Press release, 15 June 2011

New positive study results presented for Dymista

Meda presents new positive results from a Phase-III clinical trial of Dymista (also known as MP29-02) at the annual meeting of the European Academy of Allergy and Clinical Immunology (EAACI) in Istanbul, Turkey (11–15th June 2011)[1-5].

By 2015, half of all Europeans will suffer from an allergy according to the European Federation of Allergy and Airway Diseases[6]. Allergic rhinitis (AR) has become a challenge to treat, mainly due to an increase in the prevalence of severe allergic rhinitis over the last decade. Currently, 500 million people around the world suffer from AR with approximately three quarters suffering from moderate-to-severe forms of the disease[7,8,9,10]. Up to 77.8% are non-compliant with their intranasal corticosteroid therapy[11,12], while 3 out of 4 patients use various combination therapies to control their symptoms[13]. The cost associated with AR is significant[14].

According to the ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines, there is a need for high-quality, direct comparison rhinitis effectiveness studies[15] that will allow healthcare professionals and patients to assess the added value of new products over currently used ones in their efforts to manage AR more effectively.

Earlier this year, Meda presented parts of the Dymista clinical development program at the AAAAI meeting in San Francisco showing that Dymista was more effective in reducing nasal rhinitis symptoms than the leading nasal corticosteroid fluticasone. Meda will now present data from 3 randomized, placebo-controlled, parallel-group studies at EAACI 2011, conducted with over 2,200 patients. The results show that Dymista is a breakthrough product for the treatment of AR, as it is more effective than intranasal fluticasone propionate or azelastine nasal sprays in reducing nasal rhinitis symptoms, while presenting no safety concerns[1–5].

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Importantly, Dymista provides clinically relevant symptom improvement significantly earlier and in more patients than compared to current standard therapies. It is also highly effective in controlling ocular symptoms associated with allergic rhinoconjunctivitis.[1-5]

In study MP4001, a post-hoc responder analysis revealed that almost half of all patients treated with Dymista (49.1%) achieved a clinically-significant 50% improvement in rTNSS (Total Nasal Symptom Score). Time to reach this clinically relevant response also favored Dymista, at 5–6 days earlier than fluticasone propionate or azelastine monotherapy.

The benefits of Dymista were summarized by Professor Claus Bachert (Professor of Medicine at the University of Ghent in Belgium) who concluded that "*the novel Dymista nasal spray shows better efficacy than standard therapy for AR and provides clinically relevant TNSS reduction significantly earlier and in a larger number of patients".*

The fact that Dymista provides relevant TNSS reduction earlier than standard therapy for AR was highlighted in the spring study (MP4002) presented by Professor Jean Bousquet (Professor of Pulmonary Medicine at the University of Montpellier in France and Founder and Chairman of ARIA). The significant superiority of Dymista over conventional rhinitis therapies became apparent from the first day of evaluation. The rapid response to Dymista is important, as patients want fast-acting and long-lasting symptom relief[16].

Results from study MP4004, conducted during the autumn allergy season, were presented by Professor David Price (Professor of Primary Care Respiratory Medicine at the University of Aberdeen in Scotland) and Dr Warner Carr (MD, FAAAAI, FACAAI, Allergy & Asthma Associates of Southern California and principal investigator). In this study, onset of action and efficacy against ocular symptoms (rTOSS) was assessed. Onset of action was achieved within 30 minutes following Dymista administration. Dymista also significantly reduced ocular (rTOSS) symptoms to a greater extent than fluticasone propionate. This is an important attribute of Dymista, as patients with AR frequently have the associated condition of allergic conjunctivitis and as a result suffer from bothersome ocular symptoms in addition to nasal symptoms.

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"Dymista is an important product since it has the potential to help millions of AR suffers find better relief from their symptoms. A new drug application for Dymista was submitted to the FDA in April 2011. The application was recently accepted by the FDA as sufficiently complete to permit a substantive review. We expect to submit the file to European regulatory authorities later this year", said Anders Lönner, CEO of Meda AB.

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