Indivior Publishes Design and Patient Characteristics for Real-World Study of Life Changes in People Treated with SUBLOCADE™ (Buprenorphine Extended-Release) in *Contemporary Clinical Trials*

RECOVER study designed to understand the long-term clinical, environmental and socio-economic outcomes of SUBLOCADE treated individuals

Slough, UK and Richmond, VA, 20 December 2018 – Indivior PLC (LON: INDV) today announced the publication of the study design and participant characteristics of the RECOVER (Remission from Chronic Opioid Use-Studying Environmental and Socio-Economic Factors on Recovery) study in *Contemporary Clinical Trials*. This multisite, longitudinal observational study measures life changes, such as quality of life and employment, in people with moderate to severe opioid use disorder (OUD) for up to 24 months following participation in a Phase 3 trial evaluating treatment with once-monthly SUBLOCADE™ (buprenorphine extended-release) injection for subcutaneous use (CIII) in combination with counseling[1].

"Real-world studies like RECOVER present an important opportunity to better understand recovery in opioid use disorder, how it evolves and the role of medications such as SUBLOCADE," 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 study author. "In treating moderate to severe opioid use disorder, we believe there is an opportunity to drive change in not only traditional outcomes, such as treatment retention and abstinence from opioids, but also important patient-centered outcomes, such as family relationships, integration to the community, healthcare costs, crime and employment. This study is designed to help us assess these life changes outside of the clinic."

The opioid epidemic in the United States is a public health crisis that has grown[2]. In fact, in 2016, an average of 115 people died of opioid overdose each day – a number that is five times higher than it was in 1999[3, 4]. Addiction can have a devastating personal and societal impact for the affected individuals, families and communities – it doesn't discriminate, and it influences people from all walks of life[5,6]. Beyond medical treatment, patients in treatment and their families require support from community services and employers to promote a healthy environment for recovery[7].

"Quality care of patients suffering from opioid use disorder requires the generation of data that not only address the clinical efficacy and safety of a treatment, but also helps increase the understanding of how patients are pursuing the life changes they aspire to achieve, which is what true recovery is all about," said Dr. Christian Heidbreder, Chief Scientific Officer, Indivior, Inc. "We believe that the RECOVER study, which actively engages patients in their real-world environment, will contribute to a better understanding of how patients are navigating through their pathway towards recovery, ultimately providing a more comprehensive approach to the treatment of opioid use disorder and breaking down barriers and misconceptions about this disease."

More information about the study design can be found in the online publication of *Contemporary Clinical Trials* and the full data will be published at a future date.

About the Study

The RECOVER (Remission from Chronic Opioid Use-Studying Environmental and Socio-Economic Factors on Recovery) Study is a multisite, non-interventional cohort study examining long-term recovery in individuals with moderate to severe OUD who received at least one dose of study treatment during the Phase 3 clinical trials (NCT02357901 and NCT02510014) for SUBLOCADE[1]. Results are being analyzed to understand the clinical, socio-economic and environmental factors associated with continuous effects of medication-assisted treatment (MAT) after a clinical trial[1].

Participants (n=533) who were enrolled in the SUBLOCADE Phase 3 trials joined the RECOVER study after 28 days of completing or terminating participation[1]. Demographics and psychosocial characteristics of the RECOVER participants were compared with those of a subset of respondents to the 2015 National Survey on Drug Use and Health (NSDUH) in order to understand how this group generalizes to the population of individuals with OUD in the United States[1].

The RECOVER study uses data from three main sources: self-administered assessments from enrolled individuals, urine drug screens (UDS) and data collected from several public sources[1]. Recovery is examined over 24 months – the self-administered assessment and UDS results are completed by participants every three months over the course of this period[1].

Linking the clinical trial data with real-world, post-trial observational data provides a holistic view of both short- and long-term outcomes. RECOVER's length of follow-up and frequency of assessments present a unique opportunity to study how recovery evolves in several ways, such as stability of the treatment effect, factors related to relapse and the role of ongoing treatments sought in the community[1]. These data will support analysis of the societal effect of recovery progress made among individuals affected by OUD, in terms of costs of healthcare use, crime and employment[1]. Looking forward, future analyses of RECOVER data will include longitudinal investigations of clinical, environmental and socio-economic outcomes characterizing patient recovery.

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 days[8]. It should be administered only by healthcare providers and should be used as part of a complete treatment program that includes counseling and psychosocial support[8]. 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 reactions[8]. Common adverse reactions associated with buprenorphine included constipation, nausea, vomiting, abnormal liver enzymes, headache, sedation and somnolence[8]. Injection site reactions were reported in 16.5 percent of patients in Phase 3 studies[8]. Most of the injection site adverse reactions (ADRs) were of mild to moderate severity[8]. None of the injection site reactions were serious and one led to study treatment discontinuation[8].

SUBLOCADE has a BOXED WARNING and is available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program[8]. 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 patient[8]. Moreover, certified healthcare settings and pharmacies must not distribute, transfer, loan or sell SUBLOCADE[8].

For further product information, see full Prescribing Information including BOXED WARNING and Medication Guide at www.SUBLOCADE.com.

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.

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.

About Opioid Use Disorder (OUD)

Opioid use disorder (OUD), sometimes referred to as opioid addiction, is a chronic disease[8]. 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 condition[9]."

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 year[10]. From 1999 to 2016, the rate of deadly prescription opioid overdoses increased five-fold[4]. In 2016, an average of 115 people died of opioid overdose each day in the United States[3]. In addition, in 2016, 935,000 adults used heroin and approximately 625,000 adults had a heroin use disorder[10]. In 2015, opioids accounted for 70 percent of the disease burden associated with drug use disorders worldwide[5].

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 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

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 harbor 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 may or may not 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 the Indivior Group's financial guidance for 2018 and its medium- and long-term growth outlook, its operational goals, its 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, including the ongoing investigative and antitrust litigation matters; 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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