Marlborough, Mass., November 22, 2019 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced the resubmission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for apomorphine sublingual film (APL-130277) to treat motor fluctuations (OFF episodes) experienced by people living with Parkinson’s disease (PD) in response to the January 29, 2019 Complete Response Letter (CRL). This submission included information about intended packaging as well as additional analyses of clinical data.

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. 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. While OFF episodes are experienced by 40 to 60 percent of people with PD, there are limited on-demand treatment options available for motor OFF episodes.

“OFF episodes in people with Parkinson’s disease can occur at any point throughout the day, often occurring in the morning after awakening and periodically throughout the day and can disrupt the ability to perform everyday activities,” said Antony Loebel, M.D., President and Chief Executive Officer at Sunovion. “We look forward to continuing our dialogue with the FDA during the review period with the intention of bringing a much needed on-demand treatment option for OFF episodes to those living with Parkinson’s disease.”

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. 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.

About Parkinson’s Disease and OFF Episodes
By 2020 nearly one million people in the U.S. and an estimated 10 million people worldwide will be living 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 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 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.

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 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.

SUNOVION is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd. © 2019 Sunovion Pharmaceuticals Inc. All rights reserved.

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

References

