

Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces Results from New Analysis of Pooled Data on Ryaltris™, an Investigational Product for the Treatment of Seasonal Allergic Rhinitis, at the AAAAI 2019 Annual Meeting

Ryaltris (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), formerly GSP 301 Nasal Spray, is the company's leading respiratory pipeline asset and currently under review with the U.S. Food and Drug Administration (FDA) as a treatment of seasonal allergic rhinitis in patients 12 years and older

Paramus, NJ, February 25, 2019 – Glenmark Pharmaceuticals, a global innovative pharmaceutical company, today announced results from new analyses of pooled data from clinical studies of Ryaltris™ (olopatadine hydrochloride and mometasone furoate monohydrate nasal spray), an investigational fixed-dose combination nasal spray for the treatment of seasonal allergic rhinitis (SAR) in patients 12 years of age and older, at the 2019 Annual Meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI 2019) in San Francisco, California. Ryaltris (also known as GSP 301 Nasal Spray) has been conditionally accepted by the FDA as the brand name.

“The majority of patients affected by SAR report taking medicines to help relieve their symptoms,¹ but approximately 50% of patients report needing multiple prescriptions and over-the-counter therapies, which suggests monotherapies may be inadequate, and a need exists for new combination treatment options.”^{1,2} said Mahboob Rahman, Chief Medical Officer at Glenmark Pharmaceuticals. “The findings from these pooled analyses provide robust evidence that a combination nasal spray like Ryaltris may offer fast and sustained relief, with side effects and tolerability similar to monotherapy treatment options.”

In a pooled analysis of efficacy and safety from three SAR clinical trials involving more than 2,900 patients, treatment with Ryaltris demonstrated significant and clinically meaningful improvements in average morning and evening reflective Total Nasal Symptoms Scores (rTNSS) ($P < 0.001$) and instantaneous TNSS ($P < 0.001$) versus placebo. Similarly, Ryaltris provided significant and clinically meaningful improvements in rTNSS and iTNSS versus the monotherapy active controls (olopatadine, $P = 0.002$ and $P = 0.001$, respectively; mometasone, $P = 0.001$ and $P < 0.001$, respectively). Rates of treatment emergent adverse events (TEAEs) were consistent between Ryaltris (13.9%), olopatadine (13.2%), mometasone (7.9%) and placebo (9.5%).³

Another pooled analysis of data from the same clinical study population demonstrated a rapid, 15-minute onset of action with Ryaltris ($P = 0.011$). Additionally, the onset of action with Ryaltris treatment was maintained over the duration of the assessment (four hours), in comparison to placebo ($P < 0.001$). Additionally, Ryaltris treatment resulted in statistically significant improvements in ocular symptoms versus placebo on day one through day 14 ($P < 0.001$).⁴

The third pooled analysis of data from this clinical study population showed that treatment with Ryaltris led to statistically significant improvements in overall quality of life, compared to placebo ($P < 0.001$), as demonstrated by the Rhinoconjunctivitis Quality of Life Questionnaire-Standardized Activities [RQLQ(S)]. Ryaltris treatment also provided statistically significant improvements versus placebo in each individual domain of RQLQ(S) ($P < 0.001$, all): activities; emotional; eye symptoms; nasal symptoms; non-nose/eye symptoms; practical problems; and sleep.⁵

Glenmark Pharmaceuticals has studied Ryaltris in seven clinical trials involving more than 4,000 patients. Results from these clinical trials of Ryaltris have been previously presented at key medical 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 States are affected by seasonal allergic rhinitis every year.⁶ 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.^{6,7}

About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals is a research-driven, global, integrated pharmaceutical organization with operations in more than 80 countries. 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, immunology and pain.

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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