

For Immediate Release

Contact: Mike Beyer  
Sam Brown Inc.  
773-463-4211  
[beyer@sambrown.com](mailto:beyer@sambrown.com)

**Steroid-Free Astelin® Nasal Spray Demonstrated Seasonal Allergy Symptom Improvement  
Within 15 Minutes in Clinical Study**

– Data Presented at AAAAI Annual Meeting –

SOMERSET, NEW JERSEY – February 25, 2007 – The prescription antihistamine Astelin® (azelastine HCl) Nasal Spray relieved the major symptoms of pollen allergy, including sneezing, runny nose and congestion, within 15 minutes of application compared to placebo and maintained efficacy at all time points for 8 hours in a randomized, single dose, double-blind, placebo-controlled study, MedPointe Pharmaceuticals announced today. In addition, a group of patients treated with intranasal Nasonex® (mometasone furoate monohydrate) did not show symptom improvement compared to placebo during the eight hour study period. Data from the 450-patient study, conducted in a controlled environmental exposure unit (EEU), were presented at the 2007 American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting in San Diego, California.

“Patients suffering from seasonal allergies want rapid relief from their symptoms. These new data confirm that the second-generation antihistamine nasal spray ASTELIN is fast-acting and maintains significant control of moderate to severe allergy symptoms,” said William E. Berger, MD, Clinical Professor, Department of Pediatrics, Division of Allergy and Immunology, University of California, Irvine, and Medical Director of Allergy and Asthma Associates of Southern California. “Because ASTELIN rapidly relieves the full range of rhinitis symptoms, including congestion, caused by both seasonal allergens and environmental irritants, and is well-tolerated, it is a particularly effective first-line therapy for most patients.”

**About the Study**

The study was designed to compare the onset of action of ASTELIN and the intranasal steroid Nasonex to placebo in patients symptomatic for seasonal allergic rhinitis (SAR) after controlled exposure to ragweed pollen in an EEU.

Treatment activity was evaluated on the basis of total nasal symptom scores (TNSS), combining patient-assessed severity of sneezing, nasal itching (pruritis), runny nose (rhinorrhea), and congestion on a 4-point scale (0 for no symptoms to 3 for severe symptoms). Patients who demonstrated moderate to severe rhinitis symptoms upon exposure to ragweed were admitted to the study. A total of 450 patients, 150 in each study arm, were randomized to receive two metered sprays per nostril of either ASTELIN, Nasonex or placebo spray and then asked to record their symptoms at specified intervals over 8 hours of pollen exposure in the EEU.

By the first post-dose observation at 15 minutes, ASTELIN® (azelastine HCl) Nasal Spray® produced a significant reduction from baseline TNSS of 3.12 units, compared to 1.28 units in the placebo arm ( $p < .001$ ). This significant difference in symptom reduction for ASTELIN persisted at each time point during the 8-hour allergen exposure versus placebo.

Nasonex® (mometasone furoate monohydrate) did not produce a significant reduction from baseline TNSS compared to placebo at any time point ( $p \geq .09$ ). ASTELIN demonstrated a significant reduction from baseline TNSS compared to Nasonex at each time point during the 8-hour study period ( $p \leq .001$ ).

“This study contributes to the robust body of data we’ve been assembling on the broad utility of ASTELIN in the treatment of seasonal allergies and nonallergic vasomotor rhinitis,” said Paul R. Edick, President and CEO of MedPointe Pharmaceuticals. “This single-dose study demonstrated that ASTELIN provided significant, rapid relief of nasal symptoms as early as 15 minutes and maintained efficacy over the entire 8 hour study period, while Nasonex did not separate from placebo at any time point in the study. Because ASTELIN is a product in a highly competitive therapeutic category where fast relief is important, an established rapid onset of action gives ASTELIN the hallmark of a potential market leader.”

## **Safety**

Both ASTELIN and Nasonex were well tolerated in the study. The only adverse event that occurred in more than 2 percent of patients in any treatment group was headache in 3 (2.0 percent) patients receiving Nasonex, 4 (2.7 percent) receiving placebo, and 0 receiving ASTELIN. There were no severe or serious adverse events in any treatment group and all 450 randomized patients completed the study.

## **Impact of Allergies**

As many as 58 million people, approximately 20 percent of the U.S. population, suffer from seasonal allergies, caused by pollen, spores, and other plant allergens, and associated with familiar nasal symptoms (seasonal allergic rhinitis) including sneezing, runny nose and congestion. Millions of Americans affected by seasonal allergies also may be sensitive to environmental triggers, including such irritants as air pollution, cigarette smoke, cold or dry air, and cleaning solutions, which cause similar nasal symptoms (nonallergic vasomotor rhinitis). In addition to its impact on quality of life and lost productivity, allergic rhinitis results in more than 20 million physician visits each year and up to \$6 billion in healthcare costs. Accurate diagnosis, specifically the identification of symptom triggers, and the evaluation of symptom severity and duration are critical to the selection of appropriate therapy.

## **Additional Information About ASTELIN**

Astelina® (azelastine HCl) Nasal Spray is a steroid-free antihistamine nasal spray, available by prescription only, that provides rapid relief from symptoms, including congestion, runny nose, postnasal drip, itchy eyes/nose, and sneezing, associated with seasonal allergies or environmental irritants. ASTELIN is the only prescription antihistamine nasal spray approved by the U.S. Food



and Drug Administration (FDA) to treat symptoms of both seasonal allergic rhinitis and nonallergic vasomotor rhinitis.

ASTELIN is indicated for the treatment of the symptoms of seasonal allergic rhinitis in patients 5 years of age and older and nonallergic vasomotor rhinitis in patients 12 years of age and older.

The most commonly reported adverse events in seasonal allergic rhinitis and nonallergic vasomotor rhinitis patients 12 years and older were bitter taste, headache, somnolence, and nasal burning. The adverse event profile in seasonal allergic rhinitis patients 5 to 11 years was similar to that in the adult population.

Additional information and/or full Prescribing Information on ASTELIN is available by calling 1-800-598-4856 or by visiting [www.astelin.com](http://www.astelin.com).

#### **About MedPointe Pharmaceuticals**

MedPointe Pharmaceuticals is a privately held, specialty pharmaceutical company located in Somerset, New Jersey. MedPointe specializes in respiratory, allergy, central nervous system, and cough-cold products. The company maintains a manufacturing facility in Decatur, Illinois. For more information on MedPointe, visit <http://www.medpointepharma.com>.

###

Nasonex is a registered trademark of Schering Corporation.