Sunovion Presents Phase 3 Data Showing Safety, Efficacy and Improvement in Quality of Life Outcomes in Patients with Moderate-to-Very Severe Chronic Obstructive Pulmonary Disease Treated with SUN-101/eFlow® (glycopyrrolate)

Release Date:
Tuesday, May 23, 2017 9:15 am EDT

Terms:

Dateline City:
MARLBOROUGH, Mass.

Presentations at the American Thoracic Society 2017 International Conference (ATS 2017) included data on the safety and efficacy of SUN-101/eFlow® and patient satisfaction with the investigational eFlow® closed system nebulizer from the GOLDEN clinical study program –

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) presented data from the Phase 3 GOLDEN trials, showing that treatment with SUN-101/eFlow® significantly improved lung function, health related quality of life and respiratory symptoms among people with moderate-to-very severe chronic obstructive pulmonary disease (COPD), at the American Thoracic Society 2017 International Conference (ATS 2017) held May 19-24, 2017, in Washington D.C. Sunovion also presented data from the long-term safety trial showing a high rate of patient reported satisfaction and confidence with the use of the investigational eFlow® closed system nebulizer.

“There are no approved nebulized, long-acting muscarinic antagonists (LAMAs) currently available for use in COPD,” said Thomas H. Goodin, Ph.D., Senior Director, Clinical Development at Sunovion. “These data suggest that for moderate-to-very severe patients, SUN-101/eFlow® could potentially be an effective and well-tolerated maintenance therapy.”

If approved, SUN-101/eFlow® will be the first nebulized LAMA approved for the treatment of COPD in the U.S. The investigational eFlow® closed system nebulizer, developed by PARI Pharma GmbH, is portable, virtually silent, designed to deliver the medication in two to three minutes and, unlike handheld inhalers, allows patients to breathe normally while using the device.

“COPD symptoms can severely impact patients’ daily activities and health related quality of life, and it is important for any treatment to be not only well-tolerated and effective, but also easy to administer,” said Gary Ferguson, M.D., Pulmonary Research Institute of Southeast Michigan and Principal Investigator for the GOLDEN-5 clinical trial. “With its efficacy and tolerability profile as well as the portability and short administration time, SUN-101/eFlow® could be a valuable treatment option for patients with COPD.”

Results from three Phase 3 studies (GOLDEN-3, GOLDEN-4, GOLDEN-5) demonstrate the efficacy and safety of SUN-101/eFlow® in a population of patients with real-world characteristics representing its potential as an important maintenance therapy in patients with moderate-to-very severe COPD. Key data presented included:

- In the GOLDEN-3 and GOLDEN-4 trials, both doses of SUN-101/eFlow® resulted in statistically significant, clinically important improvements in pulmonary function measured by change in trough FEV₁ (p<0.0002) and trough FVC (p<0.0008) from baseline, at Week 12 compared to placebo. In both studies, compared to patients receiving placebo, those who received SUN-101/eFlow® treatment (25 mcg and 50 mcg twice daily) had significant improvements in patient-reported respiratory symptoms measured by the Evaluating Respiratory Symptoms in COPD (E-RS™: COPD) Total score, starting as early as Week 2 (p<0.05 vs placebo for both doses).

- In the GOLDEN-3 and GOLDEN-4 trials, SUN-101/eFlow® significantly improved patients’ disease specific health related quality of life, measured by improvement in St. George’s Respiratory Questionnaire (SGRQ) Total score, compared to placebo. The pooled data showed that 46.1 percent and 42.3 percent of patients receiving 25 mcg and 50 mcg twice daily, respectively, and 34.2 percent of patients receiving placebo demonstrated clinically meaningful changes (≤ -4.0 unit reductions) in SGRQ Total score at week 12.

- SUN-101/eFlow® was well tolerated in GOLDEN-3 and -4 trials, with a combined overall incidence of treatment emergent adverse events (TEAEs) being numerically lower with SUN-101 25 and 50 mcg twice daily than with placebo (43.4 percent and 50.7 percent versus placebo 52.3 percent). Although there were observed numeric differences, the difference between the groups is not meaningful.

- A safety analysis of the 48 week GOLDEN-5 trial demonstrated that the results of GOLDEN-5 were consistent with results of GOLDEN-3 and 4 at 12 weeks, with cough and dyspnea occurring more frequently in the SUN-101/eFlow® treatment group. Additionally, numerically lower major adverse cardiovascular events were reported for SUN-101/eFlow® compared to the open-label, active comparator Spiriva® (tiotropium bromide) (6.4 per thousand person-years vs. 20.3, respectively). Discontinuation rate due to AEs was 10 percent and 2.8 percent in the SUN-101/eFlow® and Spiriva groups, respectively and may reflect an effect on airway reflexes and open label study design.

- A survey of GOLDEN-5 patients, which collected patient-reported satisfaction and the ability to use the investigational eFlow® closed system nebulizer, suggested that regardless of previous nebulizer use, a majority of patients (75 percent) were “satisfied” or “very satisfied” with the investigational eFlow® closed system nebulizer. Most patients (83 percent) also reported being “confident” to “very confident” that SUN-101 was being efficiently delivered to their lungs by the investigational eFlow® closed system nebulizer. Additionally, greater than 70 percent of the patients also rated the investigational eFlow® closed system nebulizer as “easy” or “very easy” to assemble, operate and clean.

The expected action date by the U.S. Food and Drug Administration (FDA) under the Prescription Drug User Fee Act (PDUFA) for SUN-101/eFlow® is May 29, 2017.

About SUN-101/eFlow®
SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary investigational eFlow® closed system nebulizer. SUN-101/eFlow® is currently in development as a nebulized treatment for patients with moderate-to-very severe chronic obstructive pulmonary disease (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 U.S. Food and Drug Administration (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 report, these are currently the first-line standard of care maintenance therapy for symptomatic patients with COPD, and helps the muscles around the airways in lungs stay relaxed 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. 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. A variety of endpoints were 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 patients who were taking effective background long acting bronchodilator therapy but also patients 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 patients 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 patients at 111 investigational sites in the United States and Europe. The study evaluated 50 mcg of SUN-101/eFlow® delivered twice 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 who took treatment-emergent serious adverse events (SAE), the number and percentage of study participants who discontinued the study due to TEAEs and the number and incidence of subjects with MACE. The secondary endpoint was the mean change from baseline over 48 weeks in trough FEV1 for all subjects. The study included not only patients who were taking effective background long acting bronchodilator therapy but also patients 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 patients 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 in and/or small airway 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. Symptoms of COPD include coughing, wheezing, shortness of breath, and excess production of mucus in the lungs, which can lead to breathing difficulties. Approximately 30% of people with COPD have high-risk cardiovascular conditions, cognition, depression and increased mortality.

Expanding Sunovion's Heritage in COPD

Sunovion is committed to expanding its heritage of advancing new treatments for serious respiratory medical conditions, including the 15.7 million people in the U.S. who are living with chronic obstructive pulmonary disease (COPD). The company offers the broadest COPD portfolio in the U.S., providing treatment options for people at various stages of COPD, as well as the flexibility to choose hand-held or nebulized delivery based on individual needs. Sunovion goes beyond treatment offerings to support awareness and understanding with the entire COPD community -- health care providers, patients and caregivers -- and to advancing disease state education through its partnerships with various organizations.

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 conditions. Sunovion's track record of discovery, development and commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCl) and Aptiom® (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 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.

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