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News Release

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SUNOVION ANNOUNCES FDA ACCEPTANCE OF NEW DRUG APPLICATION FOR CICLESONIDE HFA NASAL AEROSOL

NDA filing adds potential third ciclesonide compound to company's respiratory portfolio

MARLBOROUGH, Mass., June 6, 2011 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the New Drug Application (NDA) submitted for ciclesonide nasal aerosol in a hydrofluoroalkane (HFA) formulation has been accepted by the U.S. Food and Drug Administration (FDA). The proposed dosing for ciclesonide HFA nasal aerosol is 74 mcg once-daily (37 mcg per spray; one-spray per nostril) and the proposed indication is for the treatment for symptoms of Seasonal Allergic Rhinitis (SAR) and Perennial Allergic Rhinitis (PAR), in adults and adolescents age 12 and older. Sunovion has been granted exclusive development, marketing and commercialization rights for ciclesonide in the United States by Nycomed.

The NDA for ciclesonide HFA nasal aerosol reflects data from several clinical trials. The efficacy of ciclesonide HFA nasal aerosol was evaluated in three randomized, double blind, parallel-group, multi-center, placebo-controlled clinical trials with primary efficacy endpoints evaluated over 2 to 6 weeks duration conducted in the U.S. in adolescents and adults with allergic rhinitis. The three trials included a total of 2,488 subjects. Of these, 761 received the 74 mcg once-daily dose. The primary endpoint within the pivotal trials was the difference from placebo in the change from baseline of the average morning and evening reflective total nasal symptom scores (rTNSS). Additional efficacy endpoints assessed included reflective total ocular symptom scores (rTOSS) and quality of life measured via the use of the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ).

The safety data are based on five clinical trials evaluating doses of ciclesonide HFA nasal aerosol up to 282 mcg. One trial did not evaluate the 74 mcg dose. Four of the clinical trials were 2 to 6 weeks in duration and one trial was 26 weeks in duration. Data from the first 6 weeks of the 26 week trial were pooled with the short-term data from the other four studies. Short-term data of 2 to 6 weeks duration in the four short-term trials was evaluated, including 884 patients with SAR or PAR who were administered the 74 mcg dose.

The delivery system for ciclesonide HFA nasal aerosol is a pressurized metered-dose, nasal aerosol formulation designed to dispense a small volume (50 mcL) of the fine, dry mist of ciclesonide medication to a patient's nose.

“We are pleased to achieve this important regulatory milestone as part of the FDA review process for ciclesonide HFA nasal aerosol,” said Antony Loebel, M.D., executive vice president of clinical research and affairs at Sunovion Pharmaceuticals Inc. “If approved after full review, ciclesonide HFA nasal aerosol will offer a new therapeutic option for the millions of individuals suffering with seasonal and perennial nasal allergies.”

“Ciclesonide HFA nasal aerosol has the potential to be a valuable new treatment option for patients who suffer from seasonal and perennial allergies,” said Michael Blaiss, M.D., Clinical Professor of Pediatrics and Medicine at The University of Tennessee Health Sciences Center. “If approved at the proposed dose, this new product could offer symptom relief with a low volume nasal spray."

The FDA has communicated that the application will be subject to a standard review. Acceptance of the NDA filing does not represent final evaluation of the adequacy of the data submitted in the NDA.

The NDA filing and acceptance demonstrates the company’s commitment to developing additional respiratory therapies. If approved by the FDA, ciclesonide HFA nasal aerosol will be the sixth respiratory medication commercialized by Sunovion.

About Ciclesonide

Ciclesonide HFA nasal aerosol is the third ciclesonide formulation studied by Sunovion, with the others being ALVESCO® (ciclesonide) Inhalation Aerosol in a 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, is a collection of symptoms, predominantly in the nose and eyes, to allergens such as dust, dander and pollen. It is the most common allergic disease in the U.S., affecting an estimated 50 million people[1], approximately between 10-30% of adults and as many as 40% of children. 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 the fifth leading chronic disease among all ages, resulting in nearly 4 million missed or lost workdays each year and costing more than $700 million in total lost productivity.[3] Each year, nearly 17 million physician office visits are attributed to allergic rhinitis, with seasonal allergic rhinitis (SAR) accounting for more than half of all allergy visits.[1]

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 section of the country 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 inhalation aerosol in a HFA formulation.

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 CDC Fast Facts A-Z," Vital Health Statistics, 2003

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 Chronic Conditions: A Challenge for the 21st Century. National Academy on an Aging Society, 2000.

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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