Sunovion to Present Data on Nebulized Treatment Options for COPD at the American College of Chest Physicians® (CHEST) Annual Meeting 2017

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Presentations include safety and efficacy data from Phase 3 studies of SUN-101/eFlow® as a potential maintenance treatment for moderate-to-very-severe COPD –

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) will present three podium presentations and five posters at the American College of Chest Physicians® (CHEST) Annual Meeting 2017 to be held October 28 – November 1, 2017, in Toronto, Canada. Presentations include data analyses from the SUN-101/eFlow® GOLDEN Phase 3 program in patients with moderate-to-very-severe chronic obstructive pulmonary disease (COPD).

“Our presentations at CHEST underscore the important role of nebulized treatments for people with moderate-to-very-severe COPD,” said Thomas H. Goodin, Ph.D., Senior Director, Clinical Development at Sunovion. “At Sunovion, we have a strong heritage in advancing new treatments for COPD. We are pleased to highlight SUN-101/eFlow® as a potential new nebulized option for the treatment of COPD, if approved.”

In June 2017, Sunovion announced that the U.S. Food and Drug Administration (FDA) accepted for review the resubmission of the New Drug Application (NDA) for SUN-101/eFlow® for the long-term, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. If approved, SUN-101/eFlow® will be the first nebulized long-acting muscarinic antagonist approved for the treatment of COPD in the U.S. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is December 15, 2017.

Sunovion presentations at CHEST 2017 include:

**SUN-101/eFlow®**

- Podium Presentation: The Effect of Concurrent Bronchodilator Therapy on the Efficacy and Safety of a Novel, Nebulized Glycopyrrolate in Phase 3 Studies in Subjects with Moderate-to-very-severe Chronic Obstructive Pulmonary Disease (COPD) (Convention Center – 602B, Tuesday, October 31, 11:15 a.m. – 11:30 a.m. EST)
- Podium Presentation: The Efficacy and Safety of a Novel, Nebulized Glycopyrrolate for the Treatment of Chronic Obstructive Pulmonary Disease (COPD) in Phase 3 Placebo-controlled Studies: Effect of Baseline Lung Function and Age (Convention Center – 602B, Tuesday, October 31, 11:45 a.m. – 12:00 p.m. EST)
- Poster #226: Risk of Moderate or Severe COPD Exacerbation Events Among Patients Treated With Nebulized SUN-101 (Glycopyrrolate/eFlow® CS) and Tiotropium in the GOLDEN-5 Study: Analyses by Baseline COPD Severity (Convention Center – Exhibit Hall, Wednesday, November 1, 1:30 p.m. – 2:30 p.m. EST)
- Poster #231: Cardiovascular (CV) Safety and Efficacy of Nebulized Glycopyrrolate/eFlow® CS in Phase 3 Trials of Patients with Moderate-to-very-severe Chronic Obstructive Pulmonary Disease (COPD) (Convention Center – Exhibit Hall, Wednesday, November 1, 1:30 p.m. – 2:30 p.m. EST)
- Poster #232: Exploratory Analysis of Exacerbation Incidence by Patient Subgroup in Three Phase 3 Trials of Nebulized Glycopyrrolate/eFlow® CS (Convention Center – Exhibit Hall, Wednesday, November 1, 1:30 p.m. – 2:30 p.m. EST)
- Poster #243: Peak Inspiratory Flow Rate (PIFR) Baseline Measurements in Placebo-controlled Phase 3 Studies of a Novel, Nebulized Glycopyrrolate Formulation (Convention Center – Exhibit Hall, Wednesday, November 1, 1:30 p.m. – 2:30 p.m. EST)
- Poster #244: Analysis of Patient Characteristics and Peak Inspiratory Flow Rates (PIFR) in Three Phase 3 Trials of Nebulized Glycopyrrolate in Moderate-to-very-severe Chronic Obstructive Pulmonary Disease (COPD) (Wednesday, November 1, 1:30 p.m. – 2:30 p.m. EST)

**Brovana®**

- Podium Presentation: Medication Management Patterns Among Medicare Beneficiaries with Chronic Obstructive Pulmonary Disease (COPD) Initiating Nebulized Arformoterol Treatment (Convention Center – 602B, Tuesday, October 31, 2:45 p.m. – 3:00 p.m. EST)

About SUN-101/eFlow®

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary investigational eFlow® closed system nebulizer developed by Parion Pharma GmbH. SUN-101/eFlow® is currently in development as a nebulized treatment for people with moderate-to-very-severe COPD. The investigational combined product, consisting of SUN-101 and the investigational eFlow® closed system nebulizer, which has been optimized for SUN-101 delivery, has not been approved by the FDA for the treatment of COPD.

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.

About COPD

Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or lung abnormalities usually caused by significant exposure to toxic particles or gases. The main risk factor for COPD is tobacco smoking, but other environmental exposures may contribute. Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD. It is estimated that several million more adults have undiagnosed COPD. COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S. COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to...
perform routine activities. 3 Symptoms of COPD include coughing, wheezing, shortness of breath, excess production of mucus in the lungs, the inability to breathe deeply and the feeling of being unable to breathe. 4 The symptoms of COPD can be most severe during the day, impaired health status and increased risk of exacerbation. 5 Night-time symptoms disturb sleep, reduce sleep quality and, in the long term, may be associated with development or worsening of cardiovascular diseases, cognition, depression and increased mortality. 6

About Sunovion Pharmaceuticals Inc. (Sunovion)
Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory disorders. Sunovion's track record of discovery, development and/or commercialization of important therapies has included Utbron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Brovana® (arformoterol tartrate) Inhalation Solution, Latuda® (lurasidone HCl) and Aiptoni® (eslicarbazepine acetate).


About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com. [13].

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For a copy of this release, visit Sunovion's web site at www.sunovion.com [12].

References

Language:
English

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