



## Virginia Tech and Indivior Announce New Collaboration to Study Long-Term Recovery in People with Opioid Use Disorder



*The RECOVER™ study is assessing real-world, patient-centered outcomes including abstinence from illicit opioids and life changes, such as improved health, employment status and connection to community following treatment with SUBLOCADE™ (Buprenorphine Extended-Release) Injection.*

**Slough, UK and Richmond, VA, 10 December 2019**– Indivior PLC (LON: INDV) today announced a new research collaboration with Virginia Tech extending the RECOVER (Remission from Chronic Opioid Use-Studying Environmental and Socio-Economic Factors on Recovery) Study™. RECOVER is a multisite, non-interventional cohort study examining long-term recovery in individuals with moderate to severe opioid use disorder who received at least one dose of study treatment during the SUBLOCADE Phase 3 clinical trials (NCT02357901 and NCT02510014).<sup>1</sup> The study design and participant characteristics of the RECOVER study can be found in Contemporary Clinical Trials.<sup>2</sup> This study will be led by a team of researchers at the Fralin Biomedical Research Institute at Virginia Tech Carilion.

“The Virginia Tech-Indivior study is a powerful example of how academia and industry can collaborate to address a major health care problem that is causing tremendous hardship throughout the United States, particularly here in Virginia,” said Michael Friedlander, Vice President for Health Sciences and Technology at Virginia Tech and the Executive Director of the Fralin Biomedical Research Institute. “Together we are determined to find scientifically sound solutions to the opioid crisis.”

The study will be carried out by a team of researchers led by Warren Bickel, a Virginia Tech addiction researcher and professor at the Fralin Biomedical Research Institute.

Researchers hope the extended study may also provide further information to health care systems and policy-makers on how successful treatment and long-term recovery can reduce the economic burden of opioid use disorder. The scope and duration of these assessments may also lead to important new insights into theoretical models of recovery and allow researchers, clinicians, and patients to more accurately characterize the process of recovery, identify factors that promote or hinder success, and develop new and personalized treatment strategies.

“We believe that this Virginia Tech-Indivior study, which will actively engage patients in their real-world environment, will contribute to a better understanding of how patients are able to



pursue the life changes they aspire to achieve, which is what true recovery is all about” said Dr. Christian Heidbreder, Chief Scientific Officer, Indivior, Inc.

### **About SUBLOCADE™**

SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use (CIII) is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who have received an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine at a dose that controls withdrawal symptoms for at least 7 days. SUBLOCADE is part of a complete treatment plan that should include counseling.<sup>3</sup>

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.<sup>3</sup>

Adverse reactions commonly associated with SUBLOCADE (in  $\geq 5\%$  of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue and injection site pain. Injection site reactions were reported in 16.5% of patients in Phase 3 studies.<sup>3</sup> Most of the injection site adverse reactions (ADRs) were of mild to moderate severity.<sup>3</sup> None of the injection site reactions were serious, and one led to study treatment discontinuation.<sup>3</sup> SUBLOCADE has a BOXED WARNING and is available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program.<sup>3</sup> 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.<sup>3</sup> Moreover, certified healthcare settings and pharmacies must not distribute, transfer, loan or sell SUBLOCADE.<sup>3</sup>

### **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

Addition, 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.

For further product information, see full [Prescribing Information](#) including BOXED WARNING and [Medication Guide](#) at [www.SUBLOCADE.com](http://www.SUBLOCADE.com).

## **About Opioid Use Disorder (OUD)**

Opioid addiction isn't a moral weakness. Opioid addiction is a chronic disease called Opioid Use Disorder (OUD)<sup>4</sup> in which people develop a pattern of using opioids that can lead to negative consequences.<sup>5</sup> Opioid addiction may affect the parts of the brain that control impulses, judgment, and decision-making.<sup>5,6</sup> Patients become trapped in a cycle of opioid use, which produces changes in brain function that can reduce their ability to control their use.<sup>5,7</sup>

In 2018, an estimated 10.3 million people aged 12 or older misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. Approximately 506,000 people misused prescription pain relievers and used heroin in the past year.<sup>8</sup> SUBLOCADE is not indicated for use in children younger than 18 years of age. Buprenorphine, the active ingredient of SUBLOCADE can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it.<sup>3</sup>

## **About Indivior**

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat addiction 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 addiction. 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 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. Headquartered in the United States in Richmond, VA, Indivior employs more than 800 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://www.indivior.com) to learn more. Connect with Indivior on LinkedIn by visiting [www.linkedin.com/company/indivior](http://www.linkedin.com/company/indivior).

## **About Virginia Tech**

Dedicated to its motto, Ut Prosim (That I May Serve), Virginia Tech pushes the boundaries of knowledge by taking a hands-on, transdisciplinary approach to preparing scholars to be leaders and problem-solvers.

Since its founding as a land-grant college in 1872, Virginia Tech has grown to an enrollment of 35,000 and is the state's leading research institution. In Northern Virginia, the university is developing a 1 million-square-foot Innovation Campus that will become a global center of talent production and technology excellence. In Roanoke, the Fralin Biomedical Research Institute at VTC and the Virginia Tech Carilion School of Medicine are a part of the VTC Academic Health Center. The main campus is



Blacksburg, Virginia, while the university's international presence is anchored by the Steger Center for International Scholarship in Riva San Vitale, Switzerland.

Virginia Tech conducts more than \$530 million in research annually. The university boasts world-class research institutes and facilities — such as the Smart Road transportation research testbed, and the Cube, a four-story theater and laboratory in the Moss Arts Center.

### **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 2019 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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