Indivior Presents New Data at the College on Problems of Drug Dependence (CPDD) 2021 Annual Conference

Richmond, VA, June 24, 2021 - Indivior PLC (LON: INDV) announces the presentation of new data from three posters and one late-breaking oral presentation at the College on Problems of Drug Dependence (CPDD) 83rd Annual Scientific *Virtual* Meeting taking place June 21-24, 2021.

Data presented include an assessment of substance use during COVID-19 in a sample of participants in recovery from opioid use disorder (OUD) in the United States, a post-hoc analysis of the efficacy and safety of different maintenance doses of extended-release buprenorphine in participants who used opioids via the injection route, a study assessing the safety and tolerability of initiating extended-release buprenorphine after administration of a single dose of 4 mg transmucosal buprenorphine, and a real-world implementation study of extended-release buprenorphine in people with OUD in diverse community healthcare settings in Australia.[1,2,3,4]

"Indivior is committed to furthering the scientific understanding of substance use disorders, including opioid use disorder, and to providing data that may help clinicians determine how best they can help patients," said Christian Heidbreder, Chief Scientific Officer, Indivior. "The COVID-19 pandemic is having a devastating impact on the opioid crisis in the U.S. More than 90,000 people died from drug overdose in the 12-month period ending November 2020, and approximately 67,574 of these deaths are attributable to opioids.[5] We must focus our scientific, treatment and policy efforts on helping patients access the treatment supports they need to move onto a path to recovery."

Indivior Sponsored Studies:

Struggling with recovery from opioids: Who is at risk during COVID-19? (Oral presentation) assessed substance use during COVID-19 among those in recovery from Opioid Use Disorder (OUD).[1] The study sought to identify individual-level factors associated with COVID-19-related impacts on recovery in 216 participants originally enrolled in the SUBLOCADE® (buprenorphine extended-release) clinical program.[1]

During September 2020 through January 2021, the study asked participants how the COVID-19 crisis affected their recovery from substance use.[1] Classification and Regression Tree (CART) analysis examined the association of 28 measures with self-reported impact of COVID on recovery, including demographic (e.g., race, education, employment), substance use (e.g., opioid craving/withdrawal, treatment utilization), and psycho-social factors (e.g., depression, quality of life, stress).[1]

The main findings from the study were as follows:

- 26% of participants reported that COVID-19 had made recovery somewhat or much harder[1]
- Past-month opioid use rate was higher among those who reported that recovery was harder compared to those who did not (51% vs. 24%)[1]
- These findings suggest that a set of identified criteria in this study might be beneficial to monitor among those in recovery from OUD, particularly during large-magnitude crises and particularly when access to healthcare is reduced.[1]

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Examining the benefit of RBP-6000 300 mg versus 100 mg maintenance dose in opioid injectors (Poster QA session) compared the efficacy and safety of SUBLOCADE 300 mg versus 100 mg maintenance doses in participants who used opioids via injection route, using the data collected during the pivotal phase 3 trial.[2] Adults with moderate or severe OUD were randomized to SUBLOCADE monthly injections or placebo and studied for 24 weeks.[2] Participants receiving SUBLOCADE were given 2 monthly injections of 300 mg, followed by 4 monthly maintenance doses of 100 mg or 300 mg over the course of the study.[2]

The main findings from the study were as follows:

- Opioid-injecting users experienced continued improvement in the proportion of participants achieving abstinence with the 300 mg maintenance dose; no significant improvement was noted with the 100 mg maintenance dose[2]
- Higher retention rates during the maintenance dose period was observed for the opioid-injecting users who received 300 mg and for the opioid non-injecting users who received 100 mg[2]
- The safety profiles of 300 mg and 100 mg maintenance doses appeared comparable, including potential hepatic safety events[2]
- This post-hoc analysis suggests that although a maintenance dose of SUBLOCADE 100 mg may achieve sufficient efficacy and safety in most opioid non-injecting users, the benefit of the 300 mg maintenance dose is clinically relevant in opioid-injecting users.[2]

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Initiating Monthly Buprenorphine Injection After Single Dose of Sublingual Buprenorphine (Poster QA session) evaluated opioid withdrawal symptoms, safety and tolerability of initiating SUBLOCADE 300 mg one hour after administering a single dose of 4 mg transmucosal buprenorphine (BUP-TM).[3] During this study, 26 participants received BUP-TM, 24 proceeded to SUBLOCADE injection, and 20 completed the study.[3]

The main findings from the study were as follows:

- After SUBLOCADE injection, withdrawal symptoms and opioid craving scores improved within 12h. Improvements were sustained for 4 weeks[3]
- Two of the 24 participants experienced precipitated withdrawal. No participants had severe withdrawal[3]
- No serious Treatment Emergent Adverse Events were observed, nor were any related to SUBLOCADE treatment[3]
- The authors concluded that initiating SUBLOCADE 300 mg following a single 4 mg dose of BUP-TM show a safety profile similar to that observed with SUBLOCADE induction per current labeling.[3]

Indivior Collaborative Studies:

An Open-Label, Multicentre, Single-Arm Trial of Monthly Injections of Extended Release Buprenorphine in People With Opioid Use Disorder (Poster QA session) The Community Long-Acting Buprenorphine (CoLAB) study evaluated patient outcomes among people with OUD receiving 48 weeks of SUBLOCADE treatment and examined the implementation of SUBLOCADE in diverse community healthcare settings in Australia.[4] The primary endpoint was to assess participant retention in treatment at 48 weeks after treatment initiation.[4] The CoLAB study provides new insight into the uptake and experience of people with OUD and treatment service providers, with relevance for policy makers, health service planners, administrators, and practitioners.[4]

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Mortality of Buprenorphine and Methadone in the United States 2010-2017 **(Poster QA session)** was conducted to provide public health surveillance of buprenorphine overdose mortality by analyzing drug mentions on death certificates from 2010 to 2017.[6] The study is part of a Risk Evaluation and Mitigation Strategy for SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE tablets, and SUBUTEX® tablets.[6]

Results indicated that the buprenorphine-involved mortality rate increased from 0.006 deaths per 100,000 population in 2010 to 0.068 in 2017.[6] The proportion of polysubstance involvement among buprenorphine-involved deaths rose from 76.7% in 2010 to 93.8% in 2017.[6] Benzodiazepines were the most frequent drug substance found with buprenorphine. Maintenance therapy is a critical tool to combating the opioid crisis, and polysubstance use further complicates treatment.[6] Given the high proportion of polysubstance buprenorphine-involved deaths in 2017, there is substantial need to communicate the risks of polysubstance use to patients.[6]

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About SUBLOCADE®[7]

SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use (CIII)
INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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 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.

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.

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About SUBOXONE®[8]

SUBOXONE® (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)

Indications and Usage

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is indicated for treatment of opioid dependence. SUBOXONE Film should be used as part of a complete treatment plan that includes counseling and psychosocial support.

IMPORTANT SAFETY INFORMATION

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

CONTRAINDICATIONS: SUBOXONE Film is contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone as serious adverse reactions, including anaphylactic shock, have been reported.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBOXONE Film contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Risk of Life-Threatening Respiratory Depression and Concomitant Use of Benzodiazepines or Other CNS Depressants with Buprenorphine: Buprenorphine has been associated with life-threatening respiratory depression, overdose, and death, particularly when misused by self-injection or with concomitant use of benzodiazepines or other CNS depressants, including alcohol. Warn patients of the potential danger of self-administration of benzodiazepines, other CNS depressants, opioid analgesics, and alcohol while under treatment with SUBOXONE Film. Counsel patients that such medications should not be used concomitantly unless supervised by a healthcare provider.

Use with caution in patients with compromised respiratory function (e.g., chronic obstructive pulmonary disease, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression).

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 the time SUBOXONE Film is initiated or renewed 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, if naloxone is prescribed, how to treat with naloxone. Emphasize the importance of calling 911 or getting emergency help, even if naloxone is administered.

Unintentional Pediatric Exposure: Buprenorphine can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it. Instruct patients to store SUBOXONE Film safely out of the sight and reach of children.

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. NOWS may be life-threatening if not recognized and treated in the neonate. Newborns should be observed for signs of NOWS and managed accordingly. Advise pregnant women receiving opioid addiction treatment with SUBOXONE Film of the risk of neonatal opioid withdrawal syndrome.

Adrenal Insufficiency: Adrenal insufficiency has been reported with opioid use. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off the opioid.

Discontinuation of SUBOXONE Film Treatment: If treatment is temporarily interrupted or discontinued, monitor patients for several months for withdrawal and treat appropriately.

Risk of Hepatitis, Hepatic Events: Because cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving buprenorphine, monitor liver function tests prior to treatment and periodically during treatment.

Hypersensitivity Reactions: Hypersensitivity to buprenorphine- and naloxone-containing products have been reported most commonly as rashes, hives, and pruritus. Some cases of bronchospasm, angioneurotic edema, and anaphylactic shock have also been reported.

Precipitation of Opioid Signs and Symptoms: An opioid withdrawal syndrome is likely to occur with parenteral misuse of SUBOXONE Film by individuals physically dependent on full opioid agonists such as heroin, morphine, or methadone. SUBOXONE Film may precipitate opioid withdrawal signs and symptoms in such persons before the effects of the full opioid agonist have subsided.

Risk of Overdose in Opioid Naïve Patients: Because death has been reported for opioid naïve individuals who received buprenorphine sublingual tablet for analgesia, SUBOXONE Film is not appropriate as an analgesic.

Use in Patients With Impaired Hepatic Function: SUBOXONE Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. In patients with moderate hepatic impairment, SUBOXONE Film is not recommended for initiation of treatment, but may be used with caution and careful monitoring for maintenance treatment in patients who have initiated treatment on a buprenorphine product without naloxone.

Impairment of Ability to Drive or Operate Machinery: SUBOXONE Film may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Caution patients about driving or operating hazardous machinery until they are reasonably certain that SUBOXONE Film does not adversely affect their ability to engage in such activities.

Orthostatic Hypotension: Buprenorphine may produce orthostatic hypotension.

Elevation of Cerebrospinal Fluid Pressure: Buprenorphine may elevate cerebrospinal fluid pressure and should be used with caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased. Buprenorphine can produce miosis and changes in the level of consciousness that may interfere with patient evaluation.

Elevation of Intracholedochal Pressure: Buprenorphine has been shown to increase intracholedochal pressure, as do other opioids, and thus should be administered with caution to patients with dysfunction of the biliary tract.

Effects in Acute Abdominal Conditions: Buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

ADVERSE REACTIONS: Adverse events commonly observed with SUBOXONE Film include oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema. This is not a complete list of potential adverse events. Please see the full Prescribing Information for a complete list.

DRUG INTERACTIONS

Benzodiazepines: Use caution in prescribing SUBOXONE Film for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse.

CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under- dosing.

Antiretrovirals: In patients on chronic SUBOXONE Film treatment, monitor dose if non-nucleoside reverse transcriptase inhibitors are added to their treatment regimen. Monitor patients taking SUBOXONE Film and atazanavir with and without ritonavir, and reduce dose of SUBOXONE Film if warranted.

Serotonergic Drugs: If concomitant use with serotonergic drugs is warranted, monitor for serotonin syndrome, particularly during treatment initiation and dose adjustment. Discontinue SUBOXONE Film if serotonin syndrome is suspected.

Consult the full Prescribing Information for SUBOXONE Film for more information on potentially significant drug interactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Lactation: Buprenorphine passes into the mother's milk. Advise breastfeeding women to monitor the infant for increased drowsiness and breathing difficulties.

Fertility: Chronic use of opioids may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Geriatric Patients: Monitor geriatric patients receiving SUBOXONE Film for sedation or respiratory depression.

To report pregnancy or side effects associated with taking SUBOXONE Film, please call 1-877-782-6966.

For more information about SUBOXONE Film, the full Prescribing Information, and Medication Guide visit www.suboxone.com. For REMS information visit www.suboxoneREMS.com.

About Opioid Use Disorder (OUD)

Opioid addiction is not a moral weakness. Opioid addiction is a chronic disease called Opioid Use Disorder (OUD).[9] Opioid addiction may affect the parts of the brain that are necessary for life-sustaining functions.[10]

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.[11] Approximately 506,000 people misused prescription pain relievers and used heroin in the past year.[11] 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.[7]

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 potentially address other chronic conditions and cooccurring disorders of addiction, including alcohol use disorder. Headquartered in the United States in Richmond, VA, Indivior employs more than 700 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.

Forward-Looking Statements

This announcement contains certain statements that are forward-looking. By their nature, forward-looking statements involve risks and uncertainties 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 2021, and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; 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; challenges in the commercial execution; 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 compliance with the U.S. Department of Justice Resolution and Settlement Agreements, noncompliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; 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; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; 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.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

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