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

Release Date:
Monday, May 20, 2013 9:00 am EDT

Terms:

Dateline City:
MARLBOROUGH, Mass.

Data Presented Today at 2013 ATS International Conference Further Supports Long-term Safety Profile

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) today announced results of a one-year, non-inferiority clinical trial that evaluated BROVANA® (arformoterol tartrate) Inhalation Solution versus placebo for the risk of serious respiratory events (respiratory death or COPD-related hospitalizations due to exacerbations) in patients with moderate to severe chronic obstructive pulmonary disease (COPD). The study results, which were presented in three posters at the American Thoracic Society (ATS) International Conference in Philadelphia, showed that of 420 patients treated with BROVANA, 40 experienced at least one serious respiratory event as compared to 63 patients who experienced at least one serious respiratory event of the 421 receiving placebo. Among those patients who experienced an event, the mean time to first event was longer for BROVANA patients (171.7 days) as compared to patients receiving placebo (155 days).

"These results demonstrate no increased risk of COPD-related exacerbations leading to hospitalizations and respiratory death in patients taking BROVANA versus those taking placebo, further supporting the long-term safety profile of BROVANA," said Alistair Wheeler, M.D., Vice President, Clinical Development and Medical Affairs at Sunovion Pharmaceuticals. "These data, along with our continued commitment to research and development in COPD, affirm Sunovion’s pledge to helping COPD patients achieve long-term symptom control by providing bronchodilator treatment via nebulized delivery."

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 were given BROVANA 15 mcg or placebo twice daily for one year, and evaluated for the incidence of respiratory-related deaths and COPD exacerbation-related hospitalizations. The study participants were to be followed for up to one year after randomization to 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 ATS 2013:

- **A Long Term Safety Study Of Arformoterol Tartrate In The Maintenance Therapy Of Patients With Moderate To Severe COPD: Incidence Of Respiratory-Related Deaths And COPD Exacerbation-Related Hospitalizations** (Poster Discussion Session B23 - Poster Board # 810; Abstract A2436)

Under the conditions of this non-inferiority study, the analysis found that after one year, patients treated with BROVANA experienced no increased risk of COPD-related hospitalization and respiratory death compared to placebo, with a hazard ratio of 0.606 (confidence interval 0.425 to 0.864), indicating a relative reduction in risk. The data also showed that, among the COPD patients in the study who experienced a serious respiratory event, patients treated with BROVANA experienced a longer period until first COPD exacerbation-related hospitalization or respiratory death (171.7 days) compared to patients receiving placebo (155 days).

- **A Long Term Safety Study Of Arformoterol Tartrate In The Maintenance Therapy Of Patients With Moderate To Severe COPD: Incidence Of Adverse Events** (Thematic Poster Session A43 - Poster Board # F66; Abstract A1482)
This analysis of the large simple safety study evaluated the incidence of treatment emergent adverse events (TEAEs) in patients treated with BROVANA or placebo.

The analysis found that after one year of treatment, the incidence of TEAEs, treatment emergent serious adverse events (SAEs), treatment related adverse events (TRAES) and adverse events (AEs) resulting in discontinuation of study medication were balanced between treatment groups. Patients treated with BROVANA had a lower incidence of respiratory SAEs compared to placebo (7.6% versus 12.1%, respectively).

- **A Long Term Safety Study Of Arformoterol Tartrate In The Maintenance Therapy Of Patients With Moderate To Severe COPD: Evaluation Of Lung Function (Thematic Poster Session A43 - Poster Board # F65; Abstract A1481)**

This analysis evaluated lung function following one year of treatment with BROVANA or placebo in patients with moderate to severe COPD. In this study, patients treated with BROVANA maintained lung function (from baseline) compared with placebo. Patients treated with BROVANA were found to have a greater improvement in both trough FEV₁ (84 ml versus 33 ml for placebo) and forced vital capacity (FVC; 121 ml versus 46 ml for placebo) from baseline versus placebo.

**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 beta₂-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 beta₂-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 beta₂-agonists. BROVANA should not be used with other medications containing long-acting beta₂-agonists. Patients who have been taking inhaled short-acting beta₂-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 beta₂-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 beta₂-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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.
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® (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 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 [4].

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

Language:

English

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