Glenmark Pharmaceuticals Ltd.



Press Release

For Immediate Release

Glenmark Pharmaceuticals announces product approval for Ryaltris® in Australia

- 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 treatment of symptoms associated with allergic rhinitis (AR) and rhinoconjunctivitis in patients aged 12 and over
- Glenmark plans to commercialize Ryaltris® in several markets globally, either on its own or through partnerships

Mumbai, India, December 20, 2019: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led global integrated pharmaceutical company, today announced that Seqirus Pty. Ltd. (Seqirus) has received marketing approval for Ryaltris® from the Therapeutic Goods Administration (TGA), Australia. This paves the way for the launch of Ryaltris® in Australia through our partner, Seqirus. Australia will be the first market globally where Ryaltris® will be launched.

Seqirus, part of Australia-based specialty biotechnology company CSL Ltd., entered into an exclusive licensing agreement in July 2018 with Glenmark's subsidiary Glenmark Specialty S.A. to commercialize Ryaltris[®] in Australia.

Ryaltris[®] is a new fixed-dose combination nasal spray of an antihistamine and a steroid, indicated for treatment of symptoms associated with allergic rhinitis (AR) and rhinoconjunctivitis in patients over 12 years of age.

Under the terms of the agreement, Glenmark will be responsible for product supply and Seqirus will be responsible for regulatory filing and commercialization of the product in Australia. Glenmark is entitled to receive commercial milestone payments from Seqirus. Ryaltris® will be manufactured at Glenmark's Baddi manufacturing facility, Himachal Pradesh, India.

Australia has one of the world's highest rates of allergic rhinitis with nearly 20% of the country's population suffering annually from this disease. Allergic rhinitis can lead to a reduction in quality of life and functional impairment.ⁱⁱ

"We are delighted to receive an approval from TGA for Ryaltris® through our partner Seqirus to commercialize Ryaltris® in Australia. Seqirus' strong presence in allergy in this market makes them an ideal partner for Glenmark," said Glenn Saldanha, Chairman and Managing Director of Glenmark Pharmaceuticals.

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"We are very excited to be working with Glenmark on the distribution, marketing and sales of their novel fixed dose combination product for allergic rhinitis. Ryaltris® is an important addition to Segirus' growing product range and strengthens our broad portfolio of in-licensed pharmaceuticals and vaccines in Australia," said Dr. Lorna Meldrum, Seqirus' VP Asia Pacific Commercial Operations.

Glenmark plans to commercialize Ryaltris[®] in several key markets globally. Glenmark will explore commercial partnerships for Ryaltris® in markets where it doesn't have direct presence.

About Glenmark Pharmaceuticals - Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 countries primarily focused in the areas of oncology, respiratory and dermatology. Glenmark has a significant presence in generic drugs market and has improved lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit www.glenmarkpharma.com

About Segirus - In Australia and New Zealand, Segirus is a fully integrated pharmaceutical company operating with expertise in specialty and primary care pharmaceuticals and vaccines. The Seqirus sales and marketing teams are multi-award winning and recognised as leaders within the pharmaceutical industry. Globally, Seqirus is the world's largest influenza vaccine manufacturer. With extensive research and production expertise and manufacturing plants in the US, UK and Australia, Segirus is a transcontinental partner in pandemic preparedness and a major contributor to the prevention of control of influenza globally. Segirus has a workforce of over 3000 employees and a presence in 20 countries.

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 treatment of symptoms associated with allergic rhinitis and rhinoconjunctivitis in patients over 12 years of age in Australia.

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 nosebleeds. Other rare ore more serious side effects may occur.

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Application for registration of brand name Ryaltris has been accepted, advertised and is under process by IP Australia, The Registrar of Trademark.

ii Reference: William B Smith and Frank E Kette Med J Aust 2017; 206 (2): 60-61.