**Press Release – For Immediate Release**

# Glenmark Pharmaceuticals Presents New Data on Ryaltris™, an Investigational Product for the Treatment of Seasonal Allergic Rhinitis at the AAAAI/WAO Joint Congress

*Ryaltris (mometasone furoate (25 mcg) and olopatadine hydrochloride (665 mcg)), formerly GSP 301 Nasal Spray, is Glenmark's leading respiratory candidate with a New Drug Application filing anticipated in the first half of 2018*

**Mumbai, India; March 6, 2018** – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced poster presentations of data from three clinical studies of Ryaltris™, an investigational fixed-dose combination nasal spray for seasonal allergic rhinitis (SAR), at the AAAAI/WAO Joint Congress in Orlando, Florida.

> *"Glenmark has a long history of expertise in respiratory diseases, and is committed to developing new and innovative treatments," said Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. "We have studied the safety and efficacy of Ryaltris in more than a thousand patients over several years, and we are pleased to share these data at the AAAAI/WAO Joint Congress."*

Data included in two of the posters (# 537 and # 546) are from Phase 3, double-blind, placebo and active-controlled studies (Study 1 and Study 2) that randomized more than 2,400 patients to 14 days of twice-daily treatment with Ryaltris or placebo. Both studies assessed average change from baseline, in morning and evening, reflective Total Nasal Symptom Score (rTNSS) versus active comparators and placebo as the primary endpoint. Onset of action versus placebo was assessed using instantaneous Total Nasal Symptom Score (iTNSS) from 15 minutes through four hours post-first dose. Improvement in ocular symptoms, assessed as mean change in reflective Total Ocular Symptom Score (rTOSS) from baseline to study end, was also assessed.

A rapid onset of action with Ryaltris was observed, with an effect seen at 15 minutes post-dose versus placebo in Study 1 (p=0.013) and Study 2 (p=0.028), which was maintained at each subsequent time point assessed. In both studies, Ryaltris also improved rTOSS versus placebo (p=0.001). Treatment emergent adverse events (TEAEs) were low and comparable across treatments. The most frequent adverse events (AEs) reported with Ryaltris included decreased taste sensitivity (Study 1: Ryaltris 3.3%, placebo 0.7%; Study 2: Ryaltris 3.8%, placebo 0.0%) and headache (Study 1: Ryaltris 0.7%, placebo 2.8%; Study 2: Ryaltris 0.0%, placebo 0.7%). (Poster # 537)

Ryaltris resulted in statistically significant and clinically meaningful improvements in the primary efficacy endpoint of nasal symptom scores compared to placebo in Study 1, which was sustained for the entire treatment duration. (Poster # 546)

> *"Results of these robust studies demonstrates that consistent, significant relief from symptoms may be rapidly achieved and sustained with Ryaltris," said Frank Hampel, Principal Investigator, Central Texas Health Research. "These findings, combined with prior studies demonstrating the long-term effects of Ryaltris on patient-reported outcomes, present a promising profile for a potential new treatment for SAR."*

Data were also presented from a double-blind, Phase 2, proof-of-concept study that randomized 180 patients to 14 days of treatment with Ryaltris twice-daily or once-daily versus twice-daily azelastine/fluticasone*, olopatadine hydrochloride* or placebo in a ragweed pollen Environmental Exposure Chamber. The study assessed mean change in iTNSS as the primary endpoint. Onset of action was assessed by average change from baseline in iTNSS at time points from five minutes to four hours post-dose versus placebo. Ocular symptoms were also assessed using instantaneous Total Ocular Symptom Score (iTOSS). Onset of action with twice-daily Ryaltris versus placebo was observed at 10 minutes after the first dose (p=0.019) and was maintained at later time points except at 2.5 hours (p=0.06). Onset of action could not be defined for Ryaltris dosed once-daily. Ryaltris also improved symptoms in iTOSS compared to placebo (once-daily p=0.015, twice-daily p=0.001). The percentage of patients reporting TEAEs was comparable between treatments. Headache (Ryaltris 11.1%, placebo 8.3%) and decreased taste sensitivity (Ryaltris 5.6%, placebo 0.0%) were the most common AEs reported among patients taking Ryaltris twice-daily. (Poster # 220)

**Posters Presented at the Joint Congress of the American Academy of Allergy Asthma & Immunology and World Allergy Organization:**

1. Poster # 220: Rapid Onset of Action on Nasal Symptoms and Ocular Symptom Relief With Olopatadine/Mometasone Combination Nasal Spray in a Ragweed Environmental Exposure Chamber, Presentation Date: Saturday, March 3, 2018
2. Poster # 537: Rapid Onset of Action on Nasal Symptoms and Ocular Symptom Improvement With Olopatadine/Mometasone Combination Nasal Spray in Patients With Seasonal Allergic Rhinitis, Presentation Date: Sunday, March 4, 2018
3. Poster # 546: Abstract Title: Efficacy and Safety of Olopatadine/Mometasone Combination Nasal Spray in Patients With Seasonal Allergic Rhinitis, Presentation Date: Sunday, March 4, 2018

## 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 four investigational treatments across the disease spectrum and devices. This includes Ryaltris (GSP 301 Nasal Spray), a combination steroid plus antihistamine nasal spray for the treatment of allergic rhinitis, which has completed three Phase 3 trials and is preparing for an NDA submission. It also includes GSP 304, currently in Phase 2 trials, which is a long-acting muscarinic receptor agonist being investigated as a nebulized treatment for COPD; GBR 310 (omalizumab), a proposed biosimilar candidate intended for the treatment of allergic asthma and chronic idiopathic urticaria; and GRC 39815, which is pre-clinically being investigated for the treatment of COPD.

## 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-us.com**.

*Marketed formulations were used for the active comparators in this study