Allergic Rhinitis. Each unit of Ryaltris™ nasal spray contains 665 mcg of olopatadine hydrochloride, a histamine-1(H1)-receptor inhibitor, and 25 mcg of mometasone furoate, a corticosteroid. The combination drug product nasal spray is indicated for the treatment of symptoms associated with seasonal allergic rhinitis in adults and pediatric patients 12 years of age and older. The safety and effectiveness of Ryaltris™ in pediatric patients younger than 12 years of age has not been established.

The recommended daily dose for Ryaltris™ is 2 sprays in each nostril twice daily.

Ryaltris™ will be marketed and distributed in the United States through our partner Hikma Specialty U.S.A. Inc., Columbus, OH.

Ryaltris™ has been approved and is marketed in Australia, the Czech Republic, Poland, Russia, South Africa, Ukraine, the United Kingdom, and Uzbekistan. In April 2021, Glenmark concluded the DCP regulatory procedure in Europe, enabling approval in 17 countries across EU and UK.

Glenmark has entered into commercial agreements with several partners around the world, including Menarini for the commercialization of Ryaltris™ in select EU markets, and with Bausch Health in Canada (where it is under review by Health Canada).

U.S. Important Safety Information for Ryaltris™

- Ryaltris™ is an intra-nasal spray and should not be administered orally, instilled in the eyes, ears or applied to the skin.
- In clinical studies, the most common adverse events that were observed in those 12 years of age and over using Ryaltris™, were altered taste (3%), nose bleeds (1%) and nasal discomfort (1%).
- Ryaltris™ should not be used by anyone who has had an allergic reaction to olopatadine or mometasone.
- Close medical supervision is required in anyone who has a weakened immune system, including those who have had infections with opportunistic pathogens. Increased risk of occurrence or potential worsening of pre-existing infections (e.g. tuberculosis) with fungi, bacteria or viruses can occur; including fatal chickenpox, measles and herpes infections in susceptible patients.
- Ryaltris™ should be used under close medical supervision in anyone who has had nose bleeds or nasal perforation. Recurrence, worsening or persistence of these nasal problems can occur.
- Close growth monitoring of pediatric patients (12 years and over) by a medical practitioner is recommended with the use of Ryaltris™.
- Ryaltris™ effect on pregnancy and through transmission in breast milk is not known. Talk to your doctor if you are pregnant, plan to become pregnant or breastfeeding, to ensure it is safe for you to use.

For full prescribing information, please write to corpcomm@glenmarkpharma.com.

About Glenmark Pharmaceuticals Limited (Mumbai, India)

Glenmark Pharmaceuticals Limited (Glenmark) is a global research-led pharmaceutical company with presence across generics, specialty and OTC businesses and with operations in over 80 countries. Glenmark's key therapeutic areas of focus are respiratory, dermatology and oncology. It ranks among the world's top 50 Generics and Biosimilar 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. 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 being featured in the index. For more information, visit www.glenmarkpharma.com.

For more information, please contact

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