Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces FDA Acceptance of the Company's First New Drug Application for Ryaltris™ for Patients with Seasonal Allergic Rhinitis

The Prescription Drug User Fee Act (PDUFA) target action date for completion of the FDA review is March 21, 2019

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); August 8, 2018 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the U.S. Food & Drug Administration (FDA) has accepted for review the company's New Drug Application 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.

> *"We are pleased that Glenmark's rigorous study of Ryaltris led to today's filing acceptance by the FDA," said Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. "We look forward to offering a potential new treatment option for people suffering from seasonal allergic rhinitis."*

The filing for Ryaltris includes efficacy and safety results from two pivotal, randomized, multicenter, double-blind, placebo-controlled trials in adults and adolescents 12 years of age and older with SAR. The similarly designed trials lasted two weeks and enrolled 2,352 patients. Assessment of efficacy was based on patient-reported reflective total nasal symptom score (rTNSS), along with other patient-reported measures of nasal and ocular symptoms. Across the two studies, treatment with Ryaltris resulted in statistically significant improvements in rTNSS compared to placebo.

Additionally, the filing includes data from a long-term safety study in 601 adults and adolescents 12 years of age and older with perennial allergic rhinitis (PAR). This trial was a three-arm, double-blind, randomized, parallel group, placebo-controlled safety study that randomized patients to 52 weeks of twice-daily treatment with Ryaltris, or two different formulations of a placebo nasal spray. The study also evaluated efficacy as a secondary endpoint, assessed as change from baseline in average morning patient-reported rTNSS. Ryaltris demonstrated a statistically significant and clinically meaningful improvement compared to placebo ($p<0.0001$) over 52 weeks of treatment.

The incidence of adverse reactions in four placebo-controlled clinical studies was 13.9% in the Ryaltris treatment groups versus 9.5% of patients in the placebo groups. The most frequently reported adverse reactions with Ryaltris greater than placebo was loss of taste sensitivity (3.0% vs. 0.3%, respectively), nosebleed (1.0% vs. 0.6%) and nasal discomfort (1.0% vs. 0.8%).

About Seasonal Allergic Rhinitis

According to the most recent CDC data, over 17 million adults in the United Sates are affected by seasonal allergic rhinitis every year.[1] 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.[1,2]

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), an investigational 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 **https://www.glenmarkpharma-us.com/**.

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[1] Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012, Table 3, 4.
[2] National Ambulatory Medical Care Survey: 2010 Summary Tables, Table 13.