

Press Release

For Immediate Release

## Glenmark's Ryaltris® - innovative single nasal spray, ready to market in Russia

- Marketing approval received from the Ministry of Health of the Russian Federation
- Indicated to treat seasonal allergic and perennial allergic rhinitis in patients over 12 years of age
- This is Glenmark's first global brand launch of a convenient single spray option for patients

**Mumbai, India, February 22, 2021:** Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led global integrated pharmaceutical company, today announced that its Swiss subsidiary, Glenmark Specialty S.A., received marketing approval from the Ministry of Health of the Russian Federation for its innovative Ryaltris® Nasal Spray - a novel fixed-dose combination nasal spray.

This paves the way for commercialization of Ryaltris® in Russia which is expected to be made available to patients in the country in Q1 FY 2021-22.

**Ryaltris® (olopatadine hydrochloride 665 mcg and mometasone furoate 25 mcg), is indicated for symptomatic treatment of seasonal and perennial allergic rhinitis in adults and children over 12 years of age. Ryaltris® relieves symptoms of allergic rhinitis, including stuffy nose, runny nose, nasal itching, sneezing, as well as itchy, red and watery eyes.**

In Russia, allergic rhinitis affects 10-20% of the population on average, with certain regions having a higher prevalence rate of 18 - 38%. Allergic rhinitis can impact a person's quality of life and lead to functional impairments, as well as increase the risk of having asthma<sup>1</sup>.

*"Glenmark has built strong capabilities in the area of respiratory medicine and is among the leading players in this therapy area across several markets globally. Russia is one of the key markets for us and we are consistently looking to expand our product portfolio. We are delighted to receive an approval for Ryaltris® nasal spray in the Russian market. This new innovative addition to our portfolio is yet another major step in strengthening Glenmark's respiratory focus in Russia and the CIS region. Glenmark has a strong established presence in Russia for over 30 years, which will enable us to lead the commercialization of this product in the country. We look forward to being able to make this innovative product available to patients in Russia as soon as possible," said Csaba Kantor, Senior Vice President – Russia & CIS region, Glenmark Pharmaceuticals.*

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<sup>1</sup> Levina Iu.G., Namazova-Baranova L.S., Torshkoeva R.M., Vishneva E.A., Alekseeva A.A., Efendieva K.E. Allergic rhinitis: current approach to treatment // VSP. 2010. - No. 6, Russia

**About Glenmark Pharmaceuticals Ltd.:**

Glenmark Pharmaceuticals Ltd. (GPL) is a global research-led pharmaceutical company with presence across Generics, Specialty and OTC business with operations in over 50 countries. Glenmark's key therapy focus areas globally are respiratory, dermatology and oncology. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2019).

The company has been listed in the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for the third consecutive year in a row. DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally with only the top ranked companies in terms of Corporate Sustainability within each industry are featured in the index. For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com)

**About Ryaltris:**

Ryaltris® (olopatadine hydrochloride (665 mcg) and mometasone furoate (25 mcg)) is a new fixed-dose combination nasal spray of an antihistamine and a steroid, indicated for symptomatic treatment of seasonal and perennial allergic rhinitis in adults and children over 12 years of age in Russia. Ryaltris® relieves symptoms of allergic rhinitis, including stuffy nose, runny nose, nasal itching, sneezing, as well as itchy, red and watery eyes.

Side effects: Ryaltris® may have unwanted side effects. More common side effects include: unpleasant taste, nosebleeds and nasal discomfort. Other less common side effects include sleepiness or drowsiness, nasal problems such as crusting in the nose or nose bleeds. Other rare or more serious side effects may occur.

Ryaltris™ Nasal Spray, the company's respiratory pipeline asset, is currently under review with the U.S. Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the USA. At the end of 2020, Glenmark and Menarini entered into an Exclusive Licensing Agreement for commercializing Ryaltris™ Nasal Spray across numerous markets throughout Europe. The licensing agreement will be effective in 33 countries throughout the European region including France, Italy, and Spain. Under the terms of the agreement, Glenmark will be responsible for the development and regulatory approval of Ryaltris™ by relevant European Regulatory Authorities, while Menarini Group will be responsible for the commercialization of Ryaltris™ across these markets.

Ryaltris sales continues to progress well in Australia, after the successful launch earlier in this financial year by Glenmark's partner, Seqirus Pty. Ltd. During the second quarter of this financial year, Ryaltris® was launched in South Africa. In the CIS region, Glenmark initiated commercial launch in Ukraine in January 2021 and is planning to commercialize the product in Uzbekistan in the fourth quarter of this financial year. The company is awaiting regulatory approvals for its filings in various markets across Europe, Canada, Brazil, Malaysia, Saudi Arabia and several other emerging markets. Glenmark's partner in China, Grand Pharmaceutical (China) Co. Ltd., plans to submit an IND in this financial year.

**For more information:**

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