



## Positive study results presented for Dymista

Meda announced today positive results from a Phase III clinical trial of Dymista (also known as MP29-02), a novel formulation of azelastine hydrochloride and fluticasone propionate, in patients with seasonal allergic rhinitis (SAR). Patients treated with Dymista experienced a 40 percent greater improvement in nasal symptoms, including congestion, relative to fluticasone. The mono substances (in the nasal antihistamine and corticosteroid markets respectively) both have leading positions in the U.S. The fast onset compared to placebo, as well as more rapid relief and greater response rate compared to either fluticasone and azelastine alone, or placebo, was also demonstrated in this study. The study results are published online in *Journal of Allergy Clinical Immunology*<sup>i,ii</sup> and are being presented at the 2011 annual meeting of the American Academy of Asthma, Allergy and Immunology (AAAAI) in San Francisco, CA.

*“Seasonal allergic rhinitis is a condition causing great discomfort and inconvenience for many people,”* said Warner W. Carr, MD, FAAAAI, FAAAAI, Allergy & Asthma Associates of Southern California, principal investigator and lead author of this study. *“These results suggest that Dymista provides greater relief of the most frequent nasal symptoms than these treatments alone, and is well tolerated.”*

### Clinical Trial

Dymista was studied in a Phase III randomized, double-blind, placebo-controlled trial of two weeks duration conducted in nearly 800 patients with seasonal allergic rhinitis (SAR). The primary efficacy variable was the change from baseline in the 12-hour reflective Total Nasal Symptom Score (TNSS), consisting of nasal congestion, sneezing, itchy nose, and running

nose. Symptoms were scored twice daily on a 4-point scale. In this study, Dymista was compared to placebo (same vehicle as Dymista minus azelastine and fluticasone), azelastine hydrochloride monotherapy (in the Dymista vehicle) and fluticasone propionate (in the Dymista vehicle).

In this study, Dymista nasal spray significantly improved the TNSS compared to placebo and either fluticasone or azelastine alone during a 14-day treatment period. Dymista demonstrated a 40 percent improvement in TNSS relative to fluticasone. Both fluticasone or azelastine alone were more effective than placebo ( $P < .001$ ). Dymista was effective for treating all individual symptoms of the TNSS ( $P < .001$  vs. placebo), including nasal congestion vs. fluticasone. The therapy was generally well-tolerated. Headache (3.1%) and dysgeusia (2.1%) were the most commonly reported adverse events with Dymista.

In another analysis of this study, a key secondary efficacy variable was onset of action, defined as sustained statistically significant superiority versus placebo in instantaneous TNSS during a 4-hour observation period. Onset of action was achieved within 30 minutes following the first dose with Dymista vs. placebo. In a post-hoc analysis of time-to-treat response (50% change in TNSS), response was reached days earlier which was statistically significant and more responders were observed with Dymista (53.5% vs.  $\leq 43.7\%$ ) than with either fluticasone or placebo.

*“Optimal treatment of this common condition should reduce symptoms as effectively and quickly as possible”, continued Dr. Carr. “These data clearly show that Dymista applied right at the site – in the nasal passage – is more effective than fluticasone propionate, a current standard of care, and provides fast-acting relief of nasal symptoms associated with seasonal allergic rhinitis.”*

*“Based on these positive data, we intend to submit a marketing application to the FDA during the first half of 2011,” said Anders Lönner, CEO Meda AB. “Dymista could become the first product which has better efficacy than currently available standard allergic rhinitis nasal therapy. We hope to deliver this new option for the treatment of SAR to benefit the patients who routinely suffer from this condition.”*

---

**For further inquiries, please contact:**

Anders Larnholt, Vice President Corporate Development & IR    ph: +46 709-458 878

---

**MEDA AB (publ)** is a leading international specialty pharma company. Meda's products are sold in 120 countries worldwide and the company is represented by its own organizations in 50 countries. The Meda share is listed under Large Cap on the Nasdaq OMX Nordic Stock Exchange in Stockholm. Find out more, visit [www.meda.se](http://www.meda.se).

---

<sup>i</sup> Bernstein JA, Munzel U, et al. Onset of Action of MP29-02 in the Treatment of Seasonal Allergic Rhinitis. J Allergy Clin Immunol 2011; 127; 2; Abstracts 199

<sup>ii</sup> Carr W, Shah SR, et al. MP29-02 in the Treatment of Nasal Symptoms of Seasonal Allergic Rhinitis. J Allergy Clin Immunol 2011; 127; 2; Abstracts 199