

## “Our allergic rhinitis drug is technologically superior, masks bitterness and 52% cheaper”

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Mumbai-based Glenmark Pharmaceuticals is the first company in the world to launch Ryaltris-AZ as a novel fixed dose combination of Mometasone furoate 50 mcg + Azelastine 140 mcg, for the treatment of moderate to severe allergic rhinitis. Recently, it has become the first company to launch the branded generic version, in the form of Ryaltris-AZ Nasal Spray, at an affordable cost for the treatment of allergic rhinitis in India. Aiming to provide patients a far more convenient, and cost effective treatment option in the country, Glenmark is currently working on strengthening its respiratory segment, which is the need of the hour. Alok Malik, Group Vice President & Head, India Formulations, Glenmark Pharmaceuticals, Mumbai spoke to BioSpectrum in detail about the growth plans of the company in the allergic rhinitis space. Edited excerpts



### How big is the allergic rhinitis market in India? Who are the key players?

Around 600 million people in the world are suffering from allergic rhinitis (AR). Of this, the incidence of AR in India is around 20 to 30 per cent. Majority of the patients in India suffer from nasal obstruction as a major symptom of AR. The overall AR market in India is divided into two parts: Oral Antihistamines (OAH) valued at Rs 1599 crore and Intranasal Corticosteroids & Comb (Nasal Spray) valued at Rs 280 crore. The total market accounts for around Rs 1879 crore in India. The key players of the nasal spray market include Cipla, Lupin and Zydus.

### What are the current challenges facing this market?

In India, Intranasal Corticosteroid (INCs) and combination market is dominated by few players. However, most of the existing brands made available in the market by such players offer high cost of therapy as compared to Oral Antihistamines (Tablets). As, in India, patients have to bear the drug cost on their own, the price of the drug becomes a major factor that impacts treatment adherence.

### **How do you plan to make a difference in the allergic rhinitis market with Ryaltris-AZ Nasal Spray?**

To address the challenges, Glenmark became the latest entrant in this category and the first company in the world to launch its novel fixed dose combination of Mometasone Furoate (INCS) 50 mcg and Azelastine (INAH) 140 mcg, under the brand name Ryaltris –AZ, at an affordable price. Being a topical therapy, Ryaltris-AZ offers many advantages over oral therapies, such as delivering greater concentrations of drug to the receptor sites at the source of the allergic inflammation and reduced risk of systemic side effects. Mometasone has been found to have least systemic bioavailability and least systemic side effects as compared to other Intranasal Corticosteroids. Ryaltris-AZ Nasal Spray relieves symptoms of allergic rhinitis, including stuffy nose, runny nose, nasal itching, sneezing, as well as itchy, red and watery eyes – for patients over 12 years of age. This will provide patients a far more convenient, effective treatment option in the country.

### **Take us through the R&D of this product. How is it unique?**

AR is a widespread chronic condition that manifests itself with a number of debilitating symptoms of the nose and eyes, having a significant impact on the quality of life and health of the patient, forcing them to consult a doctor. The prevalence of AR ranges from 2 to 25 per cent in children and from 1 to 40 per cent in the adult population. It reduces the quality of life of many patients by impairing sleep quality and cognitive function, causing fatigue and depression.

Intranasal corticosteroids and antihistamines form the basis of pharmacotherapy for AR but often, especially in patients with seasonal AR, the use of combination therapy with these drugs is required. But concomitant use of these drugs can increase their effectiveness, which is often required in patients with severe forms who are not satisfied with the current therapy.

Azelastine is a second-generation topical antihistamine with a rapid effect on the symptoms of AR and vasomotor rhinitis. We found that the fixed combination of azelastine hydrochloride 140 mcg + mometasone furoate 50 mcg in the form of a nasal spray is no less effective and safer than the original preparations of azelastine hydrochloride nasal spray; and mometasone furoate nasal spray applied from separate devices. The USP of our product is that it is a technologically superior formulation, it masks the bitterness of Azelastine, and less amount of drug is required to deliver the same dosage.

### **What is the current cost for Ryaltris-AZ Nasal Spray in India?**

While the average cost of therapy of top 10 existing brands of the similar drug category is Rs 365, Glenmark's Ryaltris-AZ nasal spray has been launched at a breakthrough price of Rs 175 per pack of 75 metered doses (MD). This cost is around 52 per cent less as compared to the average price of the top 10 brands of the similar drug category in the market.

### **Are you planning to launch this product in APAC countries?**

Ryaltris (olopatadine hydrochloride and mometasone furoate) Nasal Spray is the company's respiratory pipeline asset and is currently under review with the US Food and Drug Administration (US FDA) as a treatment for seasonal allergic rhinitis in the USA. Glenmark's response to the US FDA's Complete Response Letter (CRL) is targeted to be submitted to the US FDA shortly. Ryaltris sales continue to progress well in Australia and South Africa. Glenmark has also initiated the commercial launch of Ryaltris in Ukraine and Uzbekistan during the fourth quarter of FY 2021-22.

Glenmark and Bausch Health have entered into an exclusive licensing agreement for the commercialisation of Ryaltris in Canada. Ryaltris is currently under review by Health Canada. We have completed several regulatory filings for Ryaltris in Q4,

notably in Egypt, Singapore, Jamaica, Kazakhstan and Maldives. The company is awaiting regulatory approvals for its filings in various markets across Canada, Brazil, Malaysia, Saudi Arabia and several other emerging markets. In Q4 FY21, our partner in China, Grand Pharmaceutical (China) Co. Ltd., submitted a revised development and registration strategy for Ryaltris in China through a Pre-IND application. CDE has since provided positive feedback which will enable IND submission in China by mid FY22. Glenmark is working with its partner in South Korea, Yuhan Corporation, to submit the pediatric efficacy supplement in FY22.

**Do you plan to launch any other drugs to treat allergic rhinitis in future?**

Yes, we plan to launch new products for the treatment of AR in the near future.

**What are the major plans in store for the next five years in India?**

Over the next five years, Glenmark plans to further strengthen its franchise for AR in the country.

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