Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
Tel 508-481-6700

# NewsRelease

Kirsten Fallon
Associate Director, Portfolio Communications
Sunovion Pharmaceuticals Inc.
774-369-7116
kirsten.fallon@sunovion.com

## Sunovion and BIAL Enter European Licensing Agreement for Apomorphine Sublingual Film for the Treatment of Parkinson's Disease OFF Episodes

**Marlborough, Mass., September 2, 2021** – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that it has entered into an agreement with BIAL in which Sunovion has granted exclusive commercial license rights in Europe for apomorphine sublingual film (APL-130277). APL-130277, approved as KYNMOBI® (apomorphine hydrochloride) sublingual film in the U.S. and Canada, is a novel thin film formulation of apomorphine that dissolves under the tongue for the acute, intermittent treatment of OFF episodes in patients with Parkinson's disease (PD). APL-130277 is currently in Phase 3 clinical development in Europe.

By 2030, an estimated 10 million people worldwide will be living with PD.[1] OFF episodes are the re-emergence or worsening of PD symptoms otherwise controlled with oral levodopa/carbidopa. These episodes may disrupt a person's ability to perform everyday activities and are characterized, in part, by tremor, stiffness, slowed movement or other symptoms.

Under the terms of the agreement, BIAL will be responsible for submitting marketing applications consistent with marketing authorization procedures in Europe and have exclusive commercial rights to distribute and commercialize apomorphine sublingual film in the European Union (EU), the European Economic Area (EEA) as well as the United Kingdom. BIAL expects to submit a European marketing authorization application for apomorphine sublingual film by the end of 2021. Sunovion will receive an upfront payment and is entitled to receive certain milestone payments. Sunovion will supply KYNMOBI in all approved dose strengths to BIAL.

Sunovion continues to hold the exclusive commercial rights to KYNMOBI in North America and all other regions of the world outside of the EU, EEA as well as the United Kingdom. KYNMOBI is the first and only sublingual (under the tongue) therapy available for the on-demand treatment of PD OFF episodes in the U.S. and Canada.

**ABOUT KYNMOBI®**

KYNMOBI (apomorphine hydrochloride) sublingual film, a novel formulation of apomorphine, a non-ergoline dopamine agonist, is the first and only sublingual therapy approved in the United States and Canada for the fast-acting, on-demand treatment of OFF episodes associated with Parkinson's disease. In the U.S. and Canada KYNMOBI may be used up to five times a day.

Phase 3 clinical trial results, published in *Lancet Neurology*, demonstrated that patients with PD receiving KYNMOBI experienced significant improvements in motor symptoms at 30 minutes after dosing at week 12, with a mean reduction of 7.6 points, compared to placebo, on the Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III score. Separation from placebo was seen as early as 15 minutes post-dose (first time point measured) and persisted up to 90 minutes (last time point measured). Additionally, a significantly higher percentage of people treated with KYNMOBI had a patient-rated full ON response within 30 minutes at week 12, compared with people receiving placebo. KYNMOBI was generally well-tolerated. Among the most frequently reported treatment-emergent adverse events in this study (occurring in more than 5 percent of patients and at a rate greater than placebo) were nausea, oropharyngeal reactions, somnolence and dizziness.

**Important Safety Information (United States)**

**INDICATION**

KYNMOBI® (apomorphine hydrochloride) sublingual film is a prescription medicine used to treat short-term (acute), intermittent "off" episodes in people with Parkinson's disease (PD).

It is not known if KYNMOBI is safe and effective in children.

**IMPORTANT SAFETY INFORMATION FOR KYNMOBI (apomorphine hydrochloride) SUBLINGUAL FILM**

Do not take KYNMOBI if you are taking certain medicines to treat nausea called 5HT3 antagonists, including ondansetron, granisetron, dolasetron, palonosetron, and alosetron. People taking ondansetron together with apomorphine, the active ingredient in KYNMOBI, have had very low blood pressure and lost consciousness or "blacked out."

Do not use KYNMOBI if you are allergic to apomorphine hydrochloride or to any of the ingredients in KYNMOBI. KYNMOBI also contains a sulfite called sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions in some people. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are more likely to be allergic to sulfites. Call your healthcare provider if you have hives, itching, rash, swelling of the lips, tongue and mouth, redness of your face (flushing), throat tightness, trouble breathing or swallowing.

**Before starting KYNMOBI, tell your healthcare provider:**
About all of your medical conditions, including if you:

- have difficulty staying awake during the daytime
- have dizziness
- have fainting spells
- have low blood pressure
- have asthma
- are allergic to any medicines containing sulfites
- have liver problems
- have kidney problems
- have heart problems
- have had a stroke or other brain problems
- have a mental problem called a major psychotic disorder
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if KYNMOBI will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if KYNMOBI passes into your breast milk. You and your healthcare provider should decide if you will take KYNMOBI or breastfeed.

Tell your healthcare provider about all the medicines you take, including:

- prescription medicines
- over-the-counter medicines
- vitamins
- herbal supplements

KYNMOBI may affect the way other medicines work, and other medicines can affect how KYNMOBI works. Taking KYNMOBI with other medicines may cause serious side effects. If you take nitroglycerin under your tongue (sublingual) while using KYNMOBI, your blood pressure may decrease and cause dizziness. You should lie down before and after taking sublingual nitroglycerin.

**KYNMOBI can cause serious side effects, including:**

- **nausea and vomiting. Nausea is a common side effect of KYNMOBI.** Nausea and vomiting can happen with KYNMOBI. Your healthcare provider may prescribe a medicine called an antiemetic, such as trimethobenzamide to help prevent nausea and vomiting.
- **sleepiness or falling asleep during the day. Sleepiness is a serious, and common side effect of KYNMOBI.** Some people treated with KYNMOBI may get sleepy during the day or fall asleep without warning while doing everyday activities such as talking, eating, or driving a car.
- **dizziness. Dizziness is a serious, and common side effect of KYNMOBI.** KYNMOBI may lower blood pressure and cause dizziness. Dizziness can happen when KYNMOBI treatment is started or when the KYNMOBI dose is increased. Do not get up too fast from sitting or after lying down, especially if you have been sitting or lying down for a long period of time.
- **mouth (oral) irritation. Mouth (oral) irritation is a common side effect of KYNMOBI.** You should call your healthcare provider if you develop any of these signs or symptoms.
    - redness
    - mouth sores (ulceration)
    - dryness of the mouth, lips or tongue
    - swelling
    - pain
    - pain with swallowing
- **falls.** The changes that can happen with PD, and the effects of some PD medicines, can increase the risk of falling. KYNMOBI may also increase your risk of falling.
- **hallucinations or psychotic-like behavior.** KYNMOBI may cause or make psychotic-like behavior worse including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking.
- **strong (intense) urges**. Some people with PD have reported new or strong uncontrollable urges to gamble, increased sexual urges, increased urges to spend money (compulsive shopping), and other intense urges, while taking PD medicines, including KYNMOBI. If you or your family

members notice that you have strong urges, talk to your healthcare provider. The strong urges may go away if your KYNMOBI dose is lowered or stopped.

- **high fever and confusion.** KYNMOBI may cause a problem that can happen in people who suddenly lower their dose, stop using, or change their dose of KYNMOBI. Symptoms include:
  - very high fever
  - confusion
  - stiff muscles
  - changes in breathing and heartbeat

**Do not** stop taking KYNMOBI or change your dose unless you are told to do so by your healthcare provider.

- **heart problems.** If you have shortness of breath, fast heartbeat, chest pain, or feel like you are going to pass out (faint) while taking KYNMOBI, call your healthcare provider or get emergency help right away.
- **tissue changes (fibrotic complications).** Some people have had changes in the tissues of their pelvis, lungs, and heart valves when taking medicines called nonergot derived dopamine agonists like KYNMOBI.
- **prolonged painful erections (priapism).** KYNMOBI may cause prolonged, painful erections in some people. If you have a prolonged and painful erection, you should call your healthcare provider or go to the nearest hospital emergency room right away.

**The most common side effects of KYNMOBI include:**

- nausea
- dizziness
- sleepiness
- mouth swelling, pain, or sores

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

Please see full **Prescribing Information** for KYNMOBI at **https://www.kynmobi.com**.

**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 after Alzheimer's disease,[2] and the prevalence of PD is increasing as the world's population ages.

OFF episodes are the re-emergence or worsening of PD symptoms otherwise controlled with oral levodopa/carbidopa. These episodes may disrupt a person's ability to perform everyday activities, can cause anxiety and may be burdensome for patients, family and care partners. OFF episodes are experienced by nearly 60 percent of people with PD within the first four to six years of diagnosis, and may worsen in frequency and severity over the course of the illness.[3]

**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 Canada Inc., based in Mississauga, Ontario, is a wholly-owned direct subsidiary of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's websites: www.sunovion.com 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-10 listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China and other Asian countries. 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 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.



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

**References**

[1] 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 March 2021.

[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 September 2020.

[3] 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 September 2020.