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Indivior PLC
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Indivior Announces FDA Approval of Label Changes for SUBLOCADE® (buprenorphine extended-release) Injection

Rapid Initiation Protocol Reduces Time to Treatment with SUBLOCADE® From One Week to One Hour, A Significant Advancement in the Treatment of Moderate to Severe Opioid Use Disorder (OUD)

Richmond, VA, February 24, 2025 - Indivior PLC (Nasdaq/LSE: INDV), a global leader in addiction treatment, today announced that the U.S. Food and Drug Administration (FDA) has approved label changes for SUBLOCADE® including a rapid initiation protocol and alternative injection sites, marking a significant advancement in the treatment of moderate to severe opioid use disorder (OUD).

Key Label Changes Include:

- **Rapid initiation Protocol:** Healthcare providers can now initiate treatment with SUBLOCADE after a single dose of transmucosal buprenorphine and a one-hour observation period to confirm tolerability.[1,2]
- **Alternative Injection Sites:** SUBLOCADE can now be administered subcutaneously in the abdomen, thigh, buttock, or back of the upper arm, offering patients and healthcare providers increased flexibility in treatment administration[2].

These FDA label changes can provide important benefits for patients and healthcare providers. Rapid initiation may lessen some of the practical obstacles to treatment induction, which may increase the likelihood that patients and providers will start therapy quickly, thereby shortening the time to achieve SUBLOCADE's therapeutic levels that provide continuous buprenorphine concentrations above 2ng/mL.[3]

Additionally, the ability to select a different injection site may provide patients more flexibility so that they may be inclined to continue their treatment. More options for healthcare providers to administer SUBLOCADE will streamline the course of treatment and improve integration into different healthcare environments.

"These label updates for SUBLOCADE underscore our dedication to evolving our treatment options to better serve individuals battling opioid use disorder," said Dr. Christian Heidbreder, Ph.D., Chief Scientific Officer at Indivior. "These enhancements not only reflect our commitment to patient-centered care but also our ongoing efforts to align our treatments with real-world clinical needs, thereby potentially improving patient adherence and outcomes."

Indivior is committed to empowering patients on their path to recovery by providing treatments that are both effective and tailored to their medical needs. These label changes do not alter the well-established safety profile or the efficacy of SUBLOCADE and the medication continues to offer an effective treatment option for OUD while being more adaptable to patient medical needs.

The non-inferiority study supporting rapid induction with SUBLOCADE was conducted across multiple sites, included 729 participants (mean age 40.7, average opioid use of 15 years)[1,] and was stratified by fentanyl presence in urine screens. At induction 77.5% of patients were fentanyl-positive. Patients were randomized at a 2:1 ratio to rapid initiation [received a single dose of 4 mg transmucosal buprenorphine (TM-BUP), followed by a SUBLOCADE injection within one hour] or to a standard induction (daily TM-BUP over ≥7 days) before receiving injection 1. Rapid induction was effective, shown by the primary endpoint of participant retention at the second injection. The proportion of participants who received the second injection was 66.4% in the rapid induction arm and 54.5% in the standard induction arm[2].

About SUBLOCADE®

SUBLOCADE ® (buprenorphine extended-release) injection, for subcutaneous use, CIII

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

INDICATION

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

HIGHLIGHTED SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life-threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program call the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

CONTRAINDICATIONS

Hypersensitivity to buprenorphine or any other ingredients in SUBLOCADE.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Respiratory Depression: Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

Risk of Serious Injection Site Reactions: Likelihood of may increase with inadvertent intramuscular or intradermal administration. Evaluate and treat as appropriate. The most common injection site reactions are pain, erythema and pruritus with some involving abscess, ulceration and necrosis.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risk of Opioid Withdrawal with Abrupt Discontinuation:If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to and during treatment.

Risk of Withdrawal in Patients Dependent on Full Agonist Opioids:Verify that patients have tolerated transmucosal buprenorphine before injecting SUBLOCADE.

Treatment of Emergent Acute Pain:Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

For more information about SUBLOCADE, the full Prescribing information including BOXED WARNING, and Medication Guide, visit www.sublocade.com.

About Opioid Use Disorder (OUD)

Opioid Use Disorder (OUD) is a chronic disease in which people develop a pattern of using opioids that can lead to negative consequences.[4] OUD may affect the parts of the brain that are necessary for life-sustaining functions.[4]

About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat substance use disorders (SUD). Our vision is that all patients around the world will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of SUD. Indivior is dedicated to transforming SUD from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of OUD treatments, Indivior has a pipeline of product candidates designed to expand on its heritage in this category. Headquartered in the United States in Richmond, VA, Indivior employs over 1,000 individuals globally and its portfolio of products is available in over 30 countries worldwide. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/indivior.

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References

1. Data on File. Indivior Inc. North Chesterfield, VA.

2. SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use [package insert]. North Chesterfield, VA: Indivior PLC; 2025.

3. Jones AK, Ngaimisi E, Gopalakrishnan M, Young MA, Laffont CM. Population Pharmacokinetics of a Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder: A Combined Analysis of Phase II and Phase III Trials. *Clin Pharmacokinet.* 2021;60(4):527-540. doi:10.1007/s40262-020-00957-0.

4. NIDA. 2022,March 22. Drugs and the Brain. AccessedOctober 30,2023, from https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drugs-brain

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