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. – (BUSINESS WIRE) – Sunovion Pharmaceuticals Inc. (Sunovion) announced today 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 Sheer, Ph.D., CEO of The Michael J. Fox Foundation for Parkinson’s Research. “We’re heartened to see apomorphine sublingual film is successful in opening new pathways 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.”

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 in people with Parkinson’s disease 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 bioavailability study in healthy volunteers [3] and a dosing 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 patient’s ability to perform everyday activities and may be frightening to family and caregivers. OFF episodes are experienced by 40 to 60 percent of all people living with PD and there are limited on-demand treatment options available.

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 medicalCell 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 Pharmaceutical 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 [12].

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

References


Language: English

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