Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
Tel 508-481-6700

News Release

Contact: Susan Alesina
Vice President, Corporate Communications
Sunovion Pharmaceuticals Inc.
508-481-6700
susan.alesina@sunovion.com

SUNOVION ANNOUNCES UPCOMING AVAILABILITY OF ZETONNA™ (ciclesonide) NASAL AEROSOL, A NON-AQUEOUS, DRY NASAL AEROSOL SPRAY FOR ALLERGIC RHINITIS

ZETONNA Nasal Aerosol Is The Only Non-Aqueous Option Approved With One Spray Per Nostril (37mcg) And Once-Daily Dosing

MARLBOROUGH, Mass., May 7, 2012 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced the upcoming availability of ZETONNA™ (ciclesonide) Nasal Aerosol, 74 mcg once-daily, for the treatment of allergic rhinitis (AR), also known as hay fever or nasal allergies. ZETONNA Nasal Aerosol is the first and only non-aqueous, dry nasal aerosol spray with one spray per nostril (37 mcg) and once-daily dosing, and is indicated for the treatment of both ocular and nasal symptoms associated with seasonal allergic rhinitis (SAR) and the treatment of nasal symptoms associated with perennial allergic rhinitis (PAR). It also features an easy-to-read, built-in dose indicator so patients can track when their prescriptions should be refilled. ZETONNA was approved by the U.S. Food and Drug Administration (FDA) in January 2012.

“I have found in my practice that patients are more likely to stick to their treatment regimen if they are prescribed a medication that fits their individual needs, so having different options for patients continues to be important,” said Michael S. Blaiss, M.D., allergist and clinical professor of Pediatrics and Medicine at the University of Tennessee. “With the availability of ZETONNA Nasal Aerosol, patients will have an additional treatment option available to help manage their symptoms of allergic rhinitis year-round.”

ZETONNA Nasal Aerosol is FDA-approved for the treatment of SAR and PAR in adolescents and adults 12 years of age and older. It offers an alternative to conventional inhaled nasal sprays with water-based, aqueous delivery systems, some of which have been associated in some patients with bothersome effects such as dripping down the throat or out the nose. ZETONNA Nasal Aerosol will be commercially available in the U.S. starting in the third quarter of 2012, ahead of the fall allergy season.

The active compound of ZETONNA Nasal Aerosol, ciclesonide, is used in two other respiratory therapies marketed by Sunovion in the U.S., including OMNARIS® (ciclesonide) Nasal Spray, which has a hypotonic formulation, indicated for the treatment of SAR and PAR, and ALVESCO® (ciclesonide) Inhalation Aerosol, indicated for the maintenance treatment of asthma.

"Sunovion is committed to providing treatments that help address the needs of the 60 million patients affected by allergic rhinitis in the U.S., and we are proud to be able to offer two options with different delivery systems to patients with this condition," said Hiroshi Nomura, Vice Chair, Sunovion Pharmaceuticals Inc. "These treatments, together with the existing asthma and chronic obstructive pulmonary disease therapies in Sunovion's respiratory franchise, demonstrate our continued commitment to providing a full range of medications for patients with respiratory illnesses."

About ZETONNA™ (ciclesonide) Nasal Aerosol

ZETONNA™ Nasal Aerosol is a corticosteroid indicated for the treatment of symptoms associated with seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in adults and adolescents 12 years of age and older. ZETONNA Nasal Aerosol's delivery system and once-daily formulation utilizes a 50 mcL volume per spray and provides 24-hour relief. ZETONNA Nasal Aerosol uses an environmentally-friendly hydrofluoroalkane (HFA) propellant and features an easy-to-read, built-in dose indicator so patients can track when their prescriptions should be refilled.

In three Phase III clinical studies that enrolled a total of 2,488 patients, ZETONNA Nasal Aerosol demonstrated statistically and clinically significant improvements in symptoms of SAR, including nasal symptoms, ocular symptoms and quality of life measures, as well as in the nasal symptoms associated with PAR. The most common adverse reactions (≥2% incidence) included nasal discomfort, headache and epistaxis.

Important Safety Information for ZETONNA™

In clinical trials, epistaxis was observed more frequently in patients treated with ZETONNA than those who received placebo. Nasal ulceration was identified in 4 of 824 patients administered ZETONNA in the 26 week extension of the perennial allergic rhinitis trial.

Nasal septal perforation has been reported in patients following the intranasal application of ZETONNA. Nasal septal perforations were reported in 2 patients of 2,335 treated with ZETONNA compared with none of 892 treated with placebo. Before prescribing ZETONNA conduct a nasal examination to ensure that patients are free of nasal disease other than allergic rhinitis. Periodically conduct nasal examinations during treatment. If an adverse reaction (e.g., erosion, ulceration, perforation) is noted, discontinue ZETONNA. Counsel patients that ZETONNA should not be sprayed directly on the nasal septum.

In clinical trials with another formulation of ciclesonide, the development of localized infections of the nose or pharynx with *Candida albicans* has occurred. If such an infection develops with ZETONNA, it may require treatment with appropriate local therapy and discontinuation of ZETONNA.

Because corticosteroids can interfere with wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use ZETONNA until healing has occurred.

Nasal and inhaled corticosteroids may result in the development of glaucoma and cataracts. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, or cataracts.

ZETONNA is contraindicated in patients with a known hypersensitivity to ciclesonide or any of the ingredients of ZETONNA. Hypersensitivity reactions following administration of ciclesonide, such as angioedema with swelling of the lips, tongue and pharynx, have been reported.

Patients using immunosuppressive drugs are more susceptible to infections than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. If a patient has not had these diseases or been properly immunized, particular care should be taken to avoid exposure. If a patient is exposed to chicken pox or measles, prophylaxis with varicella zoster immune globulin or pooled intramuscular immunoglobulin, respectively, may be indicated. If chicken pox develops, treatment with antiviral agents may be considered. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections; or in patients with untreated fungal or bacterial infections; systemic viral or parasitic infections; or ocular herpes simplex.

When intranasal corticosteroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such effects occur, the dosage of ZETONNA should be discontinued consistent with accepted procedures for discontinuing oral steroid therapy.

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency and symptoms of corticosteroid withdrawal. Patients transferred to topical steroids after a prolonged period of treatment with a systemic corticosteroid should be carefully monitored. Rapid decreases in systemic corticosteroid dosages in patients taking them for diseases such as asthma or other conditions may cause a severe exacerbation of their symptoms.

Corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth routinely (e.g., via stadiometry) in pediatric patients receiving ZETONNA.

In trials 2-6 weeks in duration, adverse events that occurred with an incidence of at least 2% and more frequently with ZETONNA than with placebo were nasal discomfort, headache and epistaxis. In a 26-week trial in perennial allergic rhinitis, additional adverse events that occurred with an incidence of at least 2% and more frequently with ZETONNA than with placebo were upper respiratory tract infection, urinary tract infection, oropharyngeal pain, nasal mucosal/septum disorders, cough, influenza, bronchitis, streptococcal pharyngitis, muscle strain, and nausea. Nasal discomfort (5.7%) and epistaxis (11.4%) were also more frequent in the 26 week trial compared to clinical trials 2 to 6 weeks in duration.

About Ciclesonide

ZETONNA™ (ciclesonide) Nasal Aerosol will be the third ciclesonide formulation marketed 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. Nycomed was acquired by Takeda Pharmaceutical Company Limited in September 2011.

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.[1]

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.[2]

SAR is caused by "outdoor" allergens such as tree, grass or weed pollen, as well as mold, and tends to worsen during certain seasons.[3] PAR is caused by "indoor" allergens such as house dust mites, cockroaches, molds, and/or animal dander and may persist throughout the year.[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® (lurasidone HCl) tablets, LUNESTA® (eszopiclone) tablets, XOPENEX® (levalbuterol HCl) inhalation solution, XOPENEX HFA® (levalbuterol tartrate) inhalation aerosol, BROVANA® (arformoterol tartrate) inhalation solution, OMNARIS® (ciclesonide) nasal spray and ALVESCO® (ciclesonide) 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.

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.

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: **April 2, 2012**

2 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from. Accessed: **April 2, 2012**

3 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from http://www.aaaai.org/conditions-and-treatments/library/at-a-glance/outdoor-allergens.aspx Accessed: **April 2, 2012**

4 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: **April 2, 2012**

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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