News Release

Sunovion Pharmaceuticals Inc. Announces Positive Results from Two Phase 3 Clinical Studies Evaluating SUN-101/eFlow® (glycopyrrolate) in People with Moderate-to-Very Severe Chronic Obstructive Pulmonary Disease (COPD)

The GOLDEN-3 and GOLDEN-4 Phase 3 trials evaluating SUN-101/eFlow® in people with moderate-to-very severe COPD met their primary endpoint with a statistically significant change from baseline in trough FEV₁ at Week 12

MARLBOROUGH, Mass., April 27, 2016 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced positive results from the Phase 3 clinical trial program for SUN-101 (glycopyrrolate), a nebulized long-acting muscarinic antagonist (LAMA), delivered via PARI’s innovative investigational eFlow® nebulizer system (SUN-101/eFlow®), for people with moderate-to-very severe chronic obstructive pulmonary disease (COPD). The two clinical trials met their primary endpoints with a statistically significant change from baseline in trough forced expiratory volume in one second (FEV₁) at Week 12 for both the 50 mcg and 25 mcg dose groups versus placebo. SUN-101/eFlow® also was found to be well-tolerated as a twice-daily maintenance treatment of bronchoconstriction in patients with COPD.

“The results from the GOLDEN-3 and GOLDEN-4 trials represent significant progress in our mission to deliver medicines to people with COPD,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “We look forward to filing an NDA and the possibility of making SUN-101/eFlow® available for patients.”

“Physicians are constantly seeking new innovations and treatment options to help patients with COPD manage their disease,” said Dr. Selwyn Spangenthal, American Health Research and Principal Investigator for the GOLDEN-3 clinical trial. “SUN-101/eFlow®, as the first nebulized LAMA, could represent a significant breakthrough for patients.”

“We chose the closed eFlow® nebulizer system to pair with SUN-101 because it represents a new type of nebulizer system which combines the attributes of both nebulizers and hand-held inhalers,” said Alistair Wheeler, Head of Global Clinical Research, Respiratory Medicine and Biotherapeutics at Sunovion Pharmaceuticals. “This system is designed to provide COPD patients who are in need of LAMA therapy with a handheld aerosolized inhalation option.”

The innovative, proprietary, closed eFlow® nebulizer system, developed by PARI Pharma GmbH, is a unique type of closed system delivery device currently in development for the treatment of moderate-
to-very severe COPD. It is a portable, hand-held, electronic nebulizer system that uses a vibrating, perforated membrane to generate an inhalable aerosol. The closed eFlow® nebulizer system is designed to deliver the medication in two to three minutes from a distinctive proprietary drug vial inserted into the device. A standard jet nebulizer typically takes up to 10 minutes. The investigational combined product, consisting of SUN-101 and the closed eFlow® nebulizer system, has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COPD.

Sunovion will present data from the GOLDEN-3 and GOLDEN-4 studies at upcoming medical meetings. These data will also support a SUN-101/eFlow® New Drug Application (NDA) package, which the Company expects to submit to the FDA during fiscal year 2016.

**About the GOLDEN-3 and GOLDEN-4 Clinical Trials**

GOLDEN (Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer)-3 and GOLDEN-4 were 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 trials enrolled 653 and 641 people respectively who were at least 40 years old at 45 and 49 sites respectively in the United States. SUN-101/eFlow® 50 mcg, SUN-101/eFlow® 25 mcg or placebo was administered twice daily. The primary endpoint was the change from baseline in trough Forced Expiratory Volume in 1 second (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. 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 [NCT02347761 and NCT02347774].

**About SUN-101/eFlow®**

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, proprietary closed investigational eFlow® nebulizer system. 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 closed eFlow® nebulizer system 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 COPD**

Chronic obstructive pulmonary disease, also known as COPD, includes chronic bronchitis and emphysema, and is a progressive respiratory disease that causes worsening obstruction to airflow in the lungs over time.1 Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD.2 It is estimated that several million more adults have undiagnosed COPD.3 COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.3 COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.1 Symptoms of COPD include constant 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.3
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 spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. The Company 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 Brovana® (arformoterol tartrate), Latuda® (lurasidone HCl), and most recently Aptiom® (eslicarbazepine acetate).


About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce 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 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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References


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