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Glenmark announces results from a Phase 3 Study of Ryaltris™

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Glenmark Pharmaceuticals has 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.

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Mahboob Rahman, Chief Medical Officer at Glenmark Pharmaceuticals said, “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. 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.”

Glenmark Pharmaceuticals has studied Ryaltris in seven clinical trials involving more than 4,000 adult and adolescent patients (12 years of age and older).

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.

According to the most recent CDC data, almost 20 million adults in the United Sates are affected by seasonal allergic rhinitis every year. 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.