

News Release

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**Sunovion Pharmaceuticals Inc. Announces Initiation of Phase 3 Clinical Trial Program for
SUN-101/eFlow[®] (Glycopyrrolate) in Moderate-to-Very Severe
Chronic Obstructive Pulmonary Disease (COPD)**

- *SUN-101/eFlow[®] is the first nebulized long-acting muscarinic antagonist (LAMA) drug/device combination product in Phase 3 development*
- *The SUN-101/eFlow[®] Phase 3 program consists of three clinical trials which will enroll approximately 2,340 adults with moderate-to-very severe COPD*
- *SUN-101/eFlow[®] is administered via a portable, electronic nebulizer which delivers medication in approximately two minutes*

MARLBOROUGH, Mass., February 25, 2015 - Sunovion Pharmaceuticals Inc. (Sunovion) today announced the start of enrollment for the Phase 3 clinical trial program for SUN-101 (glycopyrrolate) inhalation solution delivered through the innovative investigational eFlow[®] nebulizer system (SUN-101/eFlow[®]) from PARI Pharma GmbH. SUN-101/eFlow[®] is being investigated for the twice-daily maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

SUN-101/eFlow[®] is the first nebulized long-acting muscarinic antagonist (LAMA) in Phase 3 development. Phase 2 efficacy and safety data were presented at the 2014 American College of Chest Physicians Annual Meeting (CHEST 2014) in Austin, Texas. While LAMAs are effective in controlling COPD, LAMAs delivered via nebulizer are not currently approved by the U.S. Food and Drug Administration (FDA).

“We are committed to bringing innovative medications to patients with COPD and recognize the importance of developing a LAMA that can be delivered via a convenient and easy-to-use nebulizer,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion. “There is a high prevalence of undertreated COPD patients that could benefit from new nebulized treatment

options. As a drug/device combination, SUN-101/eFlow[®] has the potential to provide the effectiveness of a LAMA coupled with a portable electronic nebulizer.”

The SUN-101/eFlow[®] Phase 3 clinical trial program includes three separate studies currently enrolling approximately 2,340 adults with moderate-to-very severe COPD. GOLDEN-3 and GOLDEN-4 are randomized, double-blind, placebo-controlled, safety and efficacy studies comparing twice-daily SUN-101/eFlow[®] 25 mcg and 50 mcg with placebo. GOLDEN-3 and GOLDEN-4 began enrollment in February 2015. GOLDEN-5, an open-label long-term safety study (48 weeks) that began enrollment in October 2014, compares 50 mcg of SUN-101/eFlow[®] delivered twice-daily and Spiriva[®] (tiotropium bromide) 18 mcg delivered once-daily by the HandiHaler[®] device.

“As the first company to introduce a long-acting nebulized maintenance medicine for COPD to the U.S. market in 2007, Sunovion continues to be a leader in this area with the current development program for SUN-101/eFlow[®],” said David Frawley, Acting Chief Commercial Officer and Senior Vice President, Global Marketing and Sales at Sunovion. “Sunovion has a long-standing dedication to the COPD community, and in addition to our development of new treatment options, we take pride in our close and productive working relationships with the respiratory community.”

About SUN-101

SUN-101, an inhalation solution of a long-acting muscarinic antagonist (LAMA) bronchodilator, glycopyrrolate, delivered by the innovative, proprietary eFlow[®] nebulizer system, is currently in development for the treatment of patients with moderate-to-very severe chronic obstructive pulmonary disease (COPD). SUN-101 is being developed by Sunovion Respiratory Development Inc., (Former Elevation Pharmaceuticals, Inc.) a wholly-owned subsidiary of Sunovion Pharmaceuticals, Inc. Neither SUN-101 nor the eFlow[®] nebulizer system, which is optimized for SUN-101, have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COPD.

About the eFlow[®] Nebulizer System

The innovative, proprietary investigational eFlow[®] nebulizer system, developed by PARI Pharma GmbH, is fast, portable, and runs silently. The vibrating membrane device reduces the time for administration, allowing patients to receive medication in approximately two minutes compared with the standard jet nebulizer which takes up to 10 minutes. The investigational eFlow[®] nebulizer system has not been approved by the U.S. Food and Drug Administration (FDA).

About SUN-101/eFlow[®] Phase 3 Clinical Trial Program

GOLDEN-3 (Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer) and GOLDEN-4 are 12-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter, efficacy and safety trials, each enrolling approximately 645 people at least 40 years old with COPD at approximately 50 sites in the United States. SUN-101/eFlow[®] 50 mcg, SUN-101/eFlow[®] 25 mcg or placebo will be administered twice daily as an oral inhalation using the investigational eFlow[®] nebulizer. The primary endpoint is change from baseline in trough forced expiratory volume in 1 second (FEV₁) at Week 12. Secondary endpoints include 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 is 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 discontinue the study due to TEAE [NCT02347761 and NCT02347774].

GOLDEN-5 is a 48-week, randomized, open-label, active-controlled, parallel-group, multicenter, long-term safety and efficacy trial that will enroll approximately 1,050 people with COPD, at 150 investigational sites in the United States and Europe. Study participants have a baseline FEV₁ of less than 80% predicted normal values and at least 0.7L, as well as at least a 10 pack-year smoking history. The study compares 50 mcg of SUN-101/eFlow[®] delivered twice-daily and Spiriva[®] (tiotropium bromide) 18 mcg delivered once-daily by the HandiHaler[®] device. The primary safety endpoints are: the number and percentage of study participants with TEAE, the number and percentage of study participants with treatment-emergent SAE and the number and percentage of study participants who discontinue the study due to TEAE. The secondary endpoints are the mean change from baseline over 48 weeks in trough FEV₁ for all subjects and number and percentage of subjects with MACE [NCT02276222].

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 to improve the lives of patients and their families.

Sunovion, an indirect, wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. 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.

eFlow® is a registered trademark of PARI GmbH.

Spiriva® HandiHaler® is a registered trademark of Boehringer Ingelheim.

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