



NEWS RELEASE

Sunovion Announces FDA Filing Acceptance of Resubmitted New Drug Application for Apomorphine Sublingual Film

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--**Sunovion Pharmaceuticals Inc.** (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for apomorphine sublingual film (APL-130277) to treat motor fluctuations (OFF episodes) experienced by people living with Parkinson's disease (PD), which was resubmitted on November 21, 2019. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is May 21, 2020.

"The unpredictable nature of OFF episodes can be extremely challenging and disruptive to the daily lives of people living with Parkinson's disease as well as their care partners," said Antony Loebel, M.D., President and Chief Executive Officer at Sunovion. "We look forward to working with the FDA over the remaining review period."

"People with Parkinson's have shared that OFF episodes can be disruptive and hamper their quality of life. New treatments could mean greater symptom control for more people, improving their ability and confidence to navigate daily life with the disease," said Todd Sherer, PhD, CEO of The Michael J. Fox Foundation for Parkinson's Research.

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, delayed ON/partial ON and end-of-dose wearing OFF. OFF episodes can cause severe disruption for someone living with PD, often causing a major disturbance in a person's ability to maintain everyday activities. OFF episodes may worsen in frequency and severity over the course of the illness.¹ While OFF episodes are experienced by 40 to 60 percent of people with PD, there are limited treatment options available to treat OFF episodes when they occur. ¹

About Apomorphine Sublingual Film

Apomorphine sublingual film (APL-130277), a novel formulation of apomorphine, a dopamine agonist, is being developed as a fast-acting on-demand treatment of OFF episodes associated with Parkinson's disease (PD). Apomorphine sublingual film is designed to offer a potential option that may be used to treat OFF episodes associated with PD up to five times throughout the day. It may help people with PD rapidly convert from the OFF to the ON state. Results of the pivotal Phase 3 study (CTH-300) of apomorphine sublingual film were recently published in **Lancet Neurology**. 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. Two early-stage APL-130277 trials were funded in part by The Michael J. Fox Foundation.

About Parkinson's Disease and OFF Episodes

By 2030 it is estimated that 1.2 million people in the U.S. and an estimated 10 million people worldwide will be living with Parkinson's disease (PD).² 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 worsening or re-emergence of PD symptoms (motor and non-motor) otherwise controlled by medications. These episodes may disrupt a person's ability to perform everyday activities and may be burdensome for patients, family and care partners. 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. ¹

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 <https://www.ds-pharma.com>.

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References

1 Denny, A. "Motor fluctuations in Parkinson's disease." Journal of the Neurological Sciences. May 1999, Vol. 165, Issue 1, p. 18-23, table 3. Available online: [http://www.jns-journal.com/article/S0022-510X\(99\)00052-0/fulltext](http://www.jns-journal.com/article/S0022-510X(99)00052-0/fulltext). Accessed February 2017.

2 Parkinson's Disease Foundation Website: <https://www.parkinson.org/about-us/Press-Room/Press-Releases/New-Study-Shows-Over-1-Million-People-in-the-United-States-Estimated-to-be-Living-with-Parkinsons-Disease-by-2030>. Accessed December 2019.

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