September 30, 2021

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.,
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001.

Ref: Scrip Code: 532296

To,
The Manager – Listing,
The National Stock Exchange of India Ltd.,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051.

Ref: Scrip Name: GLENMARK

Dear Sir,

Sub: Glenmark receives marketing approval for Ryaltris®, an innovative combination nasal spray, in 13 countries across the EU and UK

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Limited

HARISH VINAYAK KUBER
Digitally signed by HARISH VINAYAK KUBER
Date: 2021.09.30 08:49:43 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Encl: as above

Press Release **For immediate distribution**

Glenmark receives marketing approval for Ryaltris®, an innovative combination nasal spray, in 13 countries across the EU and UK

- *Ryaltris® is a fixed dose combination nasal spray that combines an antihistamine (Olopatadine) with a steroid (Mometasone Furoate) for treatment of allergic rhinitis*
- *Ryaltris® has been well received by the global medical community for the effective treatment of seasonal and perennial allergic rhinitis*
- *To be launched in Europe directly by Glenmark and through partner Menarini*
- *Over 4000 patients globally took part in Ryaltris® clinical trials initiated in 2014*
- *Phase 3 efficacy and safety trials show twice-daily treatment with Ryaltris® results in significant, clinical improvements in allergic rhinitis symptoms compared with placebo and component monotherapies*

Mumbai, India; September 30, 2021: Glenmark Pharmaceuticals Limited, a research-led, global integrated pharmaceutical company, has received marketing approval for its fixed-dose combination nasal spray Ryaltris® in 13 countries across the EU and UK. Glenmark is set to launch Ryaltris® directly in the markets of Czech Republic, Slovakia, Poland, and the UK. Ryaltris® will be marketed in the rest of Europe by the Menarini Group as part of its exclusive licensing agreement with Glenmark.

Ryaltris® (olopatadine 665 µg and mometasone furoate 25 µg), 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.

Commenting on this development, Chief Commercial Officer of Glenmark Pharmaceuticals Limited, Mr. Robert Crockart said, "Allergic rhinitis is both widespread and underreported, making it challenging to diagnose and treat in time. It impacts a person's quality of life and can lead to functional impairments, while also increasing the risk of asthma. This marketing approval will pave the way for effective and timely treatment of allergic rhinitis for thousands of patients across Europe. We are already seeing its therapeutic benefits in other regions where Ryaltris® has been launched, and we hope to extend this relief to more people across the world."

Glenmark has also partnered with Hikma Pharmaceuticals PLC and Bausch Health for the commercialisation of Ryaltris® in the US and Canada respectively. In April this year, Glenmark concluded the DCP regulatory procedure in Europe, enabling approval in 17 countries across EU and UK.

During FY21-22, Glenmark also received regulatory approval for Ryaltris® in Philippines, Zambia, Ecuador and Peru. Ryaltris® sales continue to progress well in Australia, South Africa, Ukraine and Uzbekistan. Glenmark also initiated the commercial launch in Russia in Q1, FY21-22. The company is awaiting regulatory approvals for its filings in various markets across Canada, Brazil, Malaysia, Saudi Arabia and several other emerging markets.

Currently, Ryaltris® is under review with the US Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the US. Glenmark's response to the Agency's Complete Response Letter (CRL) was submitted to the US FDA in July 2021.

Glenmark's partner in China, Grand Pharmaceutical (China) Co. Ltd., finalized the Phase 3 protocol for China, and submitted the IND application in July 2021. In South Korea, Glenmark is working with its partner Yuhan Corporation, to potentially launch the product by H2, FY21-22. Also, the company is working to submit the application for paediatric efficacy supplement in the country. In June 2021, Glenmark's partner in Australia, Seqirus Pty Ltd. received positive initial feedback from the TGA for the pediatric indication expansion.

Across Africa, the Americas, Asia and Europe, the prevalence of allergic rhinitis can be as high as 25%[i]. Symptoms like a stuffy or runny nose, nasal itching, sneezing (sometimes unrelenting), itchy, red, or watery eyes can leave patients unable to function normally for days, or even weeks in many instances, which can have significant consequences for health as well as quality of life. Low compliance to available treatments was also noted in several cases, making Ryaltris® a viable treatment option to counter the challenges posed by allergic rhinitis.

—End—

About Glenmark Pharmaceuticals Limited

Glenmark Pharmaceuticals Limited (Glenmark) is a global research-led pharmaceutical company with presence across generics, specialty and OTC businesses and with operations in over 50 countries. Glenmark's key therapy focus areas globally are respiratory, dermatology and oncology. It ranks among the world's top 50 Generics and Biosimilars 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 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 being featured in the index. For more information, visit www.glenmarkpharma.com

For more information, please contact

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[i] 1Asia Pac Allergy. 2018 Jan; 8(1): e7