

Press Release – For Immediate Release

## Glenmark Pharmaceuticals Announces the Company's First New Drug Application Submission for Ryaltris™ for Patients with Seasonal Allergic Rhinitis

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*Ryaltris (olopatadine hydrochloride 665 mcg and mometasone furoate 25 mcg), formerly GSP 301 Nasal Spray, is the company's leading respiratory pipeline asset*

**Mumbai, India; May 22, 2018** – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for its leading respiratory pipeline candidate Ryaltris™ (rye - al' - tris), an investigational fixed-dose combination nasal spray of an antihistamine and a steroid, as a treatment for seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Ryaltris (olopatadine hydrochloride (665 mcg) and mometasone furoate (25 mcg)), formerly GSP 301 Nasal Spray, has been conditionally accepted by the FDA as the brand name.

*“Our first NDA submission with Ryaltris is the culmination of years of diligent effort by our employees and clinicians,” said Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. “This is an important milestone for Glenmark, and another step in our rapid transition into becoming an innovation-led and discovery-driven life sciences company.”*

Glenmark expects the FDA will determine whether the NDA is complete for filing within 60 days. If the NDA is accepted, the Prescription Drug User Fee Act (PDUFA) target action date will be assigned at that time.

Glenmark has studied Ryaltris in seven clinical trials involving more than 4,000 patients. Phase 3 results of Ryaltris have been previously presented at key medical meetings, most recently at the Joint Congress of the American Academy of Allergy, Asthma and Immunology and the World Allergy Organization held in March 2018.

### About Seasonal Allergic Rhinitis

According to the most recent CDC data, over 17 million adults in the United States are affected by seasonal allergic rhinitis, also called hay fever, every year.<sup>1</sup> It is the primary diagnosis in over 11 million doctor's visits annually and is estimated to affect more than seven percent of adults aged 18 and over in the United States.<sup>1,2</sup>

### About Glenmark's Respiratory Pipeline

Glenmark's respiratory pipeline is specifically aimed at addressing the global public health burden of allergic rhinitis, asthma and chronic obstructive pulmonary disease (COPD), and includes investigational treatments across the disease spectrum. This includes Ryaltris (GSP 301 Nasal Spray), a combination antihistamine plus steroid nasal spray for the treatment of seasonal allergic rhinitis. It also includes GBR 310 (omalizumab), a proposed biosimilar candidate intended for the treatment of allergic asthma and chronic idiopathic urticaria; and GRC 39815, which is being investigated pre-clinically for the treatment of COPD and other respiratory diseases.

### About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development, primarily focused in the areas of oncology, respiratory disease and dermatology. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit [glenmarkpharma.com](http://glenmarkpharma.com).

<sup>1</sup> Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012, Table 3, 4.

<sup>2</sup> National Ambulatory Medical Care Survey: 2010 Summary Tables, Table 13.