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News Release

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Sunovion Receives Complete Response Letter from FDA for Apomorphine Sublingual Film (APL-130277)

Marlborough, Mass., January 30, 2019 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) announced today that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for apomorphine sublingual film (APL-130277) to treat OFF episodes (the re-emergence or worsening of Parkinson's symptoms otherwise controlled by medications) experienced by people living with Parkinson's disease (PD).

Upon review of the application, the FDA determined that it was unable to approve the apomorphine sublingual film NDA in its present form. The Agency requested additional information and analyses, but no new clinical studies are required.

"OFF episodes are a common and challenging part of Parkinson's disease with few existing treatment options," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "Sunovion remains committed to working with the FDA to address its requests so that we can bring apomorphine sublingual film to patients as expeditiously as possible."

About Apomorphine Sublingual Film (APL-130277)

APL-130277, a novel formulation of apomorphine and a dopamine agonist, is being developed for the on-demand management of OFF episodes associated with Parkinson's disease (PD). Apomorphine is currently FDA 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 it is currently available in the U.S. as a subcutaneous injection. APL-130277 is intended to rapidly convert people living with PD from the OFF to the ON state and has been studied for treatment of motor OFF episodes up to five times per day and no sooner than two hours from the previous dose. APL-130277 has not been approved by the FDA. In October 2016, Sunovion acquired Cynapsus Therapeutics Inc. along with its

product candidate APL-130277. The Michael J. Fox Foundation 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 Parkinson's Disease (PD) and OFF Episodes

One million people in the U.S. and an estimated four to six million people worldwide live with PD. PD is a chronic, progressive neurodegenerative disease in which dopamine producing cells are damaged or lost. The condition is 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 occur multiple times a 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, can cause anxiety and may be burdensome for patients, family and caregivers. OFF episodes are experienced by 40 to 60 percent of people with PD within four to six years of onset and may worsen in frequency and severity over the course of the illness.¹

About Sunovion Pharmaceuticals Inc.

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people living 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 <https://www.ds-pharma.com>.

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References

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 December 2018.