

**Court of Appeals for the Federal Circuit Lifts Preliminary Injunction on  
Generic (buprenorphine and naloxone) Sublingual Film**

**-Company will continue to defend its intellectual property and implement contingency plan-  
-FY 2018 guidance remains valid until such time a generic buprenorphine/naloxone sublingual  
film enters the market in 2018-**

**Slough, UK, 21 November 2018** – Indivior PLC (LON: INDV) (“Indivior” or the “Company”) today announced that the U.S. Court of Appeals for the Federal Circuit (CAFC) vacated the preliminary injunction (PI) previously granted against Dr. Reddy’s Laboratories (DRL) by the U.S. District Court for the District of New Jersey on July 13, 2018. The injunction had prevented DRL from selling, offering to sell, or import its generic buprenorphine/naloxone sublingual film product.

In the absence of a PI, Indivior assumes that DRL will resume the launch of its generic buprenorphine/naloxone sublingual film product in the U.S. following the issuance of the mandate from the CAFC. 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, and ongoing litigation against DRL in the District of New Jersey asserting recently-granted Orange Book-listed patents (including U.S. Patent No. 9,931,305).

The exact timing for DRL’s potential U.S. market re-entry is unknown, as the PI typically remains in effect until the issuance of a mandate by the CAFC (a formal filing by the CAFC that returns the case to the District Court for actions consistent with the CAFC’s ruling). Following today’s ruling vacating the PI, DRL filed a motion requesting that the CAFC either issue the mandate immediately or, alternatively, stay the PI pending issuance of the mandate. The Company will oppose DRL’s motion and file a petition for both panel rehearing and rehearing *en banc* of the ruling vacating the PI.

Indivior’s FY 2018 guidance for net revenue of \$990-\$1,020m and net income of \$230-255m, which was issued on September 26th and confirmed on November 1st, was based on no material changes in current market conditions in the U.S. As such, the Company’s current FY 2018 guidance remains valid unless there is certainty of generic buprenorphine/naloxone sublingual film entry in 2018, in which case there would be risk to FY 2018 guidance. The magnitude of the risk will depend upon the timing of any generic entry.

Should generic buprenorphine/naloxone sublingual film enter the market in 2018, the result would most likely be a rapid and material loss of market share for SUBOXONE<sup>®</sup> (buprenorphine and naloxone) Sublingual Film. Industry analogs<sup>1</sup> suggest that a launch in the U.S. of a generic product that can be directly substituted by a pharmacist for the branded product without consultation with the patient would result in the branded incumbent (in this case, Suboxone<sup>®</sup> Film) losing up to 80% of its market share within a matter of months. A material loss in market share in the U.S. would have a significant adverse impact on the Company’s revenues, profitability and cash flows.

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<sup>1</sup> (1) IMS Institute Report, January 2016: “Price Declines after Branded Medicines Lose Exclusivity in the U.S.”

“We are surprised and disappointed that the court has vacated the preliminary injunction,” said Shaun Thaxter, CEO of Indivior. “We will continue to vigorously pursue our infringement cases against DRL to protect our SUBOXONE® Film patent portfolio, including filing a petition with the CAFC for both panel rehearing and rehearing *en banc* of the ruling vacating the PI, as well as opposing DRL’s motion to immediately issue a mandate or stay the current PI until the mandate is issued.

“We are continuing to pursue the appeal of the U.S. District Court for the District of Delaware’s non-infringement decision related to U.S. patents 8,603,514 and 8,017,150, as well as litigating our recently listed Orange Book patents for SUBOXONE® Film.

“While we ultimately believe in the strength of our patent portfolio, we acknowledge that the Company faces challenges in the intervening period resulting from a potential material and rapid loss of market share to generic buprenorphine/naloxone sublingual film competition, including reduced earnings and cash flow.”

As the current leading provider of buprenorphine-based medication-assisted treatment (BMAT) in the U.S., Indivior is committed to continuing to realize its Vision that all patients around the world have access to evidence-based treatment for the chronic condition and co-occurring disorders of addiction. The Company is in advanced stages of contingency planning. In light of the timing of this judgement, we will now undertake a full review of our plans and will update the market on the Company’s path forward as soon as practicable.

#### [For Further Information](#)

<b>Investor Enquiries</b>	Jason Thompson	VP Investor Relations, Indivior PLC	+1 804 379 1099 jason.thompson@indivior.com
<b>Media Enquiries</b>	Jonathan Sibun	Tulchan Communications	+44 207 353 4200
		US Media Enquiries	+1 804 594 0836 Indiviormediacontacts@indivior.com

#### [Corporate Website](#)    [www.indivior.com](http://www.indivior.com)

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 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](http://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.

## 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](http://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](http://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](http://www.suboxoneREMS.com).

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