BioSpectrum
the business of Bio & Health Sciences

Glenmark announces results from new analysis on Ryaltris™

26 February 2019 | News

Ryaltris (also known as GSP 301 Nasal Spray) has been conditionally accepted by the FDA as the brand name

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.

Glenmark Pharmaceuticals has 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.

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%).

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 ($P<0.001$).

Mahboob Rahman, Chief Medical Officer at Glenmark Pharmaceuticals said, “The majority of patients affected by SAR report taking medicines to help relieve their symptoms, 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. 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.”

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.

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.