Allergic rhinitis (AR) is a prevalent condition, and places a high burden on individuals and society. The majority of AR patients present to their doctor with moderate-to-severe disease that is already treated, with approximately 75% taking 2 or more therapies. However, patients remain symptomatic, even those on multiple therapies, highlighting the need for a new and more effective AR treatment option.

Dymista is a novel intranasal formulation of azelastine hydrochloride (AZE) and fluticasone propionate (FP), indicated for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient. Approval of Dymista in Europe was supported by data from 4 large seasonal AR (SAR) clinical trials.1,2

**SAR study design**

The first of these studies compared Dymista to two marketed comparators; an intranasal antihistamine (AZE) and an intranasal corticosteroid (FP, [Flixonase]).1 610 subjects (≥12 years old) with moderate to severe SAR were randomised into this multicentre, double-blind, placebo-controlled trial to 14 days treatment with Dymista, AZE, FP or placebo nasal sprays. The primary efficacy variable was change from baseline in the AM + PM reflective total nasal symptom score (rTNSS) comprising the 4 symptoms of nasal congestion, itching, rhinorrhea and sneezing (range 0-24). Post hoc endpoints included the sum of nasal and ocular symptoms (rT7SS) comprising 7 symptoms (i.e. rTNSS plus ocular itching, watering and redness), as well as efficacy by disease severity and responder analyses. Response was predefined as substantial (i.e. ≥50% reduction in rTNSS) or complete/near-to-complete (i.e. at most mild for each symptom of the rTNSS).

Dymista twice as effective and twice as fast as an intranasal steroid in providing substantial symptom relief

- Dymista most effectively provided relief from the entire rhinitis symptom complex (relative difference in rT7SS of 52% to FP and 56% to AZE) (see Figure). Superior relief was evident from day 1 and sustained.1
- Dymista provided superior relief from each individual nasal and ocular symptom, including nasal congestion and ocular itching, the most bothersome ones.1
- Dymista provided the best symptom relief, irrespective of severity.1
- More patients treated with Dymista achieved substantial and complete/near-to-complete nasal symptom relief, and achieved these responses faster than current first-line therapy; up to 6 days faster for substantial relief (e.g. on Day 4 for Dymista vs Day 10 for FP) and up to 8 days faster for complete/near-to-complete relief (e.g. Day 6 for Dymista vs Day 14 for FP).1
- Dymista has an excellent safety profile.1

† p=0.0013 vs Dymista; ‡ p=0.004 vs Dymista

**Conclusion**

Dymista is twice as effective as an intranasal corticosteroid (the current gold-standard AR treatment option) in providing relief from patients’ nasal and ocular symptoms. It provides faster and more complete nasal symptom control than first-line therapies. It is consistently superior irrespective of severity or response criteria. Dymista may be considered the drug of choice for moderate-to-severe AR patients, since these patients remain symptomatic on current therapies.

Meda’s clinical development programme represents to date the largest body of evidence directly comparing first-line AR therapies.

**References**


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