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News Release

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SUNOVION'S INVESTIGATIONAL CICLESONIDE HFA NASAL AEROSOL EFFECTIVE IN TREATMENT OF SEASONAL ALLERGIC RHINITIS SYMPTOMS

Phase III data presented at AAAAI builds upon Sunovion legacy in respiratory therapies

MARLBOROUGH, Mass., March 22, 2011 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that data from a large scale, 671-patient, Phase III clinical study of ciclesonide nasal aerosol in a hydrofluoroalkane (HFA) formulation were presented in three separate scientific posters at the 2011 annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in San Francisco, California. The data show statistically significant improvements in reflective total ocular symptom score (rTOSS) in patients treated once daily with 74 µg of ciclesonide nasal aerosol as well as statistically significant improvements in nasal symptoms of seasonal allergic rhinitis (SAR) in patients treated once daily with both 74 µg and 148 µg of ciclesonide nasal aerosol. The overall incidence of adverse events (including epistaxis) was low and comparable to placebo. Furthermore, the data also demonstrated statistically significant improvements with 74 µg of ciclesonide nasal aerosol in the overall rhinoconjunctivitis quality of life questionnaire (RQLQ) vs. placebo with a difference of 0.64.

The delivery system in development is designed to dispense a small volume of the fine, dry mist of ciclesonide medication to a patient's nose. This delivery system may be able to reduce some of the sensory effects such as back-of-the-throat run-off and run-out out of the nose that sometimes occur with aqueous-based corticosteroids for the treatment of allergic rhinitis.

"These findings indicate that ciclesonide HFA nasal aerosol may offer value for patients with seasonal allergic rhinitis including symptoms such as congestion, itchy / watery eyes and itchy nose," said Charles P. Andrews, MD, of Diagnostics Research Group and a lead investigator of this ciclesonide HFA nasal aerosol clinical study. "We are encouraged by the results and look forward to continuing our efforts to develop treatment options for allergy sufferers."

About the Phase III Ciclesonide HFA Nasal Aerosol (CIC-HFA) SAR Study

In this Phase III, placebo-controlled, double blind, parallel group study, 671 subjects, 12 years of age or older with SAR were randomized to either CIC-HFA 74 µg (N=226), 148 µg (N=225) or placebo (N=220), administered once-daily in the morning for two weeks during the Texas Mountain Cedar pollen season.

Efficacy was evaluated by subject-reported reflective and instantaneous total nasal symptom scores (rTNSS and iTNSS) assessing the individual nasal symptoms of nasal congestion, itching, sneezing, and runny nose. Efficacy was also evaluated by subject-reported reflective and instantaneous total ocular symptom scores (rTOSS and iTOSS) assessing the individual ocular symptoms of tearing, itchy and red eyes.

Furthermore, this study measured the improvement in rhinoconjunctivitis related quality of life by administering a rhinoconjunctivitis quality of life questionnaire with standardized activities (RQLQ[S]).

Results from the Ciclesonide HFA Nasal Aerosol (CIC-HFA) SAR Study Poster Presentations:

- **A Study Evaluating the Efficacy and Safety of Ciclesonide Hydrofluoroalkane Nasal Aerosol in the Relief of Nasal Symptoms of Seasonal Allergic Rhinitis**

Both CIC-HFA 74 µg and 148 µg demonstrated a statistically significant improvement in rTNSS (P<0.0001 for both), iTNSS (P<0.001 for both) and improvements in the individual nasal symptoms of congestion, nasal itching, sneezing and runny nose.

The incidence of adverse events (including epistaxis) reported from this study for both doses of CIC-HFA were low and comparable to placebo.

- **An Evaluation of the Effect of Ciclesonide Hydrofluoroalkane Nasal Aerosol on the Ocular Symptoms of Seasonal Allergic Rhinitis**

CIC-HFA 74 µg demonstrated a statistically significant improvement in rTOSS (P=0.0124) and CIC-HFA 74 µg (P<0.05) and 148 µg (P<0.05) demonstrated improvement in iTOSS and individual ocular symptoms associated with SAR.

- **Results of the Rhinoconjunctivitis Related Quality of Life Questionnaire Administered to Subjects With Seasonal Allergic Rhinitis Following Treatment With Ciclesonide Hydrofluoroalkane Nasal Aerosol**

Both CIC-HFA 74 µg (P<0.0124) and 148 µg (P-value not determined) demonstrated improvements in the overall RQLQ[S].

In addition to the ciclesonide HFA nasal aerosol data presented at AAAAI, Sunovion also presented a poster titled, "A Post-Hoc Analysis of Asthma Control and Lung Function Following Treatment with Ciclesonide 80 µg HFA-MDI Twice Daily in Subjects with Mild-to-Moderate Persistent Asthma Previously Receiving Low Dose Fluticasone Propionate/Salmeterol" on data pertaining to the inhaled corticosteroid (ICS) asthma therapy, ALVESCO® (ciclesonide HFA inhalation aerosol). The data indicated that ALVESCO monotherapy maintained pulmonary function as measured by FEV₁ in patients with mild-to-moderate persistent asthma, who were previously treated with combination low dose ICS and Long Acting Beta Agonist (LABA) therapy.¹

About Allergic Rhinitis

Allergic rhinitis, which is commonly referred to as hay fever, is a collection of symptoms, predominantly in the nose and eyes, to allergens such as dust, 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, hives, rashes and other symptoms. Symptoms vary in severity from person to person.²

Allergic rhinitis is estimated to affect approximately 60 million people in the United States. 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.³

SAR, which is also often referred to as hay fever, is caused by an allergy to the pollen of trees, grasses, weeds or mold spores. Depending on the allergen, the season of the year and the pollination periods, SAR may occur in the spring, summer or fall and may last until the first frost.

Some people have symptoms of rhinitis no matter what the season. This is referred to as perennial allergic rhinitis, and it can be caused by allergens such as animal dander, indoor mold, dust mites and cockroaches.⁴

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[®] brand lurasidone HCl, LUNESTA[®] brand eszopiclone, XOPENEX[®] brand levalbuterol HCl Inhalation Solution, XOPENEX HFA[®] brand levalbuterol tartrate inhalation aerosol, BROVANA[®] brand arformoterol tartrate inhalation solution, OMNARIS[®] brand ciclesonide nasal spray and ALVESCO[®] brand ciclesonide HFA inhalation aerosol.

Sunovion, an indirect, wholly-owned subsidiary of Daiippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Daiippon 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 Daiippon 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.

1 Meltzer EO, Korenblat PE, Weinstein SF, et al. Efficacy and safety evaluation of ciclesonide in mild-to moderate persistent asthma previously treated with inhaled corticosteroids. Allergy Asthma Proc 30:293-303, 2009.

2 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: February 25, 2011.

3 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from <http://www.aaaai.org/media/statistics/allergy-statistics.asp>. Accessed: February 25, 2011.

4 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from <http://www.aaaai.org/patients/gallery/rhinitissinusitis.asp>. Accessed: February 25, 2011.

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