Sunovion Presents Data at CHEST 2013 from a One-year, Large Simple Safety Study of BROVANA® (arformoterol tartrate) Inhalation Solution

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Results Suggest No Increased Risk of Serious Respiratory Events Regardless of Age, Smoking Status, COPD Disease Severity

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) today announced results from a one-year, non-inferiority clinical trial, which showed that patients with moderate to severe chronic obstructive pulmonary disease (COPD) treated with BROVANA® (arformoterol tartrate) Inhalation Solution experienced no increased risk of serious respiratory events, including respiratory death or COPD exacerbation-related hospitalizations, irrespective of smoking status, age or disease severity. Additional analyses showed that BROVANA showed no increased risk or incidence of COPD exacerbations compared to placebo and improved health related quality of life (HRQoL) compared to placebo. Patients were allowed to continue treatment with their previous COPD medications, with the exception of long-acting beta2 agonists. Data will be presented at the 2013 American College of Chest Physicians Conference (CHEST 2013) in Chicago.

These data are analyses of a Large Simple Safety Study, which evaluated BROVANA versus placebo for the risk of serious respiratory events (respiratory death or COPD-related hospitalizations due to exacerbations) in patients with moderate to severe COPD. The primary endpoint of the study, time to serious respiratory events, presented earlier this year found that among patients who experienced an event, the mean time to first event was longer for BROVANA (171.7 days) as compared to patients receiving placebo (155 days) [HR: 90% repeated CI = 0.606 (RCI: 0.425, 0.864)].

“These data show no increased risk of respiratory death or COPD-related exacerbations in patients taking BROVANA versus placebo,” said Alistair Wheeler, M.D., Vice President, Clinical Development and Medical Affairs at Sunovion Pharmaceuticals. “These data are further testament to our commitment to help improve the lives of people suffering from serious respiratory disease by providing them with effective treatment options.”

BROVANA is a twice-daily nebulized long-acting beta2 agonist (LABA) approved by the U.S. Food and Drug Administration (FDA) for the long-term maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema.

About the BROVANA Large Simple Safety Study

This multicenter, double-blind, randomized, placebo-controlled, parallel group, non-inferiority study enrolled 841 patients at least 40 years old with COPD and a baseline of ≤ 65 percent forced expiratory volume in one second (FEV1), a ≥ 15-pack-year smoking history and baseline breathlessness severity grade ≥ 2. Patients received BROVANA 15 mcg or placebo twice daily for one year, and were evaluated for the incidence of respiratory-related deaths and COPD exacerbation-related hospitalizations. The study participants were followed for up to one year after randomization to treatment; 466 subjects completed 1 year of treatment. Patients in both groups were also treated with their previous COPD medications, with the exception of long-acting beta2 agonists [NCT00909779].

Large Simple Safety Study Poster Presentations by Sunovion at CHEST 2013:

- A Large Simple Safety Study of Nebulized Arformoterol Tartrate: Risk of Respiratory-related Deaths and COPD Exacerbation-related Hospitalizations by Smoking Status, Age, and Disease Severity (Poster Session 10702 COPD Safety of Treatment Posters - Poster # 2473)

Under the conditions of this non-inferiority study, the analysis of 841 patients found that after one year, 9.5 percent of patients treated with BROVANA had at least one primary event (respiratory death or first COPD exacerbation-related hospitalization) versus 15 percent of placebo-treated patients. Secondary analysis of treatment based on baseline smoking status, age and FEV1, indicative of COPD disease severity, showed BROVANA did not increase the risk of respiratory death or COPD exacerbation-related hospitalizations compared to placebo across all baseline covariates, including those patients at greatest risk for a primary event, such as current smokers (n=432; hazard ratio: 0.809) and those over age 75 (n=114; hazard ratio: 0.269), determined by hazard ratio. Additional baseline covariates analyzed
include:

- Former smokers (n=409; hazard ratio: 0.445)
- Patients younger than 65 years old (n=426; hazard ratio: 0.707)
- Patients 65 to 75 years old (n=301; hazard ratio: 0.786)
- COPD disease severity: less than 30 percent predicted FEV\textsubscript{1} (n=233; hazard ratio: 0.565)
- 30 percent to less than 50 percent predicted FEV\textsubscript{1} (n=388; hazard ratio: 0.648) and
- 50 percent or greater predicted FEV\textsubscript{1} (n=219; hazard ratio: 0.618)

A Large Simple Safety Study of Nebulized Arformoterol Tartrate: Incidence and Risk of Protocol-Defined COPD Exacerbations (Poster Session 10701 COPD Treatment Posters - Poster # 2490)

This analysis showed that after one year, BROVANA showed no increased risk or incidence of protocol-defined COPD exacerbations. Among patients treated with BROVANA, 16.9 percent had one primary event versus 17.1 percent of patients in the placebo group; 6.9 percent of patients treated with BROVANA versus 8.1 percent in the placebo group had two events; and 5.2 percent of patients treated with BROVANA versus 6.2 percent of patients in the placebo group had three or more events.

Improved Health Related Quality of Life Outcomes in Subjects with Moderate to Severe COPD Treated with Nebulized Arformoterol Tartrate: Results from a 52-Week Trial (Poster Session 10701 COPD Treatment Posters - Poster # 2496)

This analysis of 754 patients found that treatment with BROVANA improved health related quality of life (HRQoL) versus placebo, as measured by the St. George’s Respiratory Questionnaire (SGRQ), a validated 50-item self-administered instrument at randomization, and at months 3, 6 and 12. The SGRQ yields a total score and subscale scores for symptoms, activities, and impacts. SGRQ scores range from 0 – 100, with higher scores indicating worse health status. Patients treated with BROVANA had greater improvements versus placebo on total score (least squares means -4.24 vs. -2.02; p = 0.006), symptoms domain (p=0.015), and impacts domain (p = 0.001), but not the activity domain (p = 0.052) across the post-baseline trial visits.

About BROVANA® (arformoterol tartrate) Inhalation Solution

BROVANA® (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice-daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

Important Safety Information for BROVANA®

WARNING: ASTHMA-RELATED DEATH

Long-acting beta\textsubscript{2}-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta\textsubscript{2}-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

BROVANA is not indicated for the treatment of acute episodes of bronchospasm, ie, rescue therapy, and does not replace fast-acting rescue inhalers. BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition.

BROVANA should not be used in conjunction with other inhaled, long-acting beta\textsubscript{2}-agonists. BROVANA should not be used with other medications containing long-acting beta\textsubscript{2}-agonists. Patients who have been taking inhaled short-acting beta\textsubscript{2}-agonists on a regular basis should be instructed to discontinue their regular use and to use them only for symptomatic relief for acute respiratory symptoms.

All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication.

As with other inhaled beta\textsubscript{2}-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

BROVANA, like other beta\textsubscript{2}-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms.

BROVANA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually
responsive to sympathomimetic amines. BROVANA, as with other beta₂-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents.

Overall efficacy of BROVANA was maintained throughout the 12-week trial duration. Some tolerance to the bronchodilator effect of BROVANA was observed after 6 weeks of dosing (at the end of the dosing interval), although the FEV₁ improvement remained statistically significant. This was not accompanied by other clinical manifestations of tolerance.

The five most common adverse events reported with frequency ≥ 2% in patients taking BROVANA, and occurring more frequently than in patients taking placebo, were pain (8% vs 5%), chest pain (7% vs 6%), back pain (6% vs 2%), diarrhea (6% vs 4%), and sinusitis (5% vs 4%). For more information, please see the full Prescribing Information and Medication Guide for BROVANA.

For additional information, please see the full Prescribing Information and Medication Guide for BROVANA (arformoterol tartrate) Inhalation Solution.

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 [2].

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, (arformoterol 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 [3].

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a 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 area and the Oncology area, which have been designated as the focus 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 [4].

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For a copy of this release, visit Sunovion’s web site at www.sunovion.com [5].

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