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Glenmark Pharma submits First New Drug Application for Ryaltris

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Ryaltris (olopatadine hydrochloride 665 mcg and mometasone furoate 25 mcg), formerly GSP 301 Nasal Spray, isthe company's leading respiratory pipeline asset

Glenmark Pharmaceuticals, a global pharmaceutical company announced that the company has submitted a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) 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.

Glenmark expects the FDA will determine whether the NDA is complete for filing within 60 days. If the NDA is accepted, the Prescription Drug User Fee Act (PDUFA) target action date will be assigned at that time.

Glenmark has studied Ryaltris in seven clinical trials involving more than 4,000 patients. Phase 3 results of Ryaltris have been previously presented at key medical meetings, most recently at the Joint Congress of the American Academy of Allergy, Asthma and Immunology and the World Allergy Organization held in March 2018.