Press release, 5 March 2012

Positive results for Dymista in three clinical studies

Meda announced today positive results of three studies of MP29-02 (tentatively called Dymista), a novel intranasal formulation of azelastine hydrochloride and fluticasone propionate. The first study demonstrated that continuous treatment with MP29-02 for 1 year was well tolerated in patients with chronic allergic or non-allergic rhinitis, only 2.7% of patients treated with MP29-02 and 2.9% of patients treated with fluticasone propionate discontinued the study due to an adverse event. MP29-02 also provided sustained efficacy over the one-year study period. MP29-02-treated patients experienced consistently greater relief from their nasal symptoms than fluticasone treated patients over the course of the study. Statistically significant (P<.05) differences favoring MP29-02 over fluticasone were observed at months 1 through 7 and at months 9 and 11.

The second and third studies in patients with seasonal allergic rhinitis (SAR) provided evidence that MP29-02 demonstrated significantly more effective relief of nasal symptoms (P<.05 vs. azelastine, fluticasone, and placebo) and significantly greater ocular benefits compared to placebo (P<.05) over a 2-week study period. The new data was the subject of platform presentations on Sunday, March 4, 2012 at the annual meeting of the American Academy of Allergy Asthma and Immunology (AAAAI) in Orlando, Florida. MP29-02 is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of SAR.

"These data show support for the safety and efficacy of this novel nasal spray formulation, especially for patients who have persistent symptoms of seasonal allergic rhinitis that may require longer-term treatment," said William E. Berger, MD, FAAAAI, FACAAI, Asthma & Allergy Associates of Southern California, lead author of the first study.

In the United States, ocular symptoms linked to allergies, also known as "allergic conjunctivitis" or "ocular allergy", are known to affect more than 20 percent of the population[i] and can have a negative effect on visual function, daily activities, and quality of life. It is common for patients with allergic rhinitis to suffer

Meda AB (publ), corporate ID: 556427-2812
Pipers väg 2A, Box 906, SE-170 09 Solna, Sweden
info@meda.se, www.meda.se, Tel: +46-8-630 19 00. Fax: +46-8-630 19 50

from bothersome ocular symptoms in addition to nasal symptoms, with a high prevalence and pattern that correlate with season, region, and environmental triggers.

"In addition to nasal congestion, runny nose and sneezing, ocular symptoms such as watering and red, itchy eyes are particularly prevalent in seasonal allergic rhinitis sufferers and can be extremely irritating and distressing", said Paul H. Ratner, M.D., M.B.A., Sylvana Research, San Antonio, TX, principal investigator and lead author of the second and third studies. "*The potential for more complete relief of the constellation of symptoms would represent a significant benefit to patients and a major advance in the treatment of seasonal allergic rhinitis."*

Long-Term Safety Study

In study MP4000, presented by Dr. Berger, the long-term safety of MP29-02 was evaluated in 612 patients with chronic allergic or non-allergic rhinitis over the course of one year. In this randomized, open-label, active-controlled, parallel-group study, patients were treated with either MP29-02 one spray per nostril twice daily (total daily doses of azelastine and fluticasone were 548 mcg and 200 mcg, respectively) or fluticasone propionate two sprays per nostril once daily (total daily dose 200 mcg). Safety and tolerability assessments were conducted at regular intervals during the one-year study and efficacy was assessed as a secondary endpoint by the 12-hour reflective total nasal symptom score (rTNSS) scored once daily in the evening each day of the study.

The results showed that MP29-02 was well tolerated. The most common treatment-related adverse events were headache in 4.3 percent of patients taking fluticasone and dysgeusia in 2.5 percent of patients taking MP29-02. There were no clinically relevant nasal examination findings, in particular no evidence of nasal ulceration or perforations in either group. Ocular examinations were also unremarkable. No appreciable changes in laboratory values were observed during the study and there were no significant changes from baseline in serum cortisol levels in either treatment group.
In addition, based on the rTNSS, the efficacy of MP29-02 was sustained over the one-year duration of the study.[ii iii] MP29-02-treated patients experienced greater relief from their nasal symptoms than fluticasone propionate treated patients, with statistical significance ($P<0.05$) achieved up to and including week 28, and treatment difference maintained consistently for 52 weeks.

Ocular Symptoms Studies

In an analysis of two pivotal studies (MP4002 and MP4004), presented by Dr. Ratner, MP29-02 was evaluated for the treatment of ocular symptoms associated with SAR, a key secondary endpoint in the MP29-02 clinical development program.

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These key clinical efficacy and safety studies of MP29-02 were randomized, double-blind, placebo- and active-controlled two week trials conducted in more than 1600 patients with moderate-to-severe SAR. While the primary endpoint was change from baseline in the 12-hour reflective total nasal symptom score (rTNSS), the key secondary endpoint was the 12-hour reflective total ocular symptom score (rTOSS), consisting of itchy eyes, watery eyes, and eye redness. All patients were treated with one spray per nostril twice daily using the same vehicle and delivery device.

In addition to more effective relief of nasal symptoms, results demonstrated MP29-02 significantly (P<.05) improved the total ocular symptom score (TOSS) compared to placebo. In a post-hoc analysis, significantly (P<.05) more patients treated with MP29-02 experienced a clinically important 50 percent improvement in ocular symptoms than patients treated with fluticasone or azelastine in study MP 4004, and, in a second post-hoc analysis, MP29-02 appeared to be particularly effective in patients with more severe symptoms. MP29-02 was well tolerated in these two-week studies and the incidence of adverse events in the MP29-02 group generally was similar to the azelastine and fluticasone treatment groups.[iv]

"We are very pleased about the continuous flow of strong results from our Phase III pivotal studies supporting the unique clinical profile of Dymista," said Anders Lönner, CEO of Meda AB. *"These data provide additional important evidence that Dymista can offer significant benefits to patients and may play a critical role in the future treatment of patients with SAR."*

About Seasonal Allergic Rhinitis

Approximately 40 million people in the U.S. suffer from seasonal and perennial allergic rhinitis.[v] Seasonal allergic rhinitis occurs during a specific season, commonly in the fall and spring, and is caused by outdoor allergy triggers such as tree, grass or ragweed pollen. Perennial allergic rhinitis occurs throughout the year and is typically caused by indoor allergens such as dust mites, mold and animal dander. Symptoms of allergic rhinitis, or hay fever, frequently include nasal congestion, runny nose, sneezing, nose and itching.

The U.S. Food and Drug Administration informed Meda that the PDUFA (Prescription Drug User Fee Act) date for MP29-02 will be early May 2012.

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info@meda.se, www.meda.se, Tel: +46-8-630 19 00. Fax: +46-8-630 19 50

For further inquiries, please contact:

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

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[i] Leonard Bielory, MD; C. H. Katelaris, MD; Susan Lightman, FRCP, FRCOphth, PhD; Robert M. Naclerio, MD Treating the Ocular Component of Allergic Rhinoconjunctivitis and Related Eye Disorders, Medscape Today Posted: 08/15/2007; Medscape General Medicine. 2007;9(3):35 © 2007 Medscape **http://www.medscape.com/viewarticle/560750**

[ii] Berger W, et. al. Long Term Safety Study of MP29-02 (novel intranasal formulation of azelastine hydrochloride and fluticasone propionate) in Subjects with Chronic Allergic or Non-allergic Rhinitis. Presented at the 2012 Meeting of the AAAAI Mar 4, 2012.

[iii] Berger W, et. al. Long Term Safety Study of MP29-02 (novel intranasal formulation of azelastine hydrochloride and fluticasone propionate) in Subjects with Chronic Allergic or Non-allergic Rhinitis. Presented at the 2012 Meeting of the AAAAI Mar 4, 2012.

[iv] Ratner P, et. al. MP29-02 (Intranasal Formulation of Azelastine Hydrochloride and Fluticasone Propionate) in the Treatment of Ocular Symptoms of Seasonal Allergic Rhinitis (SAR). Presented at the 2012 Meeting of the AAAAI Mar 4, 2012.

[v] AAFA Allergy Fact & Figures. Available at http://www.aafa.org/display.cfm?id=9&sub=30#_ftnref1. Accessed on January 20, 2012.

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