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NewsRelease

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Sunovion Announces Health Canada Approval of KYNMOBI™ (apomorphine hydrochloride) Soluble 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 -

Mississauga, Ontario, June 15, 2020 – Sunovion Pharmaceuticals Inc. (Sunovion) announced today that Health Canada has approved KYNMOBI™ (apomorphine HCl) soluble film 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 any time throughout the day and get worse as the disease progresses. KYNMOBI was previously approved by the U.S. Food and Drug Administration (FDA) on May 21, 2020.

"The unpredictable and frequent nature of OFF episodes, which can occur despite people taking their oral maintenance medications as prescribed, makes this a particularly challenging and burdensome facet of Parkinson's disease," said Anthony E. Lang, M.D., Professor at University of Toronto and Jack Clark Chair for Parkinson's Disease Research, and Director of the Edmond J Safra Program in Parkinson's disease at Toronto Western Hospital. "KYNMOBI is a welcome on-demand treatment that physicians can offer patients to help rapidly improve their PD OFF episodes."

Parkinson's disease is a chronic neurodegenerative disease in which dopamine producing cells are lost. Approximately 94,000 Canadians are living with Parkinson's disease, and this is expected to increase by an estimated 50 percent by 2031.[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] These OFF episodes can happen in the morning, upon waking, around timed medication doses, and unpredictably throughout the day. OFF episodes may also cause anxiety and depressive symptoms in some people with PD.[3]

"As the disease progresses patients with Parkinson's are faced with challenging and disruptive OFF episodes that come with impaired mobility," said Karen Lee, PhD, CEO of Parkinson Canada. "Today's Health Canada approval is an important step forward for people living with Parkinson's disease, as they now have more options that can help manage the effects of OFF episodes as they occur."

"OFF episodes disrupt the daily lives of people living with Parkinson's disease as well as their care partners and can make simple tasks like getting ready in the morning or buttoning a shirt extremely difficult," said Antony Loebel, M.D., President and Chief Executive Officer at Sunovion. "The Health Canada approval of KYNMOBI provides healthcare providers and people living with Parkinson's disease with a novel treatment option that allows a quick and reliable transition from OFF to ON so they can more easily function in their daily lives."

Sunovion is working to make KYNMOBI available in pharmacies across the Canadian provinces as quickly as possible.

ABOUT KYNMOBI™

KYNMOBI (apomorphine hydrochloride) soluble 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. Clinical development of this medicine began in Canada. KYNMOBI is now approved in Canada and the U.S.

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™ is used, as needed, to treat OFF episodes in adults with Parkinson's disease. An OFF episode is when your Parkinson's movement symptoms (e.g., tremor, slowness, stiffness and difficulty moving) are unexpectedly not controlled by your regular Parkinson's medication. KYNMOBI is for use with other drugs to treat Parkinson's disease and does not replace the other drugs prescribed by your doctor to treat your Parkinson's symptoms.

IMPORTANT SAFETY INFORMATION FOR KYNMOBI (apomorphine hydrochloride) SOLUBLE FILM

Serious Warnings and Precautions

You can suddenly fall asleep without any warning while taking KYNMOBI. You should not:

- **Drive**
- **Use machines, or**
- **Take part in activities that require you to be alert**

You may put yourself and others at risk for serious injury or death.

If this happens to you, contact your doctor right away.

Falling asleep suddenly without warning has been reported in patients taking other similar drugs to treat Parkinson's disease.

Do not use KYNMOBI if you:

- Are allergic to apomorphine hydrochloride or to any of the ingredients in KYNMOBI. KYNMOBI contains a sulfite called sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions and asthma attacks in some people. If you have an allergic reaction to KYNMOBI you should not take it again.
- Are taking certain drugs used to treat nausea or vomiting such as ondansetron, granisetron and palonosetron. You could have very low blood pressure and loss of consciousness if you take KYNMOBI and these drugs.
- Have severe liver or kidney disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KYNMOBI. Talk about any health conditions or problems you may have, including if you:

- Have difficulty staying awake during the daytime
- Have suspicious, undiagnosed changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes or a history of skin cancer (melanoma)
- Have dizziness
- Have fainting spells
- Have asthma
- Have a history of fibrosis
- Are allergic to any medicines containing sulfites
- Have severe uncontrolled involuntary movements that can look like fidgeting, writhing or swaying called dyskinesia
- Have liver or kidney problems
- Have any unusual conditions related to your eyes or eyesight
- Have had a stroke or other brain problems
- Have any mental disorders or have seen or heard things that are not there (hallucinations)
- Drink alcohol
- Are pregnant or plan to become pregnant. It is not known if KYNMOBI will harm your unborn baby. KYNMOBI should not be used if you are pregnant.
- 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. You should not do both.

Other warnings you should know about:

- KYNMOBI can cause problems with your heart rhythm called QTc prolongation. You may have no symptoms or you may have dizziness, feeling like your heart has skipped or added a beat, fainting or seizures. If these symptoms continue, they can lead to sudden death. You may be more at risk if you have had or have:
  - a heart attack
  - congestive heart failure
  - an irregular heartbeat or heart rhythm
  - a blockage in one or more of your arteries that affects blood flow to your heart
  - an abnormally rapid heart rate
  - heart palpitations (feeling like your heart has skipped a beat or added an extra beat)
  - a family history of sudden cardiac death at less than 50 years of age
  - problems of electrocardiogram (ECG) abnormality called "Long QT syndrome"
  - diabetes
  - imbalances in the electrolytes in your body (potassium, magnesium and calcium)
- KYNMOBI may cause low blood pressure at any time or when you go from sitting or lying down to standing. Your blood pressure may be monitored while you are taking KYNMOBI especially if you are taking medication for high blood pressure, if you have a history of low blood pressure or if you have any heart problems.
- KYNMOBI can cause neuroleptic malignant syndrome. This is a disorder that causes you to have a high fever, confusion, altered states and stiffness in your muscles.
- When reducing your dose of KYNMOBI or stopping treatment, you may have withdrawal symptoms. These include lack of interest, anxiety, depression, fatigue, sweating, panic attacks, insomnia, irritability and pain.
- While taking KYNMOBI, you may have unusual urges and/or behaviors such as excessive:
  - gambling
  - sexual behavior
  - eating
  - spending

  You or your caregiver should tell the doctor if either of you notice that you have new or changes to your behavior.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with KYNMOBI:

- Other medicines used to treat Parkinson's disease, including levodopa
- Drugs used to treat nausea or vomiting called 5HT3 antagonists such as ondansetron, granisetron and palonosetron
- Alcohol. You should avoid alcohol when using KYNMOBI. It can worsen your side effects.
- Drugs to lower your blood pressure such as antihypertensive drugs or vasodilators
- Drugs that can affect the levels of electrolytes (salts) in your body
- Certain drugs that have an effect on your heart rate
- Nitroglycerin, a drug used to improve blood flow. It may decrease your blood pressure and cause dizziness. You should lie down before and after taking nitroglycerin under your tongue.

KYNMOBI can cause serious side effects, including:

- Oral irritation: redness, numbness, swelling, infection, ulceration, pain or dryness of mouth, lips or tongue
- Falls and injuries from falling

- Dyskinesia: severe uncontrolled movements
- Syncope: fainting when standing up
- Low blood pressure: dizziness, fainting, light-headedness when rising to a sitting or standing position.
- Hallucinations or psychotic-like behavior: seeing or hearing things that are not real, confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs and disorganized thinking
- Allergic reaction: hives, itching, rash, swelling of the face, lips, mouth, tongue or throat, trouble breathing and/or swallowing
- Compulsive behavior: inability to resist the impulse to perform an action that could be harmful such as gambling too much, increased sexual urges, uncontrollable urge to eat or spend money, or repeating meaningless actions
- Uneven (irregular) heart beat, palpitation, chest pain and/or discomfort, pain in jaw, shoulders, arm and/or back, shortness of breath, sweating, nausea or lightheadedness
- Neuroleptic Malignant Syndrome: high fever, confusion, altered states and stiffness in your muscles
- Skin cancer (melanoma): changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes
- Priapism: prolonged painful erection
- Excessive sleepiness or falling asleep while doing normal activities

Common side effects of KYNMOBI include:

- Nausea
- Vomiting
- Dizziness
- Dry mouth
- Fatigue
- Yawning
- Sleepiness
- Runny nose
- Increased sweating
- Headache
- Chills

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

For more information, please see the KYNMOBI Patient Information and full Prescribing Information.

About Parkinson's Disease and OFF Episodes

An estimated 94,000 Canadians are living with Parkinson's disease (PD), and this is expected to increase by an estimated 50 percent by 2031.[1] PD is a chronic, progressive neurodegenerative disease characterized, in part, 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,[4] 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 and may be burdensome for patients, family and care partners. 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.[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 Canada Inc., based in Mississauga, Ontario, and Sunovion Pharmaceuticals Europe Ltd., based in London, England, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's websites: www.sunovion.com, www.sunovion.ca and www.sunovion.eu. 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.

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

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