

## For Immediate Release

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# MEDA RECEIVES FDA APPROVAL OF NEW ASTEPRO® (azelastine HCI) NASAL SPRAY 0.15%, THE FIRST AND ONLY ONCE-DAILY NASAL ANTIHISTAMINE

ASTEPRO Nasal Spray 0.15% Offers Rapid Relief of Seasonal and Perennial Nasal Allergy Symptoms, Including Nasal Congestion

Somerset, NJ, September 2, 2009 – Meda Pharmaceuticals Inc. today announced that the US Food and Drug Administration (FDA) has approved ASTEPRO® (azelastine HCl) Nasal Spray 0.15%, for the treatment of the symptoms of seasonal and perennial allergic rhinitis (SAR and PAR). New ASTEPRO Nasal Spray 0.15% is the first nasal antihistamine to offer convenient once-daily dosing for patients who suffer from seasonal allergies. ASTEPRO Nasal Spray 0.15% relieves rhinitis symptoms, including nasal congestion, without an added decongestant such as pseudoephedrine and is formulated with azelastine, a leading nasal antihistamine in the treatment of seasonal rhinitis in the U.S. The product will be available in pharmacies in early October.

Approximately 40 million people in the U.S. suffer from seasonal and perennial allergic rhinitis. 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.

"Seasonal and perennial allergy sufferers may benefit from ASTEPRO nasal spray 0.15%, which is 50 percent more concentrated than original ASTEPRO and offers convenient once- or twice-daily dosing for SAR. It provides fast-acting relief and is applied right at the site – in the

nasal passage – to treat a broad spectrum of nasal symptoms, including congestion, caused by indoor and outdoor allergies," said William Berger, M.D, Clinical Professor, Division of Allergy and Immunology, University of California. "Based on demonstrated improvement in nasal allergy symptoms, ASTEPRO 0.15% is a good first-line therapy option for seasonal and perennial allergic rhinitis patients suffering with nasal symptoms."

"The approval of ASTEPRO Nasal Spray 0.15% represents a significant milestone for Meda as we continue to expand and strengthen our allergy treatment franchise," said Sharon Clarke, President and General Manager, Meda Pharmaceuticals Inc. "We are proud to introduce the first nasal antihistamine indicated for PAR and SAR with BID and QD dosing to the US market. We believe ASTEPRO Nasal Spray 0.15% can simplify the physician's treatment decision for patients with seasonal and perennial allergic rhinitis, and help patients who want rapid nasal symptom relief."

#### **Clinical Studies**

FDA approval was based primarily on the results of seven double-blind, placebo-controlled Phase III clinical trials of two to four weeks duration, and a long-term, 12-month safety trial, conducted in more than 2,300 patients with seasonal or perennial allergic rhinitis. In the SAR trials, patients were treated with 2 sprays per nostril of either ASTEPRO Nasal Spray 0.15% or placebo administered once or twice daily. In the PAR trial, patients were treated with 2 sprays per nostril of either ASTEPRO Nasal Spray 0.15% or placebo administered twice daily. Overall, results from the two- to four- week clinical trials showed that patients treated with ASTEPRO Nasal Spray 0.15% experienced a significant reduction in total nasal symptom scores (TNSS) over the entire study period compared to placebo. The TNSS consists of patient rated scores of nasal congestion, itchy nose, running nose and sneezing.

ASTEPRO Nasal Spray 0.15% demonstrated a rapid onset of nasal symptom relief in as early as 30 minutes in one clinical trial and in 45 minutes in a second trial.

Once-daily or twice-daily use of ASTEPRO Nasal Spray 0.15% was generally well tolerated in the seven clinical trials. The most common adverse events when dosed two sprays per nostril (once or twice daily, respectively) for SAR and PAR included bitter taste (4 percent, 6 percent), nasal discomfort (4 percent, 3 percent), epistaxis (2 percent, 1 percent), and sneezing (1 percent, 2

percent). Overall, less than two percent of patients discontinued due to adverse reactions. Withdrawal due to adverse reactions was similar among the treatment groups. In the above trials, somnolence was reported in <1% of patients treated with ASTEPRO Nasal Spray 0.15% (11 of 1544) or vehicle placebo (1 of 1339).

In the 12-month, long-term safety trial, 466 patients (12 years of age and older) with perennial allergic rhinitis were treated with ASTEPRO Nasal Spray 0.15% two sprays per nostril twice daily and 237 patients were treated with mometasone nasal spray two sprays per nostril once daily. The most frequently reported adverse reactions (>5%) with ASTEPRO Nasal Spray 0.15% were bitter taste, headache, sinusitis, and epistaxis. Focused nasal examinations were performed and no nasal ulcerations or septal perforations were observed. No patients had reports of severe epistaxis. Fifty-four patients (12%) treated with ASTEPRO Nasal Spray 0.15% and 17 patients (7%) treated with mometasone nasal spray discontinued from the trial due to adverse events over the course of 12 months.

## **About ASTEPRO**

The active ingredient in ASTEPRO Nasal Spray 0.15% is azelastine - a leading nasal antihistamine in the treatment of seasonal rhinitis in the U.S. ASTEPRO Nasal Spray 0.15% is supplied as a metered-dose solution for intranasal administration. ASTEPRO 0.15% is formulated with sucralose, a non-caloric sweetener with a safety profile established in more than 100 scientific studies. Each metered spray of ASTEPRO Nasal Spray 0.15% delivers 205.5 mcg (micrograms) of azelastine hydrochloride.

# **Important Information**

ASTEPRO® (azelastine HCI) Nasal Spray 0.15% is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis in patients 12 years of age and older.

For adults and children 12 years of age and older with seasonal allergic rhinitis, the recommended dose of ASTEPRO Nasal Spray 0.15% is 1 or 2 sprays in each nostril twice daily or 2 sprays in each nostril once daily. The recommended dose of ASTEPRO Nasal Spray 0.15% for perennial allergic rhinitis is 2 sprays in each nostril twice daily.

In 2- and 4- week clinical trials for ASTEPRO Nasal Spray 0.15%, the most common adverse reactions reported included bitter taste, nasal discomfort, epistaxis, and sneezing.

Avoid engaging in hazardous occupations requiring complete mental alertness when taking ASTEPRO Nasal Spray 0.15%.

Avoid concurrent use of alcohol or other central nervous system depressants with ASTEPRO Nasal Spray 0.15%.

ASTEPRO Nasal Spray 0.1% and 0.15% are available by prescription only.

Please see full prescribing information available at <a href="www.astepro.com">www.astepro.com</a>. For more information, contact Anders Larnholt, VP Corporate Development & Investor Relations at +46 709 458 878.

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