New Study Shows Extended-Release Buprenorphine Safely Delivers Rapid, Clinically Meaningful Reductions in Opioid Use and Supports Abstinence in High-Risk Populations

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- *Both monthly maintenance doses (100 mg and 300 mg) improved opioid abstinence and were well-tolerated with no new safety signals identified.*
- *Post-hoc analyses indicated the 300-mg monthly maintenance dose performed significantly better than the 100-mg monthly dose in participants reporting high-frequency fentanyl use.*

RICHMOND, Va., Dec. 17, 2025 /PRNewswire/ -- Indivior PLC (Nasdaq: INDV) today announced results from a randomized, double-blind clinical trial published in *JAMA Network Open.* The study found that both the 100-mg and 300-mg monthly maintenance doses of SUBLOCADE® (extended-release buprenorphine) rapidly reduced opioid use and improved opioid abstinence and were well tolerated, with no new safety signals in individuals with moderate-to-severe opioid use disorder (OUD). Participants across both dose groups experienced a rapid reduction in opioid use—from more than 43 instances per week at screening to fewer than three instances per week by week three—a decline maintained through week 38.

Post-hoc analyses also identified a subset of individuals who may benefit from the higher 300-mg maintenance dose of extended-release buprenorphine. Participants who used fentanyl daily and/or 14 or more times per week had significantly higher opioid abstinence rates with 300-mg dose compared to 100 mg, suggesting a population that may potentially benefit from the higher maintenance dose regimen.

"These findings offer evidence to consider for clinicians navigating the complexities of OUD in the fentanyl era," said Christian Heidbreder, Ph.D., Chief Scientific Officer at Indivior. "By demonstrating that extended-release buprenorphine improves abstinence, even among those with high-frequency fentanyl use, we underscore the need for treatment approaches that adapt to the realities of today's opioid crisis and give patients the best chance at recovery."

Injection-site reactions were more common in the 300-mg arm but were mild to moderate and were not associated with discontinuation. Study limitations include the exploratory nature of the post-hoc analyses, which were not pre-specified in the trial's statistical analysis plan.

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. OUD may affect the parts of the brain that are necessary for life-sustaining functions.

About Indivior
Indivior Pharmaceuticals works to help change patients' lives by developing medicines to treat opioid use disorder (OUD). Our vision is that all patients will have access to evidence-based treatment for OUD, and we are dedicated to transforming OUD from a human crisis to a recognized and treated chronic disease. Building on its portfolio of OUD treatments, Indivior has a pipeline of product candidates designed to expand on its heritage in this category. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/Indivior.

View original content to download multimedia:https://www.prnewswire.com/news-releases/new-study-shows-extended-release-buprenorphine-safely-delivers-rapid-clinically-meaningful-reductions-in-opioid-use-and-supports-abstinence-in-high-risk-populations-302644924.html

SOURCE Indivior PLC

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