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News Release

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

- SUN-101/eFlow® (glycopyrrolate) NDA resubmission is currently under review -
- December 15, 2017, anticipated PDUFA action date -

Marlborough, Mass., June 30, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the New Drug Application for SUN-101/eFlow® (glycopyrrolate) for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

This resubmission is in response to the Complete Response Letter Sunovion received from the FDA on May 26, 2017. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is December 15, 2017.

"We look forward to working with the FDA during their review of the SUN-101/eFlow® resubmission, which, if approved, would be the first nebulized LAMA for patients with COPD in the United States," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "Building on the strength of our heritage in nebulized treatment for COPD, the development of this innovative drug-device combination underscores our commitment to ensuring patients have choices in medication and delivery options with the goals of individualizing and optimizing treatment."

The NDA for SUN-101/eFlow® is supported by data from clinical trials in the GOLDEN (Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer) program, which demonstrated a statistically significant change from baseline in morning pre-dose trough forced expiratory volume in one second

(FEV_1) versus placebo in addition to safety and tolerability in a long-term study. Sunovion was not required by the FDA to conduct any additional clinical studies prior to NDA resubmission.

About SUN-101/eFlow®

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary investigational eFlow® closed system nebulizer (PARI Pharma GmbH). SUN-101/eFlow® is currently in development as a nebulized treatment for patients 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 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.[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.[2] COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.[2] 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.[4] The symptoms of COPD can be most severe during the night and early morning.[5] Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.[6] 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.[7]

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/or commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCI) and Aptiom® (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on Twitter, LinkedIn, Facebook and YouTube.

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 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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