Sunovion to Present Three Posters on Results of One-year Large Simple Safety Study for BROVANA® (arformoterol tartrate) Inhalation Solution at 2013 ATS International Conference

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Additional Data Presented by Sunovion Demonstrate Commitment to Nebulized COPD Treatments

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) announced today that the company will present six posters at the 2013 American Thoracic Society (ATS) International Conference, three of which pertain to a recently completed, one-year, placebo-controlled, large simple safety study (LSSS) for BROVANA® (arformoterol tartrate) Inhalation Solution. BROVANA is a twice-daily nebulized long-acting beta₂ agonist (LABA) that treats bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The ATS conference is being held in Philadelphia on May 17-22, 2013.

"We look forward to sharing the LSSS results with the COPD community, as these data provide insight into the relative frequency of long-term exacerbation-related hospitalizations and respiratory death in patients using BROVANA versus those using placebo," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc. "We are pleased to contribute data at this meeting that grow the body of clinical research for BROVANA while further supporting nebulized delivery for moderate and severe COPD patients."

Sunovion will also be sponsoring two posters reporting retrospective database analyses of exacerbation risk and re-hospitalization risk in COPD patients treated with nebulized LABAs [either BROVANA or PERFOROMIST® (formoterol fumarate) Inhalation Solution] or nebulized short-acting beta₂ agonists (SABAs).

Additionally, Sunovion Respiratory Development Inc., a wholly owned subsidiary of Sunovion Pharmaceuticals Inc., will present a poster regarding investigational compound SUN-101, a long-acting muscarinic antagonist (LAMA) bronchodilator in development for the treatment of COPD that will be delivered via the eFlow® nebulizer.

"We believe that COPD patients need more options for the management of their disease," said Dr. Loebel. "SUN-101 is indicative of our commitment to COPD research and to our leadership in developing potential treatments that can be delivered via a nebulizer."

Further details about the posters presented by Sunovion at ATS 2013 are available below.

**BROVANA Data Presented at ATS:**

- 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 – Sunday, May 19, 2013, 8:15 AM-4:30 PM
- 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 – Monday, May 20, 2013, 8:15-10:45AM

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**Retrospective Database Analyses Presented at ATS:**

- Risk Of Exacerbations In Chronic Obstructive Pulmonary Disease Patients Treated With Nebulized LABA Versus
Nebulized SABA Treatments – Thematic Poster Session C42 – Poster Board # H28 – Abstract A4226 – Tuesday, May 21, 2013, 8:15 AM-4:30 PM

- Re-hospitalization Risk In Patients With Chronic Obstructive Pulmonary Disease (COPD) Initiating Nebulized Long-acting Vs. Short-acting Beta2-Agonists – Thematic Poster Session C51 – Poster Board # J100 – Abstract A4394 – Tuesday, May 21, 2013, 8:15 AM-4:30 PM

SUN-101 Investigational Data Presented at ATS:

- Cardiovascular Safety Of Nebulized Glycopyrrolate (SUN-101) Compared With Tiotropium, Ipratropium And Placebo In Patients With COPD – Thematic Poster Session A43 – Poster Board # F67 – Abstract A1483 – Sunday, May 19, 2013, 8:15 AM-4:30 PM

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 [2] or call 1-800-FDA-1088.

About SUN-101 and Sunovion Respiratory Development Inc.
SUN-101, an inhalation solution of a long-acting muscarinic antagonist (LAMA) bronchodilator, glycopyrrolate, delivered by a customized eFlow® Nebulizer System, is currently in development by Sunovion Respiratory Development Inc. for the treatment of patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD). SUN-101 has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COPD. Studies evaluating the efficacy and safety of SUN-101 for the treatment of COPD are on-going. Three Phase II studies have been conducted to evaluate its efficacy and safety in patients with moderate to severe COPD. Phase III trials are expected to be initiated in the second half of 2013.

On September 5, 2012, Sunovion Pharmaceuticals Inc. completed an acquisition, by merger, of Elevation Pharmaceuticals, Inc., which resulted in Elevation, now known as Sunovion Respiratory Development Inc., becoming a direct wholly-owned subsidiary of Sunovion Pharmaceuticals Inc. As a result, the product formerly referred to as EP-101 is presently referred as SUN-101.

**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® (levosalbuterol HCl) inhalation solution, XOPENEX HFA® (levosalbuterol 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 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 Pharmaceutical 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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