Sunovion Submits New Drug Application to the FDA for Apomorphine Sublingual Film (APL-130277) for the Treatment of OFF Episodes Associated with Parkinson’s Disease

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- Submission is supported by Phase 3 clinical study data showing that the investigational medicine demonstrated superior efficacy versus placebo for the on-demand treatment of OFF episodes associated with Parkinson's disease.

MARLBOROUGH, Mass. --(BUSINESS WIRE)--(Sunovion Pharmaceuticals Inc. (Sunovion) today announced that it has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) on March 29, 2018, for apomorphine sublingual film (APL-130277) to treat motor fluctuations (OFF episodes) experienced by people living with Parkinson's disease (PD).

Apomorphine sublingual film is being developed as a fast-acting medicine for the on-demand treatment of 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 may worsen in frequency and severity over the course of the illness.1

"OFF episodes, which may be characterized by symptoms such as tremor, stiffness or slow movement, may disrupt the ability to perform everyday activities and may be burdensome for patients, families and caregivers," said Anthony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "We are pleased to have submitted the NDA for apomorphine sublingual film for the treatment of OFF episodes and look forward to working with the FDA during the review period."

Despite the significant impact of OFF episodes, which are experienced by 40 to 60 percent of people with PD, there are limited on-demand treatment options available for motor OFF episodes.2

Sunovion's NDA submission is supported by a pivotal, Phase 3 study, CTH-300 [1], which met its primary and key secondary endpoint. In the study, apomorphine sublingual film demonstrated superior efficacy versus placebo for the on-demand treatment of OFF episodes associated with PD, with the effect persisting until the last observed time point at 90 minutes. The study also showed that apomorphine sublingual film was generally well-tolerated by study participants.

The FDA has granted Fast Track Designation for apomorphine sublingual film.

About Apomorphine Sublingual Film
Apomorphine sublingual film (APL-130277), a novel formulation of apomorphine, a dopamine agonist, is being developed as a fast-acting sublingual film for the on-demand management of OFF episodes associated with Parkinson’s disease (PD). Apomorphine is currently the only medicine approved for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dosing wearable" and unpredictable "on/off" episodes) associated with advanced PD and is approved in the United States as a subcutaneous injection. Apomorphine sublingual film is designed to offer a potential solution that may be used to treat motor OFF episodes associated with PD up to five times throughout the day, which may help people with PD rapidly convert from the OFF to the ON state. Apomorphine sublingual film 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 (NCT02469090) 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 primary endpoint was a mean change from pre-dose in Movement Disorder Society Unified Parkinson’s Disease Rating Scale (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. Study results will be presented at a future scientific congress and will be posted on ClinicalTrials.gov.

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 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 may be burdensome for patients, family and caregivers. OFF episodes are experienced by 40 to 60 percent of people with PD and may worsen in frequency and severity over the course of the illness.2

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, as well as an unwavering commitment to support people with psychiatric, neurological and respiratory conditions.


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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