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News Release

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Sunovion Announces U.S. FDA Approval of KYNMOBI™ (apomorphine hydrochloride) Sublingual Film for the Treatment of Parkinson's Disease OFF Episodes

- First and only sublingual therapy approved for the on-demand treatment of Parkinson's disease OFF episodes

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- In a Phase 3 study, patients with Parkinson's disease treated with KYNMOBI experienced significant improvements in motor symptoms at 30 minutes, compared to placebo -

Marlborough, Mass., May 21, 2020 – [Sunovion Pharmaceuticals Inc.](https://www.sunovion.com) (Sunovion) announced today that the U.S. Food and Drug Administration (FDA) has approved KYNMOBI™ (apomorphine HCl) sublingual film (APL-130277) for the acute, intermittent treatment of OFF episodes in patients with Parkinson's disease (PD). OFF episodes are the re-emergence or worsening of PD symptoms otherwise controlled with oral levodopa/carbidopa. They may be characterized, in part, by tremor, stiffness, slowed movement or other symptoms. These disruptive episodes can occur in the morning upon waking and throughout the day. KYNMOBI dissolves under the tongue to help people with PD improve their OFF symptoms as needed.

"Today's approval of KYNMOBI advances treatment options for people with Parkinson's disease who experience OFF episodes and the associated disruption of everyday activities," said Antony Loebel, M.D., President and Chief Executive Officer at Sunovion. "We are pleased to offer the Parkinson's disease community a novel treatment option that we believe offers a convenient way for patients to rapidly improve impaired movements and better control their motor symptoms when they need it."

Parkinson's disease is a chronic neurodegenerative disease in which dopamine producing cells are lost. It is projected that 1.2 million Americans will be living with PD by 2030.¹ Within the first four to six years after diagnosis, regardless of disease severity, up to 60 percent of people with PD experience OFF episodes.²

"Several years after a person is diagnosed with Parkinson's disease they may notice problems such as having trouble getting out of bed in the morning or having difficulty getting out of a chair, or that they feel frozen while trying to walk as the effect of their maintenance medication diminishes," said Stewart Factor, D.O.,

Professor of Neurology, Director of the Movement Disorders Program and Vance Lanier Chair of Neurology at Emory University School of Medicine. "The approval of KYNMOBI affords health care providers with a needed option that can be added to their patients' medication regimen to adequately address OFF episodes as their Parkinson's disease progresses."

"We know from our research and discussions with the Parkinson's community that OFF episodes can significantly disrupt a patient's daily life," said Todd Sherer, Ph.D., CEO, The Michael J. Fox Foundation for Parkinson's Research. "The Foundation supported early clinical development of sublingual apomorphine, and this approval brings an important new treatment option for people with PD who experience OFF."

Sunovion expects KYNMOBI to be available in U.S. pharmacies in September 2020.

Medical information, patient assistance and other information about KYNMOBI can be obtained by calling Sunovion Answers at 1-844-596-6624 (844-KYNMOBI) Monday through Friday from 8:00 a.m. to 8:00 p.m. ET.

ABOUT KYNMOBI™

KYNMOBI (apomorphine hydrochloride) sublingual film, a novel formulation of apomorphine, a dopamine agonist, is the first and only sublingual therapy for the fast-acting, on-demand treatment of OFF episodes associated with Parkinson's disease. 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. Initial clinical improvements were seen at 15 minutes post-administration. 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

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 liver problems
 - have dizziness
 - have kidney problems
 - have fainting spells
 - have heart problems
 - have low blood pressure
 - have had a stroke or other brain problems
 - have asthma
 - have a mental problem called a major psychotic disorder
 - are allergic to any medicines containing sulfites
 - 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 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).¹ 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 disease³, 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.²

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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For a copy of this release, visit Sunovion's web site 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 May 2020.

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