Sunovion Announces FDA Filing Acceptance of New Drug Application for
SUN-101/eFlow® for the Treatment of Patients with Chronic Obstructive Pulmonary
Disease (COPD)

- SUN-101/eFlow® (glycopyrrolate) NDA is currently under review; if approved, it would represent the
  first available nebulized long-acting muscarinic antagonist (LAMA) for patients with COPD -
- May 29, 2017 PDUFA date -

MARLBOROUGH, Mass., October 13, 2016 – Sunovion Pharmaceuticals Inc. (Sunovion) today
announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug
Application (NDA) for SUN-101 (glycopyrrolate), a nebulized long-acting muscarinic antagonist
(LAMA), delivered via PARI’s innovative investigational eFlow® closed system nebulizer, for the long-
term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary
disease (COPD). The expected action date by the FDA under the Prescription Drug User Fee Act
(PDUFA) is May 29, 2017.

“SUN-101/eFlow® demonstrates Sunovion’s commitment to delivering innovative therapies for
patients 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. “If
approved, SUN-101/eFlow® would be the first nebulized LAMA for patients with COPD. We look
forward to working with the FDA as we seek to gain approval of this innovative drug-device
combination and further address the needs of patients with this debilitating condition.”

The innovative, proprietary eFlow® nebulizer system, developed by PARI Pharma GmbH, is a unique
closed system delivery device currently in development for the treatment of moderate-to-very severe
COPD.

“The way a medication for COPD is delivered is an important consideration,” said Dr. Gary Ferguson,
Pulmonary Research Institute of Southeast Michigan, Livonia, Michigan. “By combining glycopyrrolate,
a proven therapeutic option for COPD, with an advanced, handheld nebulizer delivery system
designed to reduce the amount of time required for a treatment, SUN-101/eFlow® has the potential to
be a valuable alternative therapeutic option for patients who suffer from COPD.”

The NDA for SUN-101/eFlow® is based on data from clinical trials in the GOLDEN (Glycopyrrolate for
Obstructive Lung Disease via Electronic Nebulizer) program, which included GOLDEN-3 and
GOLDEN-4, two 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. These two studies met their primary endpoints, showing that patients treated with SUN-101/eFlow® demonstrated a statistically significant change from baseline in trough forced expiratory volume in one second (FEV₁) at Week 12 versus placebo. An additional study, 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 and included the active comparator Spiriva® (tiotropium bromide) delivered by the HandiHaler® device.

While these data support the NDA filing which has been accepted by the U.S. Food and Drug Administration (FDA), acceptance of the NDA does not mean that SUN-101/eFlow® will be approved by the FDA for the treatment of adults with COPD.

About SUN-101/eFlow®

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, 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 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 the Phase 3 GOLDEN Clinical Trials

GOLDEN-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 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. 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 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 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 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) and the number and percentage of study participants who discontinued the study due to TEAEs. The secondary endpoints were the mean change from baseline over 48 weeks in trough FEV1, for all subjects and number and percentage of subjects with MACE. 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, 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 Aptom® (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 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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