Sunovion Presents New Analyses that Continue to Support ZETONNA® (ciclesonide) Nasal Aerosol’s Efficacy in SAR and PAR

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Post-Hoc Analyses Based on the Pooled Studies Support Efficacy in SAR and PAR Patients

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) today announced results of two post-hoc analyses for ZETONNA® (ciclesonide) Nasal Aerosol, which were presented during a scientific poster session at the annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in San Antonio, Texas. One poster included results from a pooled analysis of total and individual nasal symptoms stratified by baseline severity following treatment with ZETONNA 74 mcg once-daily (one spray per nostril) or placebo in patients 12 to 65 years of age with seasonal allergic rhinitis (SAR) (Poster #668). An additional poster presented results from a post-hoc responder analysis in patients 12 to 65 years of age with SAR or perennial allergic rhinitis (PAR). Patients following treatment with ZETONNA 74 mcg once-daily (one spray per nostril) demonstrated higher percentages of responses defined as at least 20%, 30% or 50% in symptom improvement from baseline compared with placebo patients (Poster #667).

"These post-hoc analyses provide further support for ZETONNA’s efficacy in treating symptoms associated with SAR and PAR in patients 12 years and older," said Alistair Wheeler, M.D., Vice President, Clinical Development and Medical Affairs at Sunovion Pharmaceuticals Inc. “Our findings showed there was significant improvement in patients with different degrees of baseline symptom severity in our studies.”

ZETONNA is approved by the U.S. Food and Drug Administration (FDA) for the treatment of symptoms associated with SAR and PAR in adolescents and adults 12 years of age and older. It is the only approved dry nasal aerosol with once daily, one spray per nostril (37 mcg) dosing that utilizes a hydrofluoroalkane (HFA) propellant to dispense the medication.

Poster Presentations by Sunovion at AAAAI:

• A Post-hoc Analysis of Improvement in Individual Nasal Symptoms by Their Baseline Severity Following Treatment with Ciclesonide Hydrofluoroalkane Nasal Aerosol in Patients with Seasonal Allergic Rhinitis (Poster #668)

In two randomized, double-blind, placebo-controlled Phase III SAR studies that enrolled 918 patients 12 to 65 years of age with a ≥2 year history of SAR, patients were given ZETONNA 74 mcg [CIC-HFA (37 mcg/actuation nostril)] or placebo, once daily for two weeks. The pooled analysis evaluated change from baseline in patient-reported total and individual reflective nasal symptoms of sneezing, runny nose, itching, and congestion by baseline severity.

This analysis showed that the treatment with ZETONNA resulted in greater improvement compared with placebo in all individual reflective nasal symptoms of SAR. The adjusted mean treatment differences (95% confidence intervals) were 0.31 (0.20, 0.43), 0.27 (0.17, 0.38), 0.21 (0.10, 0.32), and 0.21 (0.12, 0.31) in sneezing, runny nose, itching, and congestion, respectively for subjects with severe reflective total nasal symptom scores (rTNSS) at baseline.

• A Post-hoc Responder Analysis of Improvement in Symptoms Following Treatment with Ciclesonide Hydrofluoroalkane Nasal Aerosol in Patients with Seasonal and Perennial Allergic Rhinitis (Poster #667)

In a post-hoc responder analysis, improvement in nasal and ocular symptoms in patients with SAR and nasal symptoms in patients with PAR following treatment with ZETONNA were evaluated. Data for this analysis was collected from randomized, double-blind, placebo controlled Phase III SAR (pooled from two studies) and PAR (one study) studies. The study participants consisted of patients 12 to 65 years of age with SAR (N=918) or PAR (N=605) who received ZETONNA 74 mcg (one actuation/nostril, 37 mcg/actuation) or placebo for two weeks (SAR) or 26 weeks (PAR). The responder analysis was performed by evaluating the percent change from baseline in reflective nasal (rTNSS) and ocular (rTOSS, SAR only) symptom scores.

The analysis of the three studies showed that treatment with ZETONNA resulted in greater improvement in nasal and
ocular symptoms of SAR and nasal symptoms of PAR. For nasal symptoms, a higher percentage of SAR patients reported ≥20% improvement from baseline (40.8% ZETONNA vs. 21% placebo), ≥30% improvement from baseline (30.2% ZETONNA vs. 11.9% placebo), and ≥50% improvement from baseline (11.2% ZETONNA vs. 3.8% placebo) in rTNSS with ZETONNA compared with placebo averaged over the 2-week treatment period. A higher percentage of PAR patients during the treatment of 26 weeks also reported ≥20% improvement from baseline (61.6% ZETONNA vs. 52.6% placebo), ≥30% improvement from baseline (50.2% ZETONNA vs. 37.2% placebo), and ≥50% improvement from baseline (25.9% ZETONNA vs. 13.5% placebo) in rTNSS with ZETONNA compared with placebo. For ocular symptoms, higher percentages of ≥20% improvement from baseline (39.3% ZETONNA vs. 26.7% placebo), ≥30% improvement from baseline (27.9% ZETONNA vs. 14.8% placebo), and ≥50% improvement from baseline (12.7% ZETONNA vs. 5.5% placebo) in rTOSS were reported after treatment with ZETONNA 74 mcg compared with placebo averaged over the 2-week treatment period.

About ZETONNA® (ciclesonide) Nasal Aerosol

ZETONNA® (ciclesonide) 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 is not approved for any use in pediatric patients below the age of 12. ZETONNA’s delivery system and once-daily formulation utilizes a 50 mcL volume per spray and provides 24-hour relief. ZETONNA uses an environmentally-friendly hydrofluoroalkane (HFA) propellant and features a built-in dose indicator so patients can track when their ZETONNA 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 quality of life measures, nasal symptoms and ocular symptoms of SAR, and the nasal symptoms associated with PAR. The most common adverse reactions in these short-term two to six week studies (≥2% incidence and greater than placebo) included nasal discomfort, headache and epistaxis.

Important Safety Information for ZETONNA®

Do not spray ZETONNA Nasal Aerosol in your eyes or directly onto your nasal septum (the wall inside your nose between your 2 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.
- **thrust (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[2] 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[3], or call 1-800-FDA-1088.

About Ciclesonide

ZETONNA® (ciclesonide) Nasal Aerosol is 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 nasal symptoms of seasonal
allergic rhinitis in adults and children age 6 and older and perennial allergic rhinitis in adults and children age 12 years of age 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 Psychiatry & Neurology 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® (afiomterol tartrate) inhalation solution, OMNARIS® (ciclesonide) nasal spray, ZETONNA® (ciclesonide) nasal aerosol 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 [4].

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 Psychiatry & Neurology field, which has been designated as one of the two key 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 [5].

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