SUBLOCADE™ (Buprenorphine Extended-Release) is Now Available as First and Only Monthly Injectable Buprenorphine in the U.S. to Treat Patients with Moderate to Severe Opioid Use Disorder

Indivior launches new support services dedicated to helping streamline the access process on behalf of patients

Slough, UK and Richmond, VA, 1 March 2018 – Indivior PLC (LON: INDV) today announced that SUBLOCADE™ (buprenorphine extended-release) injection, for subcutaneous use (CIII), is now available in the United States. SUBLOCADE is approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe opioid use disorder (OUD) in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of seven days. 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[1].

"We're committed to helping the patients, families and communities impacted by the opioid epidemic, and delivering new treatment options for moderate to severe opioid use disorder," said Richard Simkin, Chief Commercial and Strategy Officer of Indivior. "The availability of SUBLOCADE, with our comprehensive support services, marks a pivotal milestone for our company."

Medication-assisted treatments (MATs) for OUD may reduce the illicit use of opioids. These therapies can be beneficial for blocking the euphoric effects of mu-opioid receptor agonists[2].

The FDA approval of SUBLOCADE was based on data from a 24-week, pivotal double blind, placebo-controlled Phase 3 study (RB-US-13-0001) in which patients (n=504) who met DSM-5 criteria for moderate to severe OUD were randomized to one of three treatment regimens evaluating SUBLOCADE 300 mg, SUBLOCADE 100 mg and placebo, in combination with individualized drug counseling (IDC). Patients were randomized to SUBLOCADE injection or placebo after withdrawal symptoms were clinically controlled following treatment initiation with a transmucosal buprenorphine-containing product. Efficacy was evaluated from weeks 5 through 24 based on weekly urine drug screens combined with self-reported use of illicit opioid use. The proportion of patients achieving treatment success (defined as patients with ≥80% opioid-free weeks) was statistically significantly higher in both groups receiving SUBLOCADE compared to the placebo group (28.4% [300 mg/100 mg], 29.1% [300 mg/300 mg], 2% [placebo])[1].

SUBLOCADE has a BOXED WARNING and will be distributed through a restricted distribution system, to ensure that SUBLOCADE is only administered by a healthcare provider. Serious harm or death could result if SUBLOCADE is 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. SUBLOCADE will only be available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program.
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. Moreover, certified healthcare settings and pharmacies must not distribute, transfer, loan, or sell SUBLOCADE[1].

The systemic safety profile for SUBLOCADE, given by healthcare providers in clinical trials, was consistent with the known safety profile of transmucosal buprenorphine, except for injection site reactions. Common adverse reactions (≥5% patients) included constipation, nausea, vomiting, abnormal liver enzymes, headache, sedation, somnolence and fatigue. Injection site reactions were reported in 16.5% of the patients. None of the injection site reactions were serious and one led to study treatment discontinuation[1].

Understanding that patients often have challenges accessing treatment, Indivior has also launched INSUPPORT™, an interactive service to help streamline the access processes on behalf of patients seeking treatment with all Indivior products. INSUPPORT provides online and telephone resources for both patients and healthcare providers, including a copay assistance program, provider locator tool and information for providers' office staff. For more information on these support services visit www.INSUPPORT.com.

The opioid epidemic in the U.S. is a national public health emergency[3]. Patients going through the treatment journey are often faced with many barriers such as social stigma, access to treatment and prescribers, and difficulty adhering to treatment plans[4].

"Patients struggle with addiction, and with an average of 115 people dying of opioid overdose per day in 2016[5], the need for more treatment options to help address this public health emergency is dire," said Amit Vijapura, M.D., psychiatrist, and a SUBLOCADE principal investigator. "I participated in the clinical trial program for SUBLOCADE, and I am glad SUBLOCADE is now an available option for patients with moderate to severe opioid use disorder."

SUBLOCADE is available through waivered healthcare providers under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of SUBLOCADE in the treatment of opioid dependence is limited to healthcare providers who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription[1].

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

About SUBLOCADE™

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

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

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[1]. 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[6].

Based on 2016 data from the National Survey on Drug Use and Health report, nearly 11.8 million Americans (age 12+ years) engaged in misuse of opioids in the last year[7]. Between 1999 and 2016 the rate of deadly prescription opioid overdoses increased five-fold[8], and in the United States alone, an average of 115 people died of opioid overdose per day in 2016[5]. In 2015 opioids accounted for 70

percent of the disease burden associated with drug use disorders worldwide[9]. In addition, 935,000 adults have used heroin in the past year and 472,000 used in the past month[7]. There were approximately 625,000 adults who had a heroin use disorder in the past year[7].

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 that all patients around the world have access to evidence-based treatment for the chronic condition and co-occurring disorders of addiction. The name is the fusion of the words individual and endeavour, 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 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 2017 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.

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

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