Indivior Sees FY 2018 Net Revenue and Adjusted Net Income Below Previous Expectations

Slough, UK, 11 July 2018 – Indivior PLC (LON: INDV) ("Indivior" or the "Company") today announced that its previous FY 2018 financial guidance (net revenue: $1,130m - $1,170m; adjusted net income: $280m - $320m) is no longer valid based on recent US market developments for SUBOXONE® and early uptake levels of SUBLOCADE™.

US Market Developments:

- **Generic Film Entry:** Further to Dr. Reddy's Laboratories' (DRL) FDA approval and launch announcement on June 15th, Indivior is now seeing the market impact of DRL's generic buprenorphine/naloxone sublingual film sold into the U.S. market prior to the granting of a temporary restraining order (TRO). Indivior does not know the exact quantity of product sold by DRL prior to the issuance of the TRO. However, the Company has observed recent accelerated market share loss for SUBOXONE® of two-and-half percentage points, to 52 percent, in the most recent weekly data(1). While the eventual impact could be materially higher depending on DRL's final stocking levels, Indivior currently anticipates the FY 2018 net revenue impact from this level of share loss to be $25m.

- **SUBOXONE® Film Channel Mix:** The level of discounting of generic tablets has now resulted in pricing of 75 to 80 percent below list price. This new level of discounting has further reduced the profitability of the most price sensitive channel (Managed Medicaid), which currently represents the majority of overall growth in the U.S. buprenorphine medication assisted treatment market (BMAT). As a result of the unfavourable mix impact, Indivior is experiencing lower than expected net revenue. The Company estimates a FY 2018 minimum net revenue impact of $50m from this market development.

SUBLOCADE™ launch:

- Indivior continues to be greatly encouraged by positive patient and physician feedback and earlier-than-expected market access, now standing at over 55 percent of covered US lives in this early stage of the launch. However, the Company is continuing to experience some friction in the new distribution and reimbursement model, which is having an impact on physician willingness to prescribe at higher levels. Indivior is working diligently to address the issues and has continued to invest in process improvements. While the progress from the Company's actions is recognizable, improvement in patient throughput remains gradual. As a result, Indivior expects FY 2018 SUBLOCADE™ net revenue to be in the range of $25m to $50m, which is approximately $50m lower than its internal expectations. Indivior remains confident in achieving peak sales of at least $1 billion-plus in annual net revenue.

(1) Source: Symphony Health, Retail PHAST Weekly Prescription Data

At this time, Indivior cannot reliably provide updated FY 2018 net revenue and adjusted net income guidance until the impact of DRL's launch is better understood. The Company expects that this will be no later than its third quarter results announcement, currently scheduled for November 1st. Indivior also continues to await a ruling from the U.S. District Court for the District of New Jersey on Indivior's motion for a preliminary injunction (PI) against DRL, which would prohibit DRL from selling or offering for sale its generic buprenorphine/naloxone sublingual film product pending the outcome of recently filed patent infringement litigation against DRL related to Indivior's U.S. Patent No. 9,931,305 (the '305 patent).

Shaun Thaxter, CEO of Indivior commented:
"Given the swift and material change in US market dynamics as well as the early-stage reimbursement and distribution model challenges we are experiencing with SUBLOCADE™, we are removing our FY 2018 net revenue and net income guidance.

We are continuing to monitor US market developments to better gauge DRL's launch impact. We know that they are skilled in rapid distribution in quantity and, as such, there is a range of uncertainty around the amount of product they were able to ship before the temporary restraining order (TRO) was granted by the court. We are making progress in overcoming SUBLOCADE's early stage challenges and continue to expect to deliver peak net revenue of $1billion-plus.

We are looking at cost saving opportunities, initially targeting at least $25m in cost savings in 2018, to partially offset the financial impact of these developments. We will provide more details on the SUBLOCADE™ launch, cost saving initiatives and overall business performance with our 2018 half-year results presentation on July 25th."

For Further Information

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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 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 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.

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 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.

INDICATION AND USAGE

SUBLOCADE™ (buprenorphine extended-release) injection, for subcutaneous use (CII) 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.

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.**

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

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.
The full prescribing information, including BOXED WARNING, for SUBLOCADE™ can be found here:
http://www.indivior.com/wp-content/uploads/2018/01/2018_01_12-CLEAN-USPI-SUBLOCADE.pdf

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