



New Combination Product for Symptoms of Seasonal Allergic Rhinitis Approved by US FDA with Aptar Pharma's VP3 Nasal Spray System

Crystal Lake, Illinois, January 27, 2022 - Aptar Pharma, a global leader in drug delivery systems, services and active material science solutions, today announced that its VP3 multidose device is the delivery system for Glenmark's Ryaltris™ nasal spray, which recently received New Drug Application (NDA) approval by the U.S. Food and Drug Administration (FDA) for the treatment of symptoms of seasonal allergic rhinitis in adults and pediatric patients 12 years of age and older.

Using Aptar Pharma's innovative VP3 nasal spray with a custom-designed reduced evaporation cap, Ryaltris™ is a metered, fixed-dose, aqueous suspension prescription combination drug product nasal spray that combines an antihistamine (Olopatadine) with a steroid (Mometasone Furoate) for the treatment of symptoms of seasonal allergic rhinitis, including nasal and ocular symptoms¹.

The reference pump for anti-allergic treatments

Aptar Pharma's VP3 technology platform has been the industry gold standard for multidose nasal sprays for over 40 years for anti-allergic treatments, for both innovator brands and generics for locally acting drug products. The technology complies with U.S. FDA requirements and other global regulatory authorities, with numerous customer reference products already commercialized worldwide.



Glenmark's Ryaltris™ Nasal Spray is delivered using Aptar Pharma's VP3 technology platform

The effort to bring Ryaltris™ Nasal Spray to market was supported by a Combination Product Documentation package from Aptar Pharma's Services offering, a comprehensive portfolio of stage-specific development packages. Aptar Pharma's dedicated Regulatory Affairs professionals and analytical scientists help customers proactively address regulatory needs to accelerate approval.

¹ https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-NDA-approval-by-USFDA-for-Ryaltris-in-US_0.PDF



“Glenmark’s constant focus is on delivering the right treatment options to the patients, using effective technology. Adapting Aptar Pharma’s innovative VP3 multidose device as the delivery system for our novel Ryaltris™ nasal spray is yet another effort in this regard,” said Robert Crockart, Chief Commercial Officer, Glenmark Pharmaceuticals Ltd.

“This NDA approval by the U.S. FDA for a combination drug product using our VP3 multidose nasal pump further demonstrates Aptar Pharma’s ability to help our customers develop and launch novel treatments,” stated Gael Touya, President, Aptar Pharma. “Our nasal systems’ proven capabilities bring added value to our customers and further convenience for patients worldwide.”

Already approved and marketed in several countries across the world, Ryaltris™ will be marketed and distributed in the United States by Hikma Specialty U.S.A., Inc. as part of its exclusive licensing agreement with Glenmark Specialty S.A. (Switzerland)².

About Aptar Pharma

Aptar Pharma is part of AptarGroup, Inc., a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing and active material science solutions. Aptar’s innovative solutions and services serve a variety of end markets including pharmaceutical, beauty, personal care, home, food and beverage. Using insights, proprietary design, engineering and science to create dispensing, dosing and protective technologies for many of the world’s leading brands, Aptar in turn makes a meaningful difference in the lives, looks, health and homes of millions of patients and consumers around the world. Aptar is headquartered in Crystal Lake, Illinois and has 13,000 dedicated employees in 20 countries. For more information, visit www.aptar.com.

About Glenmark Pharmaceuticals Limited (Mumbai, India)

Glenmark Pharmaceuticals Limited (Glenmark) is a global research-led 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

² https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-NDA-approval-by-USFDA-for-Ryaltris-in-US_0.PDF



Press Release



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 the fourth consecutive year in a row; most 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.

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