



Patient-Reported Outcomes Data on SUBLOCADE™ (Buprenorphine Extended-Release) Injection to be Presented as Late-Breaker at American Society of Addiction Medicine (ASAM) 49th Annual Conference

Data Show High Medication Satisfaction and Positive Health Outcomes in People with Moderate to Severe Opioid Use Disorder¹

Slough, UK and Richmond, VA, 13 April 2018 – Indivior PLC (LON: INDV) today announced the presentation of results from RB-US-13-0003, a study which evaluated long-term treatment with once-monthly SUBLOCADE™ (buprenorphine extended-release) injection for subcutaneous use (CIII) and individualized drug counseling (IDC) for patients with moderate to severe opioid use disorder (OUD)¹. Patient-reported outcomes, including health-related quality of life (HRQoL), that were collected as part of this clinical study will be presented as a late-breaking poster at the American Society of Addiction Medicine (ASAM) 49th Annual Conference, taking place in San Diego, CA, on April 12-15, 2018. Results showed that, in general, patients with moderate to severe OUD who were treated with SUBLOCADE demonstrated improved patient-reported health outcomes that were sustained during the study period¹. Patients in the study also reported a high level of medication satisfaction with SUBLOCADE, as measured by the Medication Satisfaction Questionnaire (MSQ)¹.

“We are proud to be one of the first companies to study and present patient-reported, health-related quality of life outcomes for medication-assisted treatment of opioid use disorder. These findings provide important insights from a patient perspective that may inform clinical decision making for this population,” said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior. “Part of our pioneering approach to developing treatments is working to increase our understanding of the impact of our medicines on patients, beyond the clinical efficacy and safety data.”

The late-breaking poster, entitled “Impact of RBP-6000 (Once-Monthly Depot Buprenorphine) on Patient-Reported Outcomes: A Long-Term Study,” will be presented on Friday, April 13, from 12:15 pm - 2:00 pm PDT, and Saturday, April 14, from 10:00 am - 11:30 am PDT.

“Addressing opioid use disorder is about more than abstinence from substance abuse. As a clinician, I also speak with my patients about having a job, health insurance and their relationships with family, as these are important factors for reengaging with society,” said Walter Ling, M.D., Professor Emeritus of Psychiatry and Founding Director of the Integrated Substance Abuse Programs (ISAP), University of California, Los Angeles, and lead author. “The study showed that patients seeking medication who received SUBLOCADE for up to 12 months were satisfied with the medication and reported positive recovery-related outcomes¹. The Treatment Effectiveness Assessment showed that patients in the de novo cohort reported a steady improvement in substance abuse, health, lifestyle and community outcomes¹.”

About the Study

RB-US-13-0003 was a multicenter, open-label, long-term safety and tolerability study of SUBLOCADE in medication-assisted treatment (MAT)-seeking adults who met the Diagnostic and Statistical Manual of

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Mental Disorders, 5th Edition (DSM-5) criteria for moderate to severe OUD for three or more months prior to enrollment (n=669)¹. The study evaluated patient-reported outcomes, including: health status, HRQoL, treatment effectiveness, addiction severity, employment/insurance status and medication satisfaction¹. For this analysis, the study population included patients who were newly initiated into the study and received 12 months of treatment (de novo cohort [n=412]) and patients from a Phase 3, multicenter, 24-week, randomized, double-blind, placebo-controlled study of SUBLOCADE (RB-US-13-0001) who received six months of treatment (roll-over SUBLOCADE [n=225] and roll-over placebo [n=32] cohorts)^{1,2,3}.

Study treatment included a run-in period where all patients underwent induction (three days) and dose stabilization (up to 11 days) with transmucosal buprenorphine¹. The run-in period was followed by 12 (de novo) or six (roll-over) monthly injections of SUBLOCADE¹. After the first SUBLOCADE 300 mg injection was administered, subsequent monthly SUBLOCADE doses were 100 mg or 300 mg based on investigator judgment¹. Patients received IDC throughout the study¹. All patients who received at least one dose of SUBLOCADE and completed at least one patient-reported outcome assessment were included in these analyses¹.

Patients in the de novo cohort demonstrated sustained improvements from baseline in patient-reported outcomes, including mental health, drug use, employment and family/social status when treated with SUBLOCADE during the study¹. Patients in the roll-over SUBLOCADE cohort reported sustained or improved outcomes during the additional six months of treatment in this study, including statistically significant improvements from baseline in medical status, drug use, family/social status and psychiatric status¹. Patient-reported outcomes in the roll-over placebo cohort remained stable¹. Changes in patient-reported outcomes in the de novo cohort mirrored those in the roll-over SUBLOCADE cohort, where improvements in the first six months of treatment (in the RB-US-13-0001 study) were followed by sustained outcomes with an additional six months of treatment (in the present study)^{1,2,3}.

More information about this study can be found online on the ASAM website [here](#).

About SUBLOCADE™

SUBLOCADE is approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe OUD in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days⁴. It should be administered only by healthcare providers and should be used as part of a complete treatment program that includes counseling and psychosocial support⁴. The overall safety profile for SUBLOCADE, given by a healthcare provider in clinical trials, was consistent with the known safety profile of transmucosal buprenorphine, except for injection site reactions⁴. Common adverse reactions associated with buprenorphine included constipation, nausea, vomiting, abnormal liver enzymes, headache, sedation and somnolence⁴. Injection site reactions were reported in 16.5 percent of patients in Phase 3 studies⁴. Most of the injection site adverse reactions (ADRs) were of mild to moderate severity⁴. None of the injection site reactions were serious and one led to study treatment discontinuation⁴.

SUBLOCADE has a BOXED WARNING and is available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program⁴. Pursuant to the SUBLOCADE REMS, all healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified and establish processes and procedures to verify the medication is dispensed directly to a healthcare provider for administration by a healthcare provider and is not dispensed directly to the patient⁴.

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Moreover, certified healthcare settings and pharmacies must not distribute, transfer, loan or sell SUBLOCADE⁴.

INDICATION AND USAGE

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 a dose adjustment period for a minimum of seven days.

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

IMPORTANT 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 bodily 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 REMS 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.

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 of the opioid.

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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.

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About Opioid Use Disorder (OUD)

Opioid use disorder (OUD), sometimes referred to as opioid addiction, is a chronic disease⁴. According to DSM-5, “OUD is characterized by signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, they are used in doses greatly in excess of the amount needed for that medical condition⁵.”

Based on 2016 data from the National Survey on Drug Use and Health report, approximately 11.8 million Americans (age 12+ years) engaged in misuse of opioids in the past year⁶. From 1999 to 2016, the rate of deadly prescription opioid overdoses increased five-fold⁷. In 2016, an average of 115 people died of opioid overdose each day in the United States⁸. In addition, in 2016, 935,000 adults used heroin and approximately 625,000 adults had a heroin use disorder⁶. In 2015, opioids accounted for 70 percent of the disease burden associated with drug use disorders worldwide⁹.

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. Our vision is for all patients around the world to have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. The name is the fusion of the words individual and endeavor, and the tagline “Focus on you” makes the Company’s commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA, Indivior employs more than 1,000 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

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Forward-Looking Statements

This press release contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that will or may occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding our financial guidance for 2018 and our medium- and long-term growth outlook, our operational goals, our product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

This press release does not constitute an offer to sell or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

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