

Hikma launches RYALTRIS™ seasonal allergic rhinitis nasal spray in the US

RYALTRIS™ is the only fixed-dose combination therapy that provides relief for both nasal and ocular symptoms of seasonal allergic rhinitis in one easy-to-use nasal spray

60 million Americans suffer from allergic rhinitis and allergic conjunctivitis yet approximately 8.5 million are still impacted by poor nasal symptom control

London, New Jersey, and Mumbai; August 30, 2022 – Hikma Pharmaceuticals PLC (Hikma, Group), the multinational pharmaceutical company, and Glenmark Specialty S.A., a subsidiary of Glenmark Pharmaceuticals Ltd. (Glenmark), an innovation driven global pharmaceutical company, announced the launch of RYALTRIS™ (olopatadine hydrochloride and mometasone furoate nasal spray) in the US. RYALTRIS™ is approved by the US Food and Drug Administration (FDA) for the treatment of symptoms of seasonal allergic rhinitis (SAR) in adult and pediatric patients 12 years of age and older. This launch builds upon Hikma's leading position as one of the largest US providers of nasally administered medicines used for treating seasonal allergies and advances its objective of growing its specialty business in the US.

RYALTRIS™ is the only fixed-dose combination therapy that provides relief for the symptoms of SAR, both nasal and ocular in one easy-to-use nasal spray. The onset of action for nasal symptom relief occurs within 15 minutes of a patient taking the first dose.^{1,2,3}

“Allergic rhinitis and allergic conjunctivitis are among the most common chronic diseases in the US today, affecting 60 million Americans each year,⁴ yet approximately one in seven US adults have reported their nasal allergy symptoms are either poorly controlled or not controlled at all,⁵ and ocular symptoms are reported to be as severe as nasal symptoms,”⁶ said Leonard Bielory, M.D. Professor of Medicine, Allergy, Immunology and Ophthalmology at Hackensack Meridian School of Medicine. “By combining two of the most frequently prescribed medicines used to address both the nasal and ocular symptoms of seasonal allergic rhinitis into one, easy-to-use nasal spray, RYALTRIS™ provides an important new treatment option for patients suffering from this chronic condition affecting the nose and eyes.”

Uncontrolled seasonal allergic rhinitis is a serious condition that places a substantial burden on patients and society as whole. The symptoms of allergic rhinitis can lead to chronic complications including asthma, sinusitis, hearing impairment, and other allergy-related complications^{7,8,9,10} which can have a significant impact on patients' quality of life.^{11,12,13} There is an important need for new treatment options like RYALTRIS™ to help treat seasonal allergic rhinitis, as patients who do not experience adequate symptom

¹ Patel P, et al. *Ann Allergy Asthma Immunol.* 2019;122(2):160-166

² Gross GN, et al. *Ann Allergy Asthma Immunol.* 2019;122(6):630-638

³ Hampel FC, et al. *Allergy Asthma Proc.* 2019;40(4):261-272

⁴ Meltzer EO. *Immunol Allergy Clin North Am.* 2016;36(2):235-248

⁵ Meltzer E, et al. *Allergy Asthma Proc.* 2012;33 (suppl 1):113-141.

⁶ Bielory L, et al. *Allergy Asthma Proc.* 2014 ;35(3):211-8..

⁷ National Institute for Health and Care Excellence. Complications allergic rhinitis. Updated April 29, 2019. Accessed January 2020.

⁸ Settipane RA. *Allergy Asthma Proc.* 1999;20(4):209-213.

⁹ Skoner, DP. *J Allergy Clin Immunol.* 2000;105(6 Pt 2) :S605-S609.

¹⁰ Chirakalwasan N, et al. *Asian Pac J Allergy Immunol.* 2014;32(4):276-286.

¹¹ D'Alonzo, GE Jr. *J Am Osteopath Assoc.* 2002;102(6 suppl 2):S2-S6.

¹² Marple et al. *Otolaryngol Head Neck Surg.* 2007;136(suppl 6):S107-S124.

¹³ Meltzer EO, et al. *Allergy Asthma Proc.* 2012;33(suppl 1):S113-S141.

relief may require therapy escalation to more costly and higher-risk treatments such as immunotherapy, biologics, and surgery.^{14,15,16,17,18}

“The launch of RYALTRIS™ is a significant step forward for Hikma in expanding our US nasal spray leadership into branded medicines and advancing our objective of growing our specialty business in the US,” said Brian Hoffmann, President of Hikma Generics. “Importantly, it will allow us to leverage our strong, existing specialty salesforce already calling on doctors within our specialty portfolio. We look forward to bringing this important new treatment option to the millions of US patients suffering from seasonal allergic rhinitis.”

“We are delighted to partner with Hikma for the launch of our novel drug RYALTRIS™ in the United States, making it our first global branded specialty product to be marketed in the country. RYALTRIS™ is a result of our consistent efforts to offer high-quality medicines that benefit patients around the world. Available in major markets across the globe, this launch is a major milestone for Glenmark and demonstrates our focus in strengthening our global respiratory leadership,” said Brendan O’Grady, Chief Executive Officer - Global Formulations Business, Glenmark Pharmaceuticals Ltd.

About RYALTRIS™

The efficacy and safety of RYALTRIS™ was established in a robust clinical studies program in over 4,000 patients with SAR. Twice-daily RYALTRIS™ provided statistically significant improvement in both nasal and ocular symptoms vs. placebo,^{1,2,3} as well as statistically significant onset of action in nasal symptom relief vs. placebo at 10-15 minutes,^{1,2,3} across three randomized, double-blind phase 3 studies (P<0.05). RYALTRIS™ also provided significant and clinically meaningful sustained improvements in nasal symptoms versus placebo over 52 weeks with no evidence of tachyphylaxis in patients with perennial allergic rhinitis (PAR).^{1,2,3} RYALTRIS™ demonstrated a safety profile consistent with placebo, monotherapy, and comparator fixed-dose-combination treatment.^{1,2,3}

About Seasonal Allergic Rhinitis

Allergic rhinitis is one of the most common chronic diseases in the United States, affecting 60 million Americans annually.⁴ Season allergic rhinitis (SAR) occurs in a specific pollen season, and is an allergic reaction to pollen from trees, grasses, and weeds. According to the most recent CDC data, almost 20 million adults in the United States are affected by seasonal allergic rhinitis every year.¹⁴ It is estimated to affect more than seven percent of adults aged 18 years and over in the US.¹³

- ENDS -

¹⁴ Seidman MD, et al. *Otolaryngol Head Neck Surg.* 2015;152(1S):S1-S43.

¹⁵ Bhattacharyya N, et al. *The Laryngoscope.* 2019;129:1969–1975.

¹⁶ ICER 2018 Final Report of Biologic Therapies for Treatment of Asthma Associated with Type 2 Inflammation. *2018 Wholesale Acquisition Costs x 1 year of dosing for allergic asthma (on-label indication). Use of biologics for SAR is off-label & dosing strategies are not established.

¹⁷ Gevaert P, et al. *J Allergy Clin Immunol.* 2013;131:110-6.

¹⁸ Wu A, et al. *J Allergy Clin Immunol Pract.* 2021;9:1107-17.

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About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,700 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY)
(LEI:549300BNS685UXH4JI75) (rated BBB-/stable S&P and Ba1/stable Moody's)

About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an innovation-driven global pharmaceutical company with a presence across Specialty, Generics and OTC businesses. It focuses on the key therapeutic areas of respiratory, dermatology and oncology. The company has 10 worldclass manufacturing facilities spread across 4 continents and operations in over 80 countries. Glenmark is ranked among the world's top 100 biopharmaceutical companies (Top 100 Companies Ranked by Pharmaceutical Sales, 2020, by In Vivo/Scrip 100) and among the world's top 50 companies in the off-patent sector (Top 50 Generics and Biosimilars Companies ranked by Sales, 2020, by Generics Bulletin/In Vivo). The company was listed on the Dow Jones Sustainability Index (DJSI), one of the world's most respected and widely accepted sustainability benchmarks, under the category of emerging markets (2021) for the fourth consecutive year. For more information, visit www.glenmarkpharma.com.

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U.S. Important Safety Information for Ryaltris™

- Ryaltris™ is an intra-nasal spray and should not be administered orally, instilled in the eyes, ears or applied to the skin.
- In clinical studies, the most common adverse events that were observed in those 12 years of age and over using Ryaltris™, were altered taste (3%), nose bleeds (1%) and nasal discomfort (1%).
- Ryaltris™ should not be used by anyone who has had an allergic reaction to olopatadine or mometasone.
- Close medical supervision is required in anyone who has a weakened immune system, including those who have had infections with opportunistic pathogens. Increased risk of occurrence or potential worsening of pre-existing infections (e.g. tuberculosis) with fungi, bacteria or viruses can occur; including fatal chickenpox, measles and herpes infections in susceptible patients.
- Ryaltris™ should be used under close medical supervision in anyone who has had nose bleeds or nasal perforation. Recurrence, worsening or persistence of these nasal problems can occur.
- Close growth monitoring of pediatric patients (12 years and over) by a medical practitioner is recommended with the use of Ryaltris™.
- Ryaltris™ effect on pregnancy and through transmission in breast milk is not known. Talk to your doctor if you are pregnant, plan to become pregnant or breastfeeding, to ensure it is safe for you to use.

[For more information, please see the full Prescribing Information and Patient Information](#)