Indivior Provides Legal and Trading Update; Confirms Launch of PERSERIS™ and Key Elements of Contingency Plan

Slough, UK, 18 December 2018 – Indivior PLC (the "Company") with today's announcement and accompanying supplement published on its website (http://www.indivior.com) is:

- Providing an update on legal matters relating to the Court of Appeals for the Federal Circuit (CAFC) vacating the preliminary injunction (PI) against Dr. Reddy's Laboratories (DRL), including next steps and estimated timelines;
- Confirming that the Company expects to meet its overall FY 2018 net revenue and net income guidance, including exceeding FY 2018 SUBLOCADE™ net revenue guidance;
- Providing an update on SUBLOCADE™ KPIs;
- Confirming the launch of PERSERIS™; and,
- Confirming key elements of its contingency plan, should a generic buprenorphine/naloxone sublingual film product enter the U.S. market.

This announcement and the accompanying supplement substitutes for the Capital Markets Day that was originally scheduled for December 5th and will now be postponed until after the Company's FY 2018 financial results on February 14th, 2019. A date will be confirmed later.

CAFC / DRL Update:

On November 20th, the CAFC vacated the preliminary injunction (PI) granted by the U.S. District Court of New Jersey, which enjoined DRL from entering the U.S. market. However, the exact timing for DRL's potential "at-risk" market re-entry in the U.S. is unknown, as the PI remains in effect until the issuance of a mandate by the CAFC. The "mandate" is a formal filing by the CAFC that returns the case to the District Court for actions consistent with the CAFC's ruling.

On December 11th, the CAFC denied DRL's motion (filed on November 20th) to issue the mandate immediately or, alternatively, stay the PI pending issuance of the mandate. Consequently, the PI will remain in place and DRL will remain enjoined from resuming the "at-risk" launch in the U.S. market of its generic buprenorphine/naloxone sublingual film until after the mandate issues. Indivior will file a petition for a rehearing by the original panel of judges as well as a rehearing *en banc* by December 20th. The CAFC must rule on Indivior's petition for the rehearings before the mandate can be issued.

Even if the CAFC issues the mandate and the PI is vacated, any DRL generic product sales in the U.S. would be on an "at-risk" basis, subject to the outcome of the appeal of the non-infringement judgments related to U.S. Patent Nos. 8,603,514 and 8,017,150 – as well as ongoing litigation against DRL in the District of New Jersey asserting recently-granted Orange Book-listed patents (U.S. Patent Nos. 9,931,305 and 9,687,454).

Indivior has made it clear that it intends to continue its vigorous assertion and protection of its intellectual property with respect to SUBOXONE® Film and will seek redress and damages from any "at-risk" launch following success in any of these cases.

Trading Update & Financial Guidance for FY 2018:

Assuming no generic buprenorphine/naloxone sublingual film entry in the U.S. before the beginning of FY 2019, Indivior confirms that it expects to meet its FY 2018 financial guidance of net revenue of $990 to $1,020 million and net income of $230 to $255 million.

Indivior also confirms that SUBLOCADE™ net revenues for FY 2018 will exceed the top end of its previous guidance range of $8 to $10 million by approximately $2 million.

The Company expects to give financial guidance for FY 2019 with its FY 2018 results on February 14th, 2019, when the Company anticipates having greater clarity on U.S. market conditions.

SUBLOCADE™ KPIs Update:

Prescription Journey KPIs have reached or are progressing toward their target range:

- As of 11/30/18 formulary access stood at 83% (versus 82% at 9/30/18).
- As of 10/31/18 (latest available data) the Prescription Journey timeline of 16 to 23 days was generally in the Company's target range (versus 16 to 22 days at 9/30/18).
- As of 10/31/18 (latest available data) the Dispense Conversion Rate improved modestly to 37% (versus 36% at 9/30/18) and continues towards the Company's target of 50%.

HCP trial and adoption KPIs as of November 30th, 2018:

- HCPs Initiating a Prescription Journey increased to 2,270 (versus 1,870 at 9/30/18).
- HCPs Administered SUBLOCADE™ increased to 1,195 (versus 824 at 9/30/18).
- HCPs Administered SUBLOCADE™ to 5-plus patients increased to 199 (versus 108 at 9/30/18).

Indivior remains confident in its peak net revenue goal for SUBLOCADE™ of $1 billion-plus.

PERSERIS™ Update:

Indivior is confirming today that the Company is moving ahead with the launch of PERSERIS™ in the U.S. with a sales force consisting of approximately 50 representatives. While PERSERIS™ has been available in the U.S. since November 19th, the commercial launch is scheduled to take place in February 2019. The PERSERIS™ team is currently engaged in creating payor access, growing prescriber awareness and interest, as well as establishing its INSUPPORT™ patient hub.

Indivior remains confident in its peak net revenue goal for PERSERIS™ of $200 to $300 million.

Contingency Planning:

Indivior has updated its contingency plan to reflect current market conditions and future outlook. The key event which may adversely impact consolidated near-term net revenue and cash flow is the potential launch of generic buprenorphine/naloxone film in the U.S. market. Until the timing of potential generic film entry is certain, the full financial impact cannot be assessed.

The objective of the contingency plan is to provide for the commercial success of SUBLOCADE™ and PERSERIS™ while ensuring a minimum cash balance of $250 million to remain in compliance with the Company's debt covenants. At the end of November 2018, the Company had a cash balance of approximately $910 million.

The contingency plan is expected to cover the transition period of net revenue loss due to potential generic erosion of the Company's SUBOXONE® Film franchise until combined net revenue growth from SUBLOCADE™ and PERSERIS™ gathers sufficient momentum to return the Company to profitable growth.

Indivior's actions to meet the Company's objective of maintaining a $250 million minimum cash balance include:

- Launching an Authorized Generic of SUBOXONE® Film upon entry by a generic buprenorphine/naloxone film by an ANDA competitor. The launch is expected to capture some share of the generic segment and generate a small amount of net revenue in the range of tens of $ millions;
- Optimizing the profitability of the base U.S. and Rest of World businesses; and,
- Streamlining actions to materially reduce Indivior's cost base to a level appropriate to the expected level of net revenue in such changed U.S. market conditions, the detail of which will depend on the exact timing of any generic entry. These savings would be derived primarily from SG&A and R&D, and would be incremental to the previously-announced targeted annual savings of $135 to $155 million versus the Company's planned operating and R&D expense base for FY 2018.

Summary:

"As the leading provider of buprenorphine-based medication-assisted treatment for opioid dependence, Indivior has a responsibility to sustain our work on behalf of patients suffering from this condition" said Shaun Thaxter, CEO of Indivior. "With SUBLOCADE™ we believe we have a potentially transformational treatment for opioid dependence. The setbacks we have experienced this year will not impede our relentless search for better treatment outcomes for patients and better options for healthcare professionals. However, given the potential for a dramatically altered market, we are prepared to take the difficult but necessary steps to ensure the viability of the business and, above all else, our ability to deliver the potential of SUBLOCADE™ through a period of challenge.

"We also remain excited about the potential of PERSERIS™ and currently are looking forward to commercial launch in February 2019. This differentiated treatment for schizophrenia provides us another attractive growth avenue in a complex disease space that often is a co-occurring disorder of substance use disorders. We look forward to sharing more of our go-to-market plans and performance updates for both SUBLOCADE™ and PERSERIS™ at our Capital Markets Day next year."

Details of the December 18th call are as follows:

Timing: 13:00 London Time / 8:00 a.m. New York Time

Webcast link: https://edge.media-server.com/m6/p/n2jx9z2b

Confirmation Code:	**3538598**
Participants, Local - London, United Kingdom:	+44 (0) 330 336 9125
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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 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 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.

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About SUBOXONE®

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 www.suboxoneREMS.com 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 http://www.fda.gov/medwatch.

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.

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.

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.**

HIGHLIGHTED 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

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.

For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide visit 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 (≥ 5% and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥ 5%) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS, the full Prescribing Information including BOXED WARNING, and Medication Guide visit www.perseris.com.