Indivior Presents New Integrated Analysis Evaluating Long-Term Benefits of SUBLOCADE® (buprenorphine-extended release) Injection

April 1, 2022

Treatment with buprenorphine extended-release injections beyond six months provides additional improvement in opioid abstinence

Data presented at American Society of Addiction Medicine (ASAM) 2022 Annual Meeting

Richmond, VA – Indivior PLC (LON: INDV) today presented an integrated analysis of three clinical Phase III studies evaluating the additional benefits of long-term treatment with SUBLOCADE® (buprenorphine extended-release) injections for up to 18 months in treatment-seeking adults with moderate or severe opioid use disorder (OUD).[1] The data will be presented at the American Society of Addiction Medicine (ASAM) 2022 Annual Meeting, taking place from March 31st to April 3rd, 2022.

The Phase III program enrolled 787 participants, who received up to 18 monthly SUBLOCADE subcutaneous injections.[1] The continued use of treatment beyond six months provided additional improvement in opioid abstinence for patients with less favorable early treatment response, while the incidence of treatment-emergent adverse events (TEAEs) decreased over time. The analysis showed that 36% of the early non-responders and 72% of the intermediate response subgroup had their on-treatment percentage of abstinence improved to >50% during months 7-18.[1]

"Furthering our scientific understanding of the long-term impact of treatment for patients with opioid use disorder is critical to building a more effective care model that helps people stay on the recovery pathway," said Christian Heidbreder, PhD, Chief Scientific Officer, Indivior.

The analysis was performed on data from three subgroups derived from participants' percentage of abstinence (defined as the proportion (%) of negative urine drug screen (UDS)) during the first six months of SUBLOCADE treatment:

1. Early non-responders: ≤20% negative UDS (n=178, 23%)

2. Intermediate responders: <20% to ≤50% negative UDS (n=103, 13%)

3. Early responders: >50% negative UDS (n=506, 64%)

Early non-responders showed a delayed response after the sixth injection; the proportion of participants with negative UDS was 16% at the end of month six, but continuously improved to 73% by the end of 18 months. Among early responders, 96% of participants retained their percentage of abstinence >50% for months 7-18.[1]

For all subgroups, the incidence of TEAEs decreased in months 7-18 when compared to those receiving treatment in months 1-6.[1] Overall, the combined efficacy and safety profiles support the clinical benefit of long-term treatment.[1]

About SUBLOCADE®[2]

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

INDICATION

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

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 called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REM requirements.**

Prescription use of this product is limited under the Drug Addiction Treatment Act.

CONTRAINDICATIONS

SUBLOCADE should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system.

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.

Opioids can cause sleep-related breathing disorders e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at SUBLOCADE initiation or renewal because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and how to treat with naloxone if prescribed.

Risk of Serious Injection Site Reactions: The most common injection site reactions are pain, erythema and pruritis with some involving abscess, ulceration, and necrosis. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome 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 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 patient is clinically stable on 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.[3] OUD may affect the parts of the brain that are necessary for life-sustaining functions.[3]

About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat substance use disorders (SUD) and serious mental illnesses. 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 both expand on its heritage in this category and potentially address other chronic conditions and co-occurring disorders of SUD, including alcohol use disorder and cannabis use disorder. Headquartered in the United States in Richmond, VA, Indivior employs more than 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/indivior

Media Contacts:

UK

Tulchan Communications

+44 207-353-4200

US

IndiviorMediaContacts@indivior.com

+1 804-594-0836

Investor Contact:

Jason Thompson

Vice President, Investor Relations

Indivior PLC (LON: INDV)

Mobile: 804-402-7123

References:

1. Rutrick, D. et al. (2022). Long-Term Treatment Benefit of BUP-XR for Patients Struggling to Abstain from Opioids. Presented at American Society of Addiction Medicine (ASAM) 2022 Annual Meeting

2. SUBLOCADE® [Prescribing Information]. Indivior Inc., North Chesterfield, VA. June 2021.

3. U.S. Department of Health and Human Services (HHS), National Institute on Drug Abuse, National Institutes of Health. Drugs, Brains, and Behavior: The Science of Addiction. HHS Publication No. (SMA) 18-5063PT5, Printed 2018.