FDA News Release

FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder

Agency encourages safe adoption and more widespread use of FDA-approved treatments to help combat opioid addiction

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For Immediate Release

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Summary

FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for moderate-to-severe opioid use disorder

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Release

The U.S. Food and Drug Administration today approved Sublocade, the first once-monthly injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder (OUD) in adult patients who have initiated treatment with a transmucosal (absorbed through mucus membrane) buprenorphine-containing product. It is indicated for patients that have been on a stable dose of buprenorphine treatment for a minimum of seven days.

Buprenorphine for the treatment of OUD is currently approved to administer as a tablet or film that dissolves in the mouth, or as an implant. Sublocade provides a new treatment option for patients in recovery who may value the benefits of a once-monthly injection compared to other forms of buprenorphine, such as reducing the burden of taking medication daily as prescribed (medical adherence). An independent **FDA advisory committee supported the approval (/AdvisoryCommittees/Calendar/ucm578548.htm)** of Sublocade at a meeting held last month.

"Given the scale of the opioid crisis, with millions of Americans already affected, the FDA is committed to expanding access to treatments that can help people pursue lives of sobriety. Everyone who seeks treatment for opioid use disorder deserves the opportunity to be offered the treatment best suited to the needs of each individual patient, in combination with counseling and psychosocial support, as part of a comprehensive recovery plan," said FDA Commissioner Scott Gottlieb, M.D. "As part of our ongoing work in supporting the treatment of those suffering from

addiction to opioids, the FDA plans to issue guidance to expedite the development of new addiction treatment options. We'll continue to pursue efforts to promote more widespread use of existing, safe and effective FDA-approved therapies to treat addiction."

Improving access to prevention, treatment and recovery services, including the full range of medication-assisted treatments (MAT), is a focus of the FDA's ongoing work to reduce the scope of the opioid crisis and one part of the **U.S. Department of Health and Human Services' Five-Point Strategy to Combat the Opioid Crisis (https://www.hhs.gov/opioids/index.html)**.

OUD is the diagnostic term used for a chronic neurobiological disease characterized by a problematic pattern of opioid use leading to significant impairment or distress and includes signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, the opioid is used in doses far greater than the amount needed for treatment of that medical condition.

MAT is a comprehensive approach that combines approved medications (currently, methadone, buprenorphine or naltrexone) with counseling and other behavioral therapies to treat patients with OUD. Regular adherence to MAT with buprenorphine reduces opioid withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making continued opioid abuse less attractive. According to the Substance Abuse and Mental Health Services Administration, patients receiving MAT for their OUD cut their risk of death from all causes in half.

Sublocade should be used as part of a complete treatment program that includes counseling and psychosocial support. Sublocade is a drug-device combination product that utilizes buprenorphine and the Atrigel Delivery System in a pre-filled syringe. It is injected by a health care professional (HCP) under the skin (subcutaneously) as a solution, and the delivery system forms a solid deposit, or depot, containing buprenorphine. After initial formation of the depot, buprenorphine is released by the breakdown (biodegradation) of the depot. In clinical trials, Sublocade provided sustained therapeutic plasma levels of buprenorphine over the one-month dosing interval.

The safety and efficacy of Sublocade were evaluated in two clinical studies (one randomized controlled clinical trial and one open-label clinical trial) of 848 adults with a diagnosis of moderate-to-severe OUD who began treatment with buprenorphine/naloxone sublingual film (absorbed under the tongue). Once the dose was determined stable, patients were given Sublocade by injection. A response to MAT was measured by urine drug screening and self-reporting of illicit opioid use during the six-month treatment period. Results indicated that Sublocade-treated patients had more weeks without positive urine tests or self-reports of opioid use, and a higher proportion of patients had no evidence of illicit opioid use throughout the treatment period, compared to the placebo group.

The most common side effects from treatment with Sublocade include constipation, nausea, vomiting, headache, drowsiness, injection site pain, itching (pruritus) at the injection site and abnormal liver function tests. The safety and efficacy of Sublocade have not been established in children or adolescents less than 17 years of age. Clinical studies of Sublocade did not include participants over the age of 65.

The FDA is requiring postmarketing studies to assess which patients would benefit from a higher dosing regimen, to determine whether Sublocade can be safely initiated without a dose stabilization period of sublingual buprenorphine, to assess the feasibility of administering Sublocade at a longer inter-dose interval than once-monthly and to determine a process for transitioning patients with long-term stability on a transmucosal buprenorphine dose to a monthly dose of Sublocade without the use of a higher dose for the first two months of treatment (loading dose).

Sublocade has a boxed warning that provides important safety information, including the risks of intravenous self-administration. If the product were to be administered intravenously rather than subcutaneously, the solid mass could cause occlusion (blockage), tissue damage or embolus (solid material that is carried in the blood and can become lodged in a blood vessel, which can lead to death). Sublocade must be prescribed and dispensed as part of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the product is not distributed directly to patients. Sublocade will be provided to HCPs through a restricted program, administered only by HCPs in a health care setting, and will require health care settings and pharmacies that dispense Sublocade to complete an enrollment form attesting that they have procedures in place to ensure that Sublocade is dispensed only to HCPs and not directly to patients.

The FDA granted this application **Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm)** and **Fast Track (/ForPatients/Approvals/Fast/ucm405399.htm)** designations.

The FDA granted the approval of Sublocade to Indivior Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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