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# Glenmark gets FDA nod of company’s first NDA for Ryaltris

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**It is 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.**

Glenmark Pharmaceuticals 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™.

It is 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.

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.