

Press release

For immediate distribution

## **Glenmark Specialty S.A. and Lotus International Pte. Ltd. enter into Exclusive Licensing Agreement for commercializing Ryaltris™ Nasal Spray in Singapore, Hong Kong and Vietnam.**

- *Under the terms of the agreement, Glenmark will be responsible for the manufacture and supply of Ryaltris™, while Lotus International Pte. Ltd. will be responsible for the commercialization of Ryaltris™ (subject to receipt of regulatory approvals) across these markets.*
- *Glenmark will receive an upfront payment as well as regulatory and sales based milestone payments from Lotus.*
- *Ryaltris™, developed by Glenmark, is a novel, fixed-dose combination nasal spray of an anti-histamine (olopatadine hydrochloride) and a steroid (mometasone furoate), indicated for treatment of symptoms associated with allergic rhinitis (AR) in adults and pediatric patients, 12 years of age and older.*

**Mumbai, India; January 20, 2022:** Glenmark Pharmaceuticals Ltd. (Glenmark), an innovation-driven, global, integrated pharmaceutical company, today announced that its Swiss subsidiary, Glenmark Specialty S.A., has entered into an exclusive licensing agreement with Lotus International Pte. Ltd., a wholly owned subsidiary of Lotus Pharmaceutical Co., Ltd. (Lotus), for commercializing its innovative nasal spray Ryaltris™ in Singapore, Hong Kong and Vietnam.

Under the terms of the agreement, Glenmark will be responsible for the manufacture and supply of Ryaltris™, whereas Lotus will be responsible for commercialization of Ryaltris™ (subject to receipt of regulatory approvals), in these markets. Glenmark will receive an upfront payment as well as regulatory and sales based milestone payments from Lotus.

***“We are excited to partner with Lotus for Ryaltris™ as it is a strong and reputed player in the region and is aligned with Glenmark’s objective to provide quality novel products to fulfill unmet needs of patients with allergic rhinitis. This partnership will provide patients access to a highly effective and proven treatment for allergic rhinitis in these key South-East Asian markets,” said Robert Crockart, Chief Commercial Officer, Glenmark Pharmaceuticals Ltd.***

***On this development, Petar Vazharov, Chief Executive Officer of Lotus said, “As being strongly committed to making a difference for all patients, we are honored to partner with Glenmark to ensure this novel spray drug accessible to patients in South East Asia. This is also the first Brand product to be included in our respiratory portfolio with strong clinical data and IP protection. The partnership not only strengthens the competitiveness of our overall product portfolio but also accelerates our expansion in key SEA countries.”***

Allergic rhinitis (AR) is a heterogeneous disorder that despite its high prevalence is often undiagnosed. It is characterized by one or more symptoms including sneezing, itching, nasal congestion, and rhinorrhea<sup>i</sup>. Allergic rhinitis can be seasonal (occurring during specific seasons) or perennial (occurring year-round)<sup>ii</sup>. AR contributes to missed or unproductive time at work, sleep problems and decreased involvement in outdoor activities. Prevalence of AR is 4.2% in Hong Kong, 4.9% in Singapore and 12.3% in Vietnam<sup>iii</sup>. Being a topical therapy, Ryaltris™ offers many advantages over oral therapies, such as delivering greater concentrations of drug to the receptor sites at the source of the allergic inflammation and reduced risk of systemic side effects<sup>iv</sup>.

**About Ryaltris™**

Ryaltris™ developed by Glenmark, is a novel fixed-dose combination nasal spray. It is a metered, fixed-dose, aqueous suspension, prescription drug product nasal spray for the treatment of symptoms associated with allergic rhinitis (AR) in adults and pediatric patients 12 years of age and older. Each unit of Ryaltris™ nasal spray contains 665 mcg of olopatadine hydrochloride, a histamine-1(H1)-receptor inhibitor, and 25 mcg of mometasone furoate, a corticosteroid.

Ryaltris™ is approved by the US FDA for treatment of symptoms associated with seasonal allergic rhinitis (SAR) in adults and pediatric patients 12 years of age and older. It will be marketed and distributed in the United States through Glenmark's partner Hikma Specialty U.S.A. Inc., Columbus, OH. Australia was the first country where Ryaltris™ was launched through Glenmark's partner Seqirus Pty. Ltd. and it continues to do well. Ryaltris™ has also been approved and is marketed in Czech Republic, Poland, Russia, South Africa, Ukraine, the United Kingdom, and Uzbekistan. In April 2021, Glenmark concluded the DCP regulatory procedure in Europe, enabling approval in 17 countries across EU and UK.

Glenmark has also entered into commercial agreements with several partners around the world, including Menarini for the commercialization of Ryaltris™ in select EU markets, with Bausch Health in Canada (where it is under review by Health Canada), with Grand Pharma in China and with Yuhan Corporation in South Korea for commercialization of Ryaltris™.

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**About Glenmark Pharmaceuticals Ltd.**

Glenmark Pharmaceuticals Limited (Glenmark) is an innovation-driven, global pharmaceutical company with presence across specialty, generics, and OTC businesses and with operations in over 80 countries. Glenmark's key therapeutic areas of focus are respiratory, dermatology and oncology. It ranks among the world's top 50 Generics and Biosimilar companies (Top 50 Company Rankings, 2020, from Informa's Generics Bulletin). The company has been listed on the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for four consecutive years in a row; mostly recently in 2021. 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 being featured in the index. For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com).

**About Lotus Pharmaceutical Co., Ltd.**

Founded in 1966, Lotus (1795: TT) is the largest pharmaceutical company in Taiwan with high-value generic products covering CNS, CVS, women health, and anti-obesity drugs in tablets and hard/soft gel capsules with a special focus on oral oncology for global markets. By boasting a best-in-class R&D and manufacturing platform in Asia, Lotus aims to benefit patients, its employees and stakeholders. Furthermore, Lotus can reach nearly every global market with its high value pipeline through its direct markets, currently encompassing Taiwan, Korea, Thailand, Vietnam, Singapore, Hong Kong, Malaysia, Philippines, and China, or via alliances with top-tier pharma companies based on its industry-leading infrastructure certified by most of the advanced regulatory authorities around the world, including US FDA, EU EMA, Japan PDMA, China FDA, and Brazil ANVISA. Lotus International Pte. Ltd. is a wholly-owned subsidiary of Lotus as a regional hub for South East Asian market.

**For more information, please contact:**

Udaykumar Murthy

Deputy General Manager, Corporate Communications

+91 9960377617 | [corpcomm@glenmarkpharma.com](mailto:corpcomm@glenmarkpharma.com)

**References:**

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<sup>i</sup> <https://pubmed.ncbi.nlm.nih.gov/11449200/>

<sup>ii</sup> [https://www.uptodate.com/contents/allergic-rhinitis-beyond-the-basics#:~:text=Seasonal%20versus%20perennial%20allergic%20rhinitis,\(occurring%20year%20round\),&text=The%20allergens%20that%20most%20commonly,and%20weeds%20\(figure%201\).](https://www.uptodate.com/contents/allergic-rhinitis-beyond-the-basics#:~:text=Seasonal%20versus%20perennial%20allergic%20rhinitis,(occurring%20year%20round),&text=The%20allergens%20that%20most%20commonly,and%20weeds%20(figure%201).)

<sup>iii</sup> "American Journal of Rhinology & Allergy" (September–October 2011, Vol. 25, No. 5 (Suppl 1))

<sup>iv</sup> Watts AM, Cripps AW, West NP, Cox AJ. Modulation of Allergic Inflammation in the Nasal Mucosa of Allergic Rhinitis Sufferers With Topical Pharmaceutical Agents. *Front Pharmacol.* 2019;10:294. Published 2019 Mar 29. doi:10.3389/fphar.2019.00294