

News Release

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SUNOVION PHARMACEUTICALS INC. ANNOUNCES NATIONWIDE AVAILABILITY OF ZETONNA™ (ciclesonide) NASAL AEROSOL FOR ALLERGIC RHINITIS

Patients Taking ZETONNA Report Improved Quality Of Life Measures (RQLQ[S]) Associated With Seasonal Allergic Rhinitis

MARLBOROUGH, Mass., July 30, 2012 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced the nationwide 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 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. It is the only dry nasal aerosol approved by the U.S. Food and Drug Administration (FDA) with once daily, one spray per nostril (37 mcg) dosing.

“I often hear from my patients that they are dissatisfied with the burden of allergies and are looking for alternative treatment options,” said William E. Berger, M.D., clinical professor with the Department of Pediatrics, Division of Allergy and Immunology, University of California, Irvine and a practicing allergist in Mission Viejo, California. “Nasal corticosteroids like ZETONNA are efficacious treatments for allergic rhinitis. Now that we have the option of prescribing either an aqueous or dry delivery formulation of this steroid, we have another way of treating our patients’ discomfort with allergies which may help them to achieve greater satisfaction.”

In three Phase III clinical studies including almost 2,500 adults and adolescents 12 years of age and older, ZETONNA Nasal Aerosol was shown to significantly improve nasal symptoms of SAR and PAR. Additionally, it is the only dry nasal aerosol approved for the treatment of ocular symptoms associated with SAR. The most common adverse events reported were nasal discomfort, headache and nosebleed.

Patients taking ZETONNA reported improved quality of life associated with SAR as measured by the Rhinoconjunctivitis Quality of Life Questionnaire with Standardized Activities (RQLQ[S]), which is based upon evaluation of activity limitation, sleep problems, nose symptoms, eye symptoms, non-nose/eye symptoms, practical problems and emotional function.

Further, patients reported high levels of satisfaction with ZETONNA, based on the Regimen Attributes Composite subscale of the Allergic Rhinitis Treatment Satisfaction and Preference (ARTSP) instrument, a

patient-reported outcome measure. These data were collected as part of a two-week, randomized, multicenter, two-period study involving 327 patients 12 years of age and older with PAR.

“ZETONNA joins OMNARIS® (ciclesonide) Nasal Spray as the newest addition in Sunovion’s ciclesonide franchise. These treatments offer different experiences for patients, as OMNARIS is an aqueous, once-daily, two spray per nostril option for SAR patients 6 and older and PAR patients 12 and older,” said Richard Russell, executive vice president and chief commercial officer of Sunovion Pharmaceuticals Inc. “We are proud to be the only company to provide patients with the option of a dry aerosol or aqueous treatment, as well as a best-in-class co-pay program that allows qualified patients to pay as little as \$17 a month for either ZETONNA or OMNARIS.”

Allergic rhinitis is estimated to affect approximately 60 million people in the United States, and its prevalence is increasing.¹ Approximately 13 million physician office visits each year are attributed to AR.² Additionally, 3.6 million missed or lost workdays each year are attributed to AR, resulting in a total cost of about \$450 million in total lost productivity.³

Additional information about ZETONNA, including prescribing information and information on the ZETONNA and OMNARIS co-pay program is available at <http://www.zetonna.com>.

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’s delivery system and once-daily formulation is delivered in a 50 mcL spray and provides 24-hour relief. ZETONNA 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 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™ (ciclesonide) Nasal Aerosol

Do not spray ZETONNA Nasal Aerosol in your eyes or directly onto your nasal septum (the wall inside your nose between your two nostrils).

ZETONNA Nasal Aerosol may cause serious side effects, including:

- **nose bleeds and nasal ulcers.** Call your healthcare provider right away if you start to have more nose bleeds or nasal ulcers.
- **hole in the cartilage in the nose (nasal septal perforation).** Stop using ZETONNA Nasal Aerosol and call your doctor right away if you have symptoms of a nasal perforation. Symptoms of nasal perforation may include: crusting in the nose, nosebleeds, runny nose, and a whistling sound when you breathe.
- **thrush (*Candida*), a fungal infection in your nose, mouth, or throat.** Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat.

- **slow wound healing.** You should not use ZETONNA Nasal Aerosol until your nose has healed, if you have a sore in your nose, if you have had surgery in your nose, or if your nose has been injured.
- **eye problems such as glaucoma and cataracts.** If you have a history of glaucoma or cataracts or have a family history of eye problems, you should have regular eye exams while you use ZETONNA Nasal Aerosol.
- **immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that may weaken your body's ability to fight infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while you use ZETONNA Nasal Aerosol. Symptoms of an infection may include: fever, pain, aches, chills, feeling tired, nausea, and vomiting.
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Call your healthcare provider right away if you experience the following symptoms of adrenal insufficiency: tiredness, weakness, dizziness, nausea, and vomiting.
- **slowed or delayed growth in children.** A child's growth should be checked regularly while using ZETONNA Nasal Aerosol.
- **allergic reactions.** Call your healthcare provider right away if you experience swelling of the lips, tongue, or throat.

The most common side effects with ZETONNA Nasal Aerosol include nasal discomfort, headache and nose bleeds.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZETONNA Nasal Aerosol.

For more information, please visit www.ZETONNA.com or call 1-888-394-7377, and refer to the accompanying Full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 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, ZETONNA[™] (ciclesonide) nasal aerosol and ALVESCO[®] (ciclesonide) 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 American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from http://www.aaaai.org/allergist/news/Pages/Allergy_Facts.aspx. Accessed: July 26, 2012.

2 Schappert SM, Rechtsteiner EA. Ambulatory medical care utilization estimates for 2007. Vital Health Stat 13 2011:1-38.

3 Crystal-Peters J, Crown WH, Goetzel RZ, Schutt DC. The cost of productivity losses associated with allergic rhinitis. Am J Manag Care. 2000;6:373-78.

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