Sunovion Presents New Phase 3 Study Analyses Supporting Safety and Efficacy of SUN-101/eFlow® (glycopyrrolate) for the Treatment of COPD

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- Data presented at the American College of Chest Physicians® (CHEST) Annual Meeting 2017 –

- If approved, SUN-101/eFlow® would be the first nebulized long-acting muscarinic antagonist for the treatment of COPD in the United States –

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc., (Sunovion) today presented new secondary analyses of safety and efficacy data from the Phase 3 GOLDEN clinical study program for SUN-101/eFlow® (glycopyrrolate) at the American College of Chest Physicians® (CHEST) Annual Meeting 2017 held October 28-November 1, 2017, in Toronto, Canada. Findings from pooled data analyses of the GOLDEN-3, GOLDEN-4 and GOLDEN-5 studies showed the investigational, nebulized, long-acting muscarinic antagonist (LAMA) improved lung function and was well tolerated in clinical trial populations with moderate-to-very-severe chronic obstructive pulmonary disease (COPD), including people with cardiovascular (CV) risk factors, on background long-acting beta2 agonist (LABA) therapy and lower peak inspiratory flow rates (PFR), as well as individuals 65 years of age and older.

“Treatment delivery is an important consideration for people with COPD, and there is a need for additional device options,” said Gary Ferguson, M.D., Pulmonary Research Institute of Southeast Michigan and Principal Investigator for the GOLDEN-5 clinical trial. “We must take a customized approach to identifying the appropriate treatment and device for each individual. If approved, SUN-101/eFlow® will offer an important new nebulized treatment for many different people living with COPD currently in need of new options.”

In June 2017, Sunovion announced that the U.S. Food and Drug Administration (FDA) accepted for review the resubmission of the New Drug Application for SUN-101/eFlow® for the long-term, maintenance treatment of airflow obstruction in people with COPD, including chronic bronchitis and/or emphysema. If approved, SUN-101/eFlow® would be the first nebulized LAMA approved for the treatment of COPD in the U.S., as well as the first use of an eFlow® technology nebulizer to treat COPD. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is December 15, 2017.

“Because COPD symptoms vary for each person and often become more severe over time, it is important to have therapeutic options to manage individuals over their disease continuum,” said Thomas H. Goodin, Ph.D., Senior Director, Clinical Development at Sunovion. “Sunovion has a long-standing commitment to improving the lives of people living with COPD, building on our heritage in nebulized treatment and advancing innovative new therapies that address unmet needs. Based on the data analyses presented at CHEST 2017, we are confident in the potential for SUN-101/eFlow® to be a well-tolerated therapy to improve lung function for people living with COPD.”

Key results from pooled data analyses presented at CHEST 2017 include:

- A secondary analysis of GOLDEN-3 and GOLDEN-4 showed that nebulized SUN-101/eFlow® (25 mcg and 50 mcg twice daily) resulted in statistical and clinically important improvements in lung function over the 12 week treatment period and was well tolerated in subgroups with baseline lung function of <50 percent and ≥50 percent predicted normal and in age ranges of <65 years, ≥65 years and ≥75 years as measured by trough FEV1. Greater improvements in the St. George’s Respiratory Questionnaire (SGRQ) total score and percent SGRQ responders compared to placebo were observed in both dose groups, regardless of baseline lung function and age.

- A secondary analysis of the effect of LABA background therapy in 30 to 40 percent of the GOLDEN-3, GOLDEN-4 and GOLDEN-5 study populations showed that nebulized SUN-101/eFlow® (25 mcg and 50 mcg twice daily) produced similar improvements in lung function over 12 and 48 weeks, as measured by trough FEV1 in subgroups with and without LABA = inhaled corticosteroids (ICS) background therapy and was well tolerated. Improvements in the SGRQ total score and percent SGRQ responders were observed in the 25 mcg and 50 mcg dose groups of the placebo and active controlled studies, at 12 weeks and 48 weeks respectively, regardless of background therapy.

- In the GOLDEN-3, GOLDEN-4 and GOLDEN-5 studies, nebulized SUN-101/eFlow® (25 mcg and 50 mcg twice daily) showed statistical and clinically important improvements in lung function over 12 and 48 weeks, as measured by trough FEV1 compared to placebo and was well tolerated. Improvements in the SGRQ total score in subgroups were observed in the 25 mcg and 50 mcg dose groups of the placebo and active controlled studies, at 12 weeks and 48 weeks respectively, regardless of background cardiovascular (CV) risk factors. The incidence of major adverse cardiac events (MACE) was not affected by CV risk status.

- In the GOLDEN-3 and GOLDEN-4 studies, nebulized SUN-101/eFlow® (25 mcg and 50 mcg twice daily) showed statistical and clinically important improvements in lung function over 12 weeks, as measured by FEV1 compared to placebo and was well tolerated in subgroups with PFR of <60 L/min and ≥60 L/min. Statistical improvements were observed in the SGRQ total scores and percent SGRQ responders compared to placebo in both dose groups.

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 PARI 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 Long-Acting Muscarinic Antagonists (LAMAs)

A long-acting muscarinic antagonist (LAMA) is a type of long-acting bronchodilator, along with long-acting beta agonists (LABAs). According to the GOLD 2017 report, these are currently the first-line standard of care maintenance therapy for symptomatic individuals with COPD. LAMAs and LABAs help the muscles around the airways in lungs relax to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath. LAMAs and LABAs are widely used and important therapeutic approaches for people with COPD.

About the Phase 3 GOLDEN Clinical Trials

GOLDEN-3 and GOLDEN-4 were pivotal Phase 3, 12-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter, efficacy and safety trials comparing SUN-101/eFlow® with placebo in adults with moderate-to-very-severe COPD. The GOLDEN-3 trial enrolled 653 people who were at least 40 years old at 45 sites in the United States. The GOLDEN-4 trial enrolled 641 people who were at least 40 years old at 49 sites in the United States. SUN-101/eFlow® 25 mcg, SUN-101/eFlow® 50 mcg or placebo was administered twice daily in these studies. The primary endpoint was the change from baseline in trough FEV₁ at Week 12. Key secondary endpoints included standardized change from baseline at Week 12 in FEV₁ area under the curve (AUC), change from baseline in trough forced vital capacity (FVC) at Week 12, change from baseline in health status measured by St. George's Respiratory Questionnaire and change in rescue medication use. Safety was assessed by the number of treatment-emergent adverse events (TEAE), serious adverse events (SAE), or major adverse cardiac events (MACE) and the number and percentage of study participants who discontinued the study due to TEAE. Both GOLDEN-3 and GOLDEN-4 studies included not only people who were taking effective background long-acting bronchodilator therapy but also individuals with very severe disease and co-existing cardiovascular illness. Approximately 10 percent of the population were elderly (≥75 years), 65 percent were classified as being high-risk cardiovascular individuals and approximately 30 percent were taking long-acting bronchodilator therapy [NCT02347761 and NCT02347774].

GOLDEN-5 was a Phase 3, 48-week, randomized, open-label, active-controlled, parallel-group, multicenter safety trial designed to evaluate the long-term safety and tolerability of SUN-101/eFlow® in adults with moderate-to-very-severe COPD. The study enrolled 1,087 individuals at 111 investigational sites in the United States and Europe. The study evaluated 50 mcg of SUN-101/eFlow® delivered twice daily and active comparator 18 mcg of Spiriva® (tiotropium bromide) delivered once daily by the HandiHaler® device. The primary safety endpoints were: the number and percentage of study participants with treatment-emergent adverse events (TEAE), the number and percentage of study participants with treatment-emergent serious adverse events (SAE), the number and percentage of study participants who discontinued the study due to TEAE and the number and incidence of subjects with MACE. The secondary efficacy endpoint was the mean change from baseline over 48 weeks in trough FEV₁ for all subjects. The study included not only people who were taking effective background long-acting bronchodilator therapy but also individuals with very severe disease and co-existing significant cardiovascular illness. Approximately 10 percent of the population were elderly (≥75 years), 65 percent were classified as being high-risk cardiovascular individuals and more than 40 percent were taking long-acting bronchodilator therapy [NCT02276222].

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. The third leading cause of death in the U.S. COPD develops slowly and the symptoms of COPD often worsen over time, potentially limiting the ability to perform routine activities. 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. The symptoms of COPD can be most severe during the night and early morning. Moring symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation. 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.

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 people at the center of everything it does, Sunovion has a mission to discover, develop and commercialize important therapies to improve the lives of patients. Sunovion’s track record of discovery, development and/or commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrrolate) Inhalation Powder, Seebri™ Neohaler® (glycopyrrrolate) Inhalation Powder, Brevana® (arformoterol tartrate) Inhalation Solution, Latuda® (lurasidone HCI) and Aptiom® (eslicarbazepine acetate).


About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and Europe. 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 Pharmaceutical 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 [11].

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