

## News Release

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### **SUNOVION'S INVESTIGATIONAL CICLESONIDE NASAL AEROSOL IN AN HFA PROPELLANT, DEMONSTRATED POSITIVE RESULTS IN PATIENTS WITH PERENNIAL ALLERGIC RHINITIS**

*Data Presented at ACAAI Builds Upon Sunovion Legacy in Respiratory Therapies*

**MARLBOROUGH, Mass., Saturday, November 5, 2011** – Sunovion Pharmaceuticals Inc. (Sunovion) today announced results from a large Phase III clinical study of ciclesonide nasal aerosol, a corticosteroid formulated with a hydrofluoroalkane (HFA) propellant, intended for the treatment of allergic rhinitis. This 26 week, double-blind, randomized study, investigated 74 mcg or 148 mcg doses of ciclesonide nasal aerosol once-daily in 1,111 patients, 12 years of age and older with perennial allergic rhinitis (PAR). Statistically significant improvements in nasal symptoms were demonstrated in patients with PAR compared to placebo, after the first six weeks of double-blind treatment, for both the 74 mcg and 148 mcg doses. Results from the full 26 week, double-blind treatment period demonstrated tolerability of both the 74 mcg and 148 mcg doses of ciclesonide nasal aerosol compared to placebo. Data from the first six weeks of treatment as well as the full six months of study treatment were presented in four separate scientific posters at the 2011 annual meeting of the American College of Allergy, Asthma & Immunology (ACAAI) in Boston, Massachusetts.

In prospectively designed analyses, statistically and clinically significant improvements with 74 mcg of ciclesonide nasal aerosol in overall rhinoconjunctivitis-related quality of life, as measured by the Rhinoconjunctivitis Quality of Life Questionnaire with Standard Activities (RQLQ[S]) over the first six weeks was also demonstrated, with a treatment difference of 0.55 compared with placebo for patients with a baseline RQLQ[S] score of  $\geq 3.0$ . The most common adverse events ( $\geq 2\%$  for the 74 mcg dose and greater than placebo) were headache and epistaxis.

"Perennial allergic rhinitis has a significant effect on millions of people nationwide and researchers and industry are committed to developing new and innovative treatment options to address a wide variety of patient needs," said lead investigator William E. Berger, MD, Clinical Professor, Department of Pediatrics, University of California, Irvine and Past President of American College of Allergy, Asthma, and Immunology. "We are encouraged by these findings from this Phase III study in PAR patients investigating ciclesonide nasal aerosol in an HFA propellant."

The delivery system in development is designed to dispense ciclesonide medication as a fine dry mist in a small volume (50 mcL) to a patient's nose, which may be able to reduce sensory effects such as back-of-the-throat run-off and run-out out of the nose that can occur with aqueous-based corticosteroids.

"We are pleased to see results for ciclesonide nasal aerosol in patients with PAR that are similar to those previously seen in patients with seasonal allergic rhinitis (SAR)," said Alistair Wheeler, M.D., Vice President, Clinical Development and Medical Affairs at Sunovion Pharmaceuticals Inc. "These results support our development program for ciclesonide nasal aerosol and underscore our company's commitment to developing treatments for patients suffering from respiratory ailments."

The New Drug Application (NDA) for ciclesonide nasal aerosol was accepted for filing by the U.S. Food and Drug Administration (FDA) in June 2011 and is currently under review. The proposed dose for ciclesonide nasal aerosol for adolescents and adults 12 years of age or older is 74 mcg (one spray/nostril) daily.

### **About the Phase III Ciclesonide Nasal Aerosol (CIC-HFA) PAR Study**

In this Phase III, placebo-controlled, double blind, parallel group study, 1,111 patients, 12 years of age or older with PAR were randomized to either CIC-HFA 74 mcg (N=297), 148 mcg (N=504) or placebo (N=305), administered once-daily in the morning for six months (NCT00953147). Results of the first six weeks of the double-blind treatment period are presented here.

Efficacy was evaluated by patient-reported reflective and instantaneous total nasal symptom scores (rTNSS and iTNSS) assessing the nasal symptoms of nasal congestion, itching, sneezing and runny nose. Furthermore, this study measured the improvement in rhinoconjunctivitis-related quality of life by administering the Rhinoconjunctivitis Quality of Life Questionnaire with Standardized Activities (RQLQ[S]) for patients with a baseline RQLQ[S] score of  $\geq 3.0$ .

### **Data from the Ciclesonide Nasal Aerosol (CIC-HFA) PAR Study Poster Presentations:**

- **A Six-week Study of the Efficacy and Safety of Ciclesonide Hydrofluoroalkane Nasal Aerosol in the Relief of Nasal Symptoms of Perennial Allergic Rhinitis (Poster#P344)**

Treatment with either CIC-HFA 74 mcg or 148 mcg doses over the first six weeks of treatment demonstrated a statistically significant improvements in rTNSS ( $P < 0.001$  for both) and iTNSS ( $P < 0.01$  for both) and improvements in the individual nasal symptoms of congestion, nasal itching, sneezing and runny nose. The most common adverse events ( $\geq 2\%$  for the 74 mcg dose and greater than placebo) were headache and epistaxis.

- **Evaluation of the Rhinoconjunctivitis Related Quality of Life in Patients With Perennial Allergic Rhinitis Following Six Weeks of Treatment With Ciclesonide Hydrofluoroalkane Nasal Aerosol (Poster#P345)**

Treatment with either CIC-HFA 74 mcg or 148 mcg ( $P < 0.01$  for both) doses over the first six weeks of treatment demonstrated improvements in the overall RQLQ[S] in impaired patients (baseline RQLQ score of 3.0 and above). A treatment difference of 0.55 from baseline was observed with the CIC-HFA 74 mcg treatment group vs placebo.

## Other Poster Presentations on Ciclesonide Nasal Aerosol at the ACAAI 2011 Annual Meeting:

Posters reporting results on nasal symptoms and RQLQ from the full six month double-blind treatment period of the above study were also presented (NCT00953147).

- **Poster#346:** Following six months of treatment with either CIC-HFA 74 mcg or 148 mcg doses, improvements in rTNSS ( $P < 0.01$  for both) and iTNSS ( $P < 0.05$  for both) were also observed. The most common adverse events ( $\geq 3\%$  for the 74 mcg dose and greater than placebo) were upper respiratory tract infection, epistaxis, headache, urinary tract infection, oropharyngeal pain, viral upper respiratory tract infection, instillation site discomfort, cough and nausea.
- **Poster#347:** Treatment with either CIC-HFA 74 mcg or 148 mcg ( $P < 0.01$  for both) doses over the full six months of treatment demonstrated improvements in the overall RQLQ[S] in impaired patients (baseline RQLQ score of 3.0 and above).

### HPA Axis Data:

- **Poster#343:** Results from a study evaluating the effect of CIC-HFA 148 mcg or CIC-HFA 282 mcg doses for six weeks on the hypothalamic-pituitary-adrenal axis (HPA) assessed by serum cortisol levels (a surrogate marker of HPA axis function) in patients with PAR were also presented. Treatment with either CIC-HFA 148 mcg or CIC-HFA 282 mcg doses did not show suppression of cortisol secretion in this study (NCT01033825).

### About Ciclesonide

Ciclesonide nasal aerosol in an HFA propellant is the third ciclesonide formulation studied by Sunovion, with the others being ALVESCO® (ciclesonide) Inhalation Aerosol in an HFA formulation for the maintenance treatment of asthma in adults and adolescents ages 12 and older and OMNARIS® (ciclesonide) Nasal Spray for the treatment of seasonal allergic rhinitis in adults and children age 6 and older and perennial allergic rhinitis in adults and children age 12 and older.

In 2008, Nycomed granted Sunovion the exclusive development, marketing and commercialization rights for ciclesonide in the United States.

### About Allergic Rhinitis

Allergic rhinitis, commonly referred to as hay fever or nasal allergies, is a collection of symptoms, predominantly in the nose and eyes, resulting from allergies to dust, molds, animal dander and pollen. The sensitized immune system produces antibodies to these allergens, which cause chemicals called histamines to be released into the bloodstream, causing itching, swelling of affected tissues, mucus production and other symptoms. Symptoms vary in severity from person to person.<sup>1</sup>

Allergic rhinitis is estimated to affect approximately 60 million people in the United States, and its prevalence is increasing. Specifically, it is estimated that between 10% and 30% of adults and as many as 40% of children are affected by the disease. Approximately 12 million physician office visits each year are attributed to allergic rhinitis.<sup>2</sup>

PAR is caused by allergens such as house dust mites, cockroaches, molds, and/or animal dander and may persist throughout the year.<sup>3</sup>

## About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the central nervous system (CNS) and respiratory disease areas and improve the lives of patients and their families. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including LATUDA<sup>®</sup> brand lurasidone HCl, LUNESTA<sup>®</sup> brand eszopiclone, XOPENEX<sup>®</sup> brand levalbuterol HCl Inhalation Solution, XOPENEX HFA<sup>®</sup> brand levalbuterol tartrate inhalation aerosol, BROVANA<sup>®</sup> brand arformoterol tartrate inhalation solution, OMNARIS<sup>®</sup> brand ciclesonide nasal spray and ALVESCO<sup>®</sup> brand ciclesonide HFA inhalation aerosol.

Sunovion, an indirect, wholly-owned subsidiary of Dainippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at [www.sunovion.com](http://www.sunovion.com).

## About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a multi-billion dollar, top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP aims to produce innovative pharmaceutical products in the CNS field, which has been designated as the key therapeutic area and will also focus in on other specialty disease categories with significant unmet medical needs, which are designated as frontier therapeutic areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at [www.ds-pharma.com](http://www.ds-pharma.com).

1 Medline Plus, a service of the U.S. National Library of Medicine and the National Institutes of Health. [Internet]. Available from <http://www.nlm.nih.gov/medlineplus/ency/imagepages/19319.htm>. Accessed: **November 1, 2011**

2 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from <http://www.aaaai.org/media/statistics/allergy-statistics.asp>. Accessed: **November 1, 2011**

3 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from <http://www.aaaai.org/conditions-and-treatments/library/at-a-glance/rhinitis.aspx>. Accessed: **November 1, 2011**

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