Sunovion Announces FDA Acceptance of New Drug Application for Apomorphine Sublingual Film (APL-130277)

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Sunovion seeks approval for apomorphine sublingual film for the on-demand treatment of OFF episodes associated with Parkinson's disease.

- **Marlborough, Mass.**—Sunovion Pharmaceuticals Inc. [2] today announced that the U.S. Food and Drug Administration (FDA) has accepted the 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). The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is January 29, 2019.

"Through our ongoing work with people living with Parkinson's disease, we know the community is eager for more treatment options that may help alleviate OFF episodes, which are often disruptive to their daily lives," said Todd Sherer, Ph.D., CEO of The Michael J. Fox Foundation for Parkinson's Research. "We're hopeful that this new approach to Parkinson's disease will be successful in helping people through the regulatory process, and we are hopeful for its approval and future availability." Two early-stage APL-130277 trials were funded in part by The Michael J. Fox Foundation.

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. Motor OFF episodes can cause severe disruption for someone living with PD, often causing a major disabling loss of ability to maintain everyday activities. While OFF episodes are experienced by 40 to 60 percent of all people living with PD there are limited on-demand treatment options available.1

"We are encouraged that the FDA has accepted our NDA for apomorphine sublingual film," said Anthony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "There currently few treatment options available to Parkinson's disease patients for the as needed treatment of OFF episodes. We look forward to working with the FDA during the review period so that we can bring a much needed new treatment option to people living with Parkinson's disease and OFF episodes."2

**About Apomorphine Sublingual Film (APL-130277)**

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 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 the OFF to the ON state and has been studied for 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 funded in part two Phase I trials of APL-130277 – a comparative biostudy in healthy volunteers [3] and a dose-finding study in people with Parkinson's disease.4

**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 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 especially taxing for 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.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.


**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 Pharma 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.dc-pharma.com [12].

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For a copy of this release, visit Sunovion's website at www.sunovion.com [13]

**References**


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