Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces Results from a Phase 3 Study of Ryaltris™, an Investigational Product for the Treatment of Seasonal Allergic Rhinitis, in Patients Aged 6 to Under 12 Years

The study of Ryaltris (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg] nasal spray) in pediatric patients aged 6 to under 12 years of age met its primary endpoint, and results were consistent with extensive clinical trial experience with Ryaltris in patients 12 years of age and older

Ryaltris, also known as GSP 301 Nasal Spray, is the company's leading respiratory pipeline asset, and currently under FDA review for the treatment of seasonal allergic rhinitis in patients 12 years of age and older

Mumbai, India; May 9, 2019: Glenmark Pharmaceuticals, a global innovative pharmaceutical company, today announced positive results from a Phase 3 study of Ryaltris, an investigational fixed-dose combination nasal spray for the treatment of seasonal allergic rhinitis (SAR). The study in patients aged 6 to under 12 years met its primary endpoint in achieving clinically meaningful and statistically significant change from baseline in average morning and evening Reflective Total Nasal Symptom Score (rTNSS) compared to placebo.[1] Ryaltris (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), also known as GSP 301 Nasal Spray, has been conditionally accepted by the FDA as the brand name.

> *"It has become increasingly important to conduct studies specifically designed for pediatric patients, so that we may gain insights into potential differences in safety, efficacy and dosing compared to studies in adult and adolescent populations," said Mahboob Rahman, Chief Medical Officer at Glenmark Pharmaceuticals. "We are pleased to report that the safety and effectiveness observed in this pediatric population is consistent with our overall Phase 3 development program in SAR patients 12 years of age and older. These robust data contribute to the extensive clinical background supporting the effectiveness and tolerability of Ryaltris."*

The primary objective of the Phase 3 study was to compare the effectiveness of Ryaltris (administered as one spray in each nostril, twice daily) versus a placebo nasal spray over 14 days in pediatric subjects (aged ≥6 to <12 year) with SAR. The study randomized 446 patients and 431 patients completed the study (96.6%). In the study, patients treated with Ryaltris compared to placebo showed a statistically significant improvement for the primary endpoint of average morning and evening rTNSS (p=0.001). Rates of treatment-emergent adverse events (TEAEs) were similar between Ryaltris versus placebo (10.4% vs. 12.0%, respectively). The most common TEAEs included distortion of taste sensation (Ryaltris 1.3%, placebo 0.0%), headache (Ryaltris 1.3%, placebo 0.5%) and nose bleed (Ryaltris 0.9%, placebo 2.3%).[1]

Glenmark Pharmaceuticals has studied Ryaltris in seven clinical trials involving more than 4,000 adult and adolescent patients (12 years of age and older). Results from those clinical trials of Ryaltris have been previously presented at key medical meetings and full results from the study of Ryaltris in pediatric patients aged 6 to under 12 years of age will be published and presented at future meetings.

If approved by the FDA, Ryaltris will be commercialized by Glenmark Therapeutics Inc. USA, a wholly-owned subsidiary of Glenmark Holding, SA, that is dedicated to launching a portfolio of branded products in the therapeutic areas of respiratory and dermatology in the US.

About Seasonal Allergic Rhinitis

According to the most recent CDC data, almost 20 million adults in the United Sates are affected by seasonal allergic rhinitis every year.[2] 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 years and over in the United States.[2,3]

About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2018). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

About Glenmark Therapeutics

Glenmark Therapeutics Inc., USA is a, wholly-owned subsidiary of Glenmark Holding, SA. The company is dedicated to building a franchise of branded products for Glenmark Pharmaceuticals. Glenmark Therapeutics will initially focus its efforts on launching and commercializing assets in the therapeutic areas of respiratory and dermatology. Glenmark Therapeutics has a short- and long-term pipeline of investigational medicines intended to meet the needs of patients suffering from a variety of dermatological and respiratory conditions and is consistently working to expand its product portfolio.

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References

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3. National Ambulatory Medical Care Survey: 2010 Summary Tables, Table 13.