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Sunovion Presents Data from Pivotal Phase 3 Study of Apomorphine Sublingual Film (APL-130277) at the 2nd Pan American Parkinson's Disease and Movement Disorders Congress

- Data shows apomorphine sublingual film has superior efficacy versus placebo for the on-demand treatment of OFF episodes associated with Parkinson's disease -

Marlborough, Mass., June 23, 2018 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today presented the positive results of its pivotal, Phase 3, randomized, double-blind, placebo-controlled trial, CTH-300. This study evaluated apomorphine sublingual film (APL-130277) in patients with Parkinson's disease (PD) who experience motor fluctuations (OFF episodes), including those who experience early morning OFF episodes. The study results were presented as a late-breaking abstract poster at the 2nd Pan American Parkinson's Disease and Movement Disorders Congress (MDS-PAS) in Miami, Florida.

Sunovion [announced top-line results](#) from this study on January 29, 2018. In addition, Sunovion [announced the U.S. Food and Drug Administration \(FDA\) accepted its NDA submission](#) for apomorphine sublingual film on June 12, 2018. The expected Prescription Drug User Fee Act (PDUFA) date is January 29, 2019.

“OFF episodes are disruptive to a person's daily routine, so a possible treatment that can help alleviate these periods is important for the Parkinson's disease community and healthcare providers,” said Fernando L. Pagan, M.D., Director of the Movement Disorders Program at Georgetown University Hospital. “These results demonstrate promise for apomorphine sublingual film as a fast-acting medicine for on-demand treatment of all types of motor OFF episodes.”

The results presented at MDS-PAS show that individuals with OFF episodes who received apomorphine sublingual film had a statistically significant treatment difference of 7.6 points in improvement of motor function 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. Statistically significant separation from placebo was seen as early as 15 minutes post-dose and persisted

up to 90 minutes (the last measured time point).¹ Similar results during the double-blind maintenance period were observed at Weeks 0 (baseline), 4, 8 and 12. The study also met its key secondary endpoint, showing that a significantly higher percentage of individuals who received apomorphine sublingual film had a patient-rated full ON response within 30 minutes at Week 12 compared with those who received placebo.

Apomorphine sublingual film was generally well-tolerated, with the majority of treatment-emergent adverse events (TEAE) being mild to moderate in severity, non-serious and reversible upon treatment discontinuation. The most frequent TEAEs in the double-blind, maintenance treatment phase were nausea (27.8 percent), somnolence (13.0 percent) and dizziness (9.3 percent).

“The results of the Phase 3 pivotal trial for apomorphine sublingual film continue to reinforce that it is potentially a novel and significant treatment option for those living with OFF episodes associated with Parkinson’s disease,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “We look forward to the continued review of the NDA by the Agency and the opportunity to bring apomorphine sublingual film to people who experience OFF episodes.”

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 or worsen. OFF episodes can happen at any point during the day, often occurring in the morning after awakening and periodically throughout the day. Motor OFF episodes can be characterized by tremor, stiffness or slow movement, among other symptoms. These episodes can disrupt a person’s ability to perform everyday activities and may impair quality of life and add to the economic burden of the disease.¹ OFF episodes can be experienced by as many as 40 to 60 percent of all people living with PD and may worsen in frequency and severity over the course of the illness.²

About Apomorphine Sublingual Film (APL-130277)

Apomorphine sublingual film (APL-130277), a novel formulation of apomorphine, a non-ergot dopamine agonist, is being developed as a fast-acting sublingual film for the on-demand management, up to five times per day, of OFF episodes associated with Parkinson’s disease (PD). Apomorphine is the only agent approved for the acute, intermittent treatment of hypomobility, “OFF” episodes (“end-of-dose wearing OFF” and unpredictable “ON/OFF” episodes) associated with advanced PD and in the U.S. is currently approved as a subcutaneous injection. Apomorphine sublingual film is intended to rapidly convert people living with PD from an OFF to an ON state and has been studied for the treatment of motor OFF episodes up to five times per day. 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. The Michael J. Fox

Foundation for Parkinson's Research funded in part two Phase I trials of APL-130277 – a [comparative biostudy in healthy volunteers](#) and a [dosing study in people with Parkinson's disease](#).

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 in the score from pre-dose in the 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 patients with a patient-rated Full ON response within 30 minutes at the 12-week visit of the Maintenance Treatment Phase.²

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 live with 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 or worsening 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. Motor OFF episodes can be characterized by tremor, stiffness, or slow movement, among other symptoms. These episodes may disrupt a person's ability to perform everyday activities and may be burdensome for patients, family and caregivers. OFF episodes can be 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 and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions.

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 websites: 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 U.S., China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area, the Oncology area and Regenerative medicine/Cell therapy field, 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 more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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¹ Schrag, A. "Dyskinesias and motor fluctuations in Parkinson's disease: A community-based study." *Brain*. November 2000, Vol. 123, Issue 11. p. 2297-2305. Available online: <https://academic.oup.com/brain/article/123/11/2297/256050>. Accessed March 2018.

² "Efficacy, Safety and Tolerability Study of APL-130277 for the Acute Treatment of OFF Episodes in Patients with Parkinson's Disease. Available online: <https://clinicaltrials.gov/ct2/show/NCT02469090>. Accessed December 2017.