Glenmark Pharmaceuticals Ltd.

Press release



For immediate distribution

Glenmark Pharmaceuticals and Menarini enter into 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.
- *Glenmark will receive an upfront payment as well as launch & sales based milestone payments from sales of Ryaltris™*

Mumbai, India; Dec 23, 2020: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led global integrated pharmaceutical company, today announced that its Swiss subsidiary, Glenmark Specialty S.A., has entered into an exclusive licensing agreement with Menarini Group (Menarini) for commercializing its innovative nasal spray RyaltrisTM across 33 countries in Europe, including the Balkan region.

Ryaltris[™] [olopatadine hydrochloride (665 mcg) and mometasone furoate (25 mcg)], developed by Glenmark, is a novel fixed-dose combination nasal spray of an anti-histamine and a steroid, indicated for treatment of symptoms associated with seasonal allergic rhinitis (SAR) in patients over 12 years of age.

Under the terms of the agreement, Glenmark will be responsible for the continued development and regulatory approval of RyaltrisTM in these markets. Menarini will be responsible for the scientific information and the commercialization of RyaltrisTM in those markets, following regulatory approval. Glenmark will receive an upfront payment as well as launch & sales based milestone payments from Menarini for RyaltrisTM sales.

"We are excited to partner with Menarini for Ryaltris[™] across Europe as they have a proven track record in partnering and commercialising respiratory products in the region. This partnership is another step in establishing Glenmark's respiratory focus in Europe. While Glenmark will launch Ryaltris[™] through its own front ends in some markets, this arrangement will allow the product to compete across Europe. This is also aligned with our vision to make Ryaltris[™] the first global brand of Glenmark by launching it in several markets across the world," said Achin Gupta, Executive Vice President, Business Head EMEA-L (Europe, Middle East, Africa, Latam) Glenmark Pharmaceuticals.

"We are delighted to have undertaken this exclusive licensing agreement with Glenmark Pharmaceuticals. Ryaltris[™] is a perfect addition to our European respiratory and allergy portfolio and we can count on our established experience in the relevant therapeutic area to bring this novel option to patients. We look forward to receiving Ryaltris[™] registration and being able to launch operations as soon as practicable," commented Pio Mei, General Manager Menarini Group



RyaltrisTM (olopatadine hydrochloride and mometasone furoate) Nasal Spray, the company's respiratory pipeline asset is partnered with Hikma Pharmaceuticals PLC for the commercialisation in the US market. RyaltrisTM sales continues to progress well in Australia, after the successful launch earlier this year by Glenmark's partner, Seqirus Pty. Ltd. Ryaltris[®] TM was also recently launched in South Africa. Glenmark plans to initiate commercial launch in Ukraine and Uzbekistan in the next few months. Glenmark is supporting its partner Yuhan Corporation to launch RyaltrisTM by the end of the March 2021 in South Korea. Glenmark has received approval for RyaltrisTM in Australia, South Korea, Cambodia, Ukraine, Uzbekistan, Namibia and South Africa. The company had already filed an application for RyaltrisTM approval in the European Union, Canada, Russia, Brazil, Malaysia, Saudi Arabia and several other markets. Glenmark's partner in China, Grand Pharmaceutical (China) Co. Ltd., plans to submit an IND in this financial year.

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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 second 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

About Menarini

The Menarini Pharmaceutical Group, with headquarters in Florence, is present in 140 countries worldwide to date, with $\notin 3,793$ million in turnover and more than 17,000 employees. With 10 centres for Research & Development, Menarini's products are present in the most important treatment areas, including those of cardiology, gastroenterology, pneumology, infectious diseases, diabetes, and anti-inflammatory/analgesic products. Pharmaceutical production is carried out in the Group's 17 manufacturing plants, located in Italy and abroad, which produce over 581 million packets of product a year and distribute them to five continents. Menarini's pharmaceutical production, in line with the highest quality standards, provides an ongoing contribution to the health of patients throughout the world.

For more information:

Glenmark Media Contacts

Udaykumar Murthy Senior Manager, Corporate Communications +91 9960377617 corpcomm@glenmarkpharma.com