Sunovion Announces Positive Topline Results from Pivotal Study of Apomorphine Sublingual Film (APL-130277) in Patients with Parkinson’s Disease

- Apomorphine sublingual film demonstrated superior efficacy versus placebo for the on-demand treatment of OFF episodes associated with Parkinson’s disease -

Marlborough, Mass., January 29, 2018 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced topline results from its pivotal Phase 3, randomized, double-blind, placebo-controlled clinical trial, CTH-300, that evaluated apomorphine sublingual film (APL-130277) in patients with Parkinson’s disease (PD) who experience motor fluctuations (OFF episodes). Study CTH-300 met its primary and key secondary endpoints, and the medicine was also generally well-tolerated by study participants.

Apomorphine sublingual film is being developed to treat all types of motor OFF episodes, including morning OFF, unpredictable OFF and end-of-dose wearing OFF. OFF episodes occur when PD symptoms, otherwise controlled by medications, re-emerge. OFF episodes can happen at any point during the day, often occurring in the morning after awakening and periodically throughout the day. OFF episodes are characterized, in part, by tremor, stiffness or slow movement. These episodes may disrupt a person’s ability to perform everyday activities and are burdensome for patients, family and caregivers. OFF episodes are experienced by as many as 40 to 60 percent of people with PD and may worsen in frequency and severity over the course of the illness.¹

“For people with Parkinson’s disease and their families, OFF episodes can have a significant emotional and practical impact, and there are currently few treatment options for these events,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “Based on these topline results, we believe that apomorphine sublingual film has the potential to be a well-tolerated, reliable, convenient
and fast-acting therapeutic option for people living with Parkinson’s disease who struggle with OFF episodes.”

The Phase 3 study met its primary endpoint, with initial results from 109 adults with PD showing that individuals with OFF episodes who received apomorphine sublingual film demonstrated a statistically significant mean reduction in the Movement Disorder Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part III score from pre-dose to 30 minutes after dosing at Week 12 compared with the placebo group, with effects persisting until the last observed time point at 90 minutes. The difference in MDS-UPDRS Part III score change from baseline 30 minutes after dosing between apomorphine sublingual film and placebo was 7.6 (p=0.0002). The MDS-UPDRS Part III scale is used to assess the motor signs of PD. The study also met its key secondary endpoint, showing that a statistically significant greater percentage of people treated with apomorphine sublingual film (35 percent predicted response rate) had a patient-rated full ON response within 30 minutes after dosing at Week 12 compared with the placebo group (16 percent predicted response rate).

“Apomorphine is a potent antiparkinsonian medication that is underutilized in Parkinson’s disease patients with troublesome OFF episodes. Apomorphine is currently only available as an injection. If an alternative method to deliver the medicine were approved, such as apomorphine sublingual film, it would be an important new option for healthcare providers and people with Parkinson’s disease,” said Stewart Factor, D.O., Professor of Neurology, Director of the Movement Disorders Program and Vance Lanier Chair of Neurology at Emory University School of Medicine, and the primary investigator on the CTH-300 study. “The study reported here demonstrated that sublingual apomorphine rapidly and safely converted people with Parkinson’s disease from the OFF to the ON state.”

Apomorphine sublingual film was generally well-tolerated in the study population. The most commonly reported treatment-emergent adverse events during both the titration and maintenance treatment phases were nausea (27.0 percent), somnolence (14.9 percent), dizziness (14.2 percent), yawning (12.8 percent) and headache (9.2 percent).

Full results of study CTH-300 are being analyzed and will be presented at a future scientific congress.

Results from the study will be used to support Sunovion’s submission of a New Drug Application (NDA) for apomorphine sublingual film that is expected in spring 2018. The FDA has granted Fast Track Designation (FTD) for apomorphine sublingual film. FTD is designed to facilitate the development and expedite the review of drugs intended to treat serious conditions with the potential to address unmet medical needs.

About Apomorphine Sublingual Film
Apomorphine sublingual film (APL-130277), a novel formulation of apomorphine, a dopamine agonist, is being developed as a fast-acting, easy-to-use, sublingual film for the on-demand management of OFF episodes associated with Parkinson’s disease (PD). Apomorphine is the only molecule approved for on-demand, intermittent treatment of OFF episodes for advanced PD patients, but in the United States is currently approved as a subcutaneous injection. Apomorphine sublingual film is designed to offer a new, simple and discreet solution that can be used first thing in the morning, up to five times throughout the day, which may help people with PD rapidly, safely and reliably convert from the OFF to the ON state. It is intended to serve as an on-demand adjunctive treatment with patients’ current levodopa treatment regimens to manage OFF episodes. Apomorphine sublingual film is in Phase 3 clinical development and has not been approved by the U.S. Food and Drug Administration (FDA). In October 2016, Sunovion acquired Cynapsus Therapeutics Inc. (Canadian Specialty Central Nervous System Biotechnology Company), along with its product candidate APL-130277.

**About CTH-300**

CTH-300 was a pivotal, 12-week, randomized, double-blind, placebo controlled, parallel group, Phase 3 study examining the efficacy, safety and tolerability of apomorphine sublingual film (APL-130277) in people with levodopa-responsive Parkinson’s disease (PD) complicated by OFF episodes. The study was intended to demonstrate a statistically significant reduction in the Movement Disorder Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part III. The primary endpoint was a mean change from pre-dose in MDS-UPDRS Part III Motor Examination at 30 minutes after dosing at the 12-week visit of the Maintenance Treatment Phase. The prospectively specified key secondary endpoint was the percentage of people with a patient-rated full ON response within 30 minutes at the 12-week visit of the Maintenance Treatment Phase.\

**About Parkinson’s Disease and OFF Episodes**

More than one million people in the U.S. and an estimated four to six million people worldwide suffer from Parkinson’s disease (PD). PD is a chronic, progressive neurodegenerative disease characterized by motor symptoms, including tremor at rest, rigidity and impaired movement, as well as significant non-motor symptoms, including cognitive impairment and mood disorders. It is the second most common neurodegenerative disease behind Alzheimer’s disease, and the prevalence of PD is increasing with the aging of the population. OFF episodes are the re-emergence of symptoms (motor and non-motor) otherwise controlled by medications. OFF episodes occur when PD symptoms, otherwise controlled by medications, re-emerge. OFF episodes can happen at any point during the day, often occurring in the morning after awakening and periodically throughout the day. OFF episodes are characterized, in part, by tremor, stiffness or slow movement. These episodes may disrupt a person’s ability to perform everyday activities and are burdensome for patients, family and caregivers. OFF episodes are experienced by as many as 40 to 60 percent of people with PD and may worsen in frequency and severity over the course of the illness.
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 Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution, Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Seebri™ Neohaler® (glycopyrrolate) Inhalation Powder, Arcapta® Neohaler® (indacaterol) Inhalation Powder, Brovana® (arformoterol tartrate) Inhalation Solution, Latuda® (lurasidone HCI) 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 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.

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References