

Indivior Provides Update on Key Business Drivers and Expectations

This announcement contains inside information.

Slough, UK and Richmond, VA, September 26, 2018 – Indivior PLC (LON: INDV) today is providing a further update on key business drivers and expectations related to:

- FY 2018 net revenue and net income guidance;
- SUBLOCADE™ net revenue development;
- Cost savings initiatives to provide further downside protection; and
- PERSERIS™ launch timing and resourcing.

FY 2018 Guidance:

Indivior today provided revised FY 2018 guidance of net revenue of \$990-\$1,020 million and net income in a range of \$230-\$255 million, excluding exceptional items and at constant FX.

- FY 2018 net revenue guidance assumes the following:
 - No material changes in current market conditions in the U.S., chiefly that the U.S. Court of Appeals for the Federal Circuit (CAFC) upholds the preliminary injunction (PI) granted by the U.S. District Court of New Jersey (the District Court) whereby Dr. Reddy's Laboratories remains prohibited from selling, offering to sell, or importing its generic buprenorphine/naloxone sublingual film product and / or generally an 'at risk' launch of a generic buprenorphine/naloxone film product will not take place during the year;
 - Intensifying competitive pressure in ROW due to continued healthcare austerity measures and increased competition in Europe, partially offset by continued growth in Australasia; and,
 - Net revenue expectations for SUBLOCADE™, which are expected to be between \$8 to \$10 million.

FY 2018 net income guidance assumes the following:

- Pre-tax savings of \$55 million from cost actions the Group is taking to streamline the organization;
- Continued investments to drive progression of SUBLOCADE™, increase access to treatment for OUD patients and to support continued compliance enhancements;
- Finance expense benefits from the prepayment of \$150m of the term loan facilities; and,
- A mid-teens effective tax rate from the recently enacted tax law change in the US, along with the Group's existing tax position.

SUBLOCADE™

While the Indivior SUBLOCADE™ team is steadily breaking down the barriers impeding accelerated treatment adoption, SUBLOCADE™ net revenue development continues to be impacted by previously highlighted inefficiencies associated with the prior authorization process across payors. As a result, net revenue for the third quarter is likely to be in the range of \$3 to \$4 million.

Previously issued FY 2018 SUBLOCADE™ net revenue guidance of \$25 to \$50 million assumed an inflection point in the fourth quarter based on a substantially improved trajectory in the prescription journey and healthcare provider (HCP) uptake. Analysis of the most recent data received indicates that the signs of net revenue inflection have not yet begun. Therefore, Indivior is updating its basis for SUBLOCADE™ net revenue progression that now conservatively assumes a linear trend in the prescription journey. Consequently, FY 2018 SUBLOCADE™ net revenue on this basis is expected to be between \$8 and \$10 million.

The long-term fundamental drivers of SUBLOCADE™ remain positive. Anecdotal feedback from patients and HCPs remains very encouraging, and we are seeing good rates of adoption once HCP trial has been successful. In addition, treatment retention rates remain largely consistent with the Group's Phase III trials. As a result, Indivior remains confident in its ability to deliver on its goal of peak annual SUBLOCADE™ net revenue of \$1 billion-plus.

Cost Savings

Further to the cost actions announced in mid-June to help protect Indivior's profitability and cash flows against a generic film entrant in the U.S., Indivior is able to confirm that it is executing further opportunities to streamline the Group and provide additional resilience. The actions involve a series of cost savings initiatives that together are expected to generate annual pre-tax savings ranging from \$80 to \$100 million in FY 2019.

These savings are comprised of \$55 million of expected pre-tax savings in 2018 (above the target of \$25 million announced in mid-June) and \$25 to \$45 million of additional pre-tax savings to be achieved in FY 2019. The Group will incur exceptional costs of approximately \$13 million pre-tax in FY 2018 to achieve these savings. Specifically, the cost actions include:

- Eliminating targeted SG&A costs and external consulting services;
- Resizing global support functions; and,
- Reprioritizing research and development activities.

The result of these cost savings actions will be a more streamlined Group focused on a growth strategy consisting of:

- Continued investment in the progression of SUBLOCADE™ in the U.S., including Phase IV studies and Health Economics Outcome Research (HEOR);
- The U.S. launch of PERSERIS™ in February 2019 (assuming the preliminary injunction against Dr. Reddy's is upheld by the U.S. Court of Appeals for the Federal Circuit) with an expected field force of 40 to 60 representatives;
- Regulatory submissions of SUBLOCADE™ dossiers in ex.-U.S. markets; and,
- Targeted early phase pipeline development.

Shaun Thaxter, CEO of Indivior, Comment:

"In the near-term, we acknowledge that with respect to SUBLOCADE we have substantially underestimated the lag time associated with the approval of medical benefit coverage of individual patients. While we have yet to see the expected inflection in net revenues, each of the key launch metrics that we have previously highlighted continues to improve. These include growing payor coverage (which now stands at over 77%), compressing the prescription journey timeline and generating increased healthcare provider awareness.

“Looking further out, we remain confident in achieving peak SUBLOCADE™ net revenue of \$1 billion-plus. Anecdotal patient and healthcare provider feedback continues to support our view that SUBLOCADE™ is a break-through treatment for moderate to severe OUD. We are steadily breaking down the treatment access barriers and we remain confident this will lead to accelerating uptake in due course.

“The organization we developed was purposely built to support our global growth ambitions in the treatment of addiction and its co-occurrences. We are now making required adjustments that preserve the strong foundation we have established, but that also acknowledge that our growth near-term may be impacted by changes in U.S. market conditions for SUBOXONE® Film and slower-than-expected uptake of SUBLOCADE™. These cost savings actions along with the recent debt paydown will help preserve Indivior’s profitability and cash flow allowing us to invest in the success of SUBLOCADE™ in our core U.S. market and progress regulatory submissions in targeted global markets, preserve our ability to launch PERSERIS™, and maintain our compliance and regulatory commitments.”

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. 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 1,000 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 announcement 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 announcement 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.

ABOUT SUBOXONE® Film

Indication

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

Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.

Important Safety Information

Do not take SUBOXONE® Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE® Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE® Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your healthcare provider can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE Film suddenly without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE® Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

You should not drink alcohol while taking SUBOXONE® Film, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent.

Your healthcare provider may monitor liver function before and during treatment.

SUBOXONE® Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE® Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE® Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE® Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE® Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting the SUBOXONE® Film product may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE® Film, tell your healthcare provider if you are pregnant or plan to become pregnant. If you are pregnant, tell your healthcare provider as withdrawal signs and symptoms should be monitored closely and the dose adjusted as necessary. If you are pregnant or become pregnant while taking SUBOXONE® Film, alert your healthcare provider immediately and you should report it using the contact information provided below. *

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

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically-authorized or illicit. Unlike opioid withdrawal syndrome in adults, NOWS may be life-threatening if not recognized and treated in the neonate. Healthcare professionals should observe newborns for signs of NOWS and manage accordingly.

Before taking SUBOXONE® Film, talk to your healthcare provider if you are breastfeeding or plan to breastfeed your baby. The active ingredients of SUBOXONE® Film can pass into your breast milk. You and your healthcare provider should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE® Film and should also consider any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE® Film affects you. Buprenorphine in SUBOXONE® Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE® Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE® Film. Please see [full Prescribing Information](#) for a complete list.

*To report pregnancy or side effects associated with taking SUBOXONE® Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about SUBOXONE Film, SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective [full Prescribing Information](#) and [Medication Guide](#) at www.suboxoneREMS.com.

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 days¹. It should be administered only by healthcare providers and should be used as part of a complete treatment program that includes counseling and psychosocial support¹. 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 reactions¹. Common adverse reactions associated with buprenorphine included constipation, nausea, vomiting, abnormal liver enzymes, headache, sedation and somnolence¹. Injection site reactions were reported in 16.5 percent of patients in Phase 3 studies¹. Most of the injection site adverse reactions (ADRs) were of mild to moderate severity¹. None of the injection site reactions were serious and one led to study treatment discontinuation¹.

SUBLOCADE has a BOXED WARNING and is available through restricted distribution under the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program¹. 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 patient¹. Moreover, certified healthcare settings and pharmacies must not distribute, transfer, loan or sell SUBLOCADE¹.

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.

**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.**

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

IMPORTANT SAFETY INFORMATION

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.

ABOUT PERSERIS™

INDICATION

PERSERIS™ (risperidone) is indicated for the treatment of schizophrenia in adults.

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH
DEMENTIA-RELATED PSYCHOSIS**

See full prescribing information for complete boxed warning.

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **PERSERIS is not approved for use in patients with dementia-related psychosis.**

CONTRAINDICATIONS

PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

Metabolic Changes: Monitor for hyperglycemia, dyslipidemia and weight gain.

Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

Potential for Cognitive and Motor Impairment: Use caution when operating machinery.

Seizures: Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

ADVERSE REACTIONS

The most common adverse reactions in clinical trials ($\geq 5\%$ and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ($\geq 5\%$) were injection site pain and erythema (reddening of the skin).

About Opioid Use Disorder (OUD)

Opioid use disorder (OUD), sometimes referred to as opioid addiction, is a chronic disease¹. 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 condition².”

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 year³. From 1999 to 2016, the rate of deadly prescription opioid overdoses increased five-fold⁴. In 2016, an average of 115 people died of opioid overdose each day in the United States⁵. In addition, in 2016, 935,000 adults used heroin and approximately 625,000 adults had a heroin use disorder³. In 2015, opioids accounted for 70 percent of the disease burden associated with drug use disorders worldwide⁶.

References

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