



INDIVIOR RESPONDS TO COURT RULINGS IN ANDA LITIGATION AND ANNOUNCES INTENTION TO APPEAL

**CONFERENCE CALL TODAY AT 2:00 P.M. UK Time (9:00 A.M. US EDT);
DIAL-IN +44(0)20-3427-1900 (UK); +877-280-2296 (US); CONFIRMATION CODE: 1978790**

This announcement contains inside information.

Slough, UK, 1 September 2017 – Indivior PLC (LON: INDV) (“Indivior” or the “Company”) today announced that the US District Court for the District of Delaware has found the asserted claims of U.S. Patent Nos. 8,017,150; 8,603,514; 8,900,497 valid, but that Dr. Reddy’s does not infringe any asserted claims of those patents, and that Watson (Actavis) and Par do not infringe the asserted claim of the ’497 Patent.

The Court has also issued a separate ruling denying Watson’s and Par’s motions to reopen the Court’s June 2016 judgment finding that their respective proposed generic products infringe valid claims of the ’514 Patent; therefore, the Court’s ruling enjoining marketing approval and sale of Watson’s and Par’s proposed generic products until the expiration of the ’514 Patent in 2024 remains in place.

The Company intends to continue vigorously defending its intellectual property and believes that it has grounds to appeal the ruling by the District Court of Delaware. Unless and until the Court’s ruling is reversed on appeal, and in the absence of other judicial relief, the Company will not be able to rely on the ’514, ’150, and ’497 Patents to prevent Dr. Reddy’s from manufacturing and marketing a generic film alternative in the US. Further, the Company may have increased difficulty successfully defending its intellectual property against future ANDA filers. As noted above, Watson and Par remain enjoined from manufacturing and marketing a generic film alternative in the US by the Court’s June 2016 ruling. However, Watson and Par are now able to pursue their respective appeals at the US Court of Appeals for the Federal Circuit.

As of 29 August 2017, FDA has not announced that it has granted tentative or final marketing authorization to any generic Suboxone[®] Film (buprenorphine and naloxone) alternative. If FDA grants approval to Dr. Reddy’s, it would be able to market a generic alternative to Suboxone[®] Film in the US. Any market launch would be on an “at risk” basis, as the Company would have a claim for damages against Dr. Reddy’s if the Company prevails on appeal.

Although it is not possible to quantify precisely the financial impact that the launch of generic alternatives to Suboxone[®] Film would have on the Company’s revenues generated from Suboxone[®] Film in the US, or how quickly such an impact would take effect, the Company believes that it could potentially result in a rapid and material loss of market share for Suboxone[®] Film in the US, an effect that could occur within months of a successful launch of a generic film alternative into the US market.

In 2016, the average market share in the US for Suboxone[®] Film was 61% (2015: 60%), and was 59% in H1 2017 (H1 2016: 61%) and sales of Suboxone[®] Film in the US represented approximately 80% of Indivior's revenue for the year ended 31 December 2016. Industry analogs¹ suggest that a launch in the US 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[®] Film) losing up to 80% of its market share within a matter of months. A material loss in market share in the US would have a significant adverse impact on the Company's revenues, profitability and cash flows.

The Company recognizes the significant challenges that an "at risk" generic film launch would present to its Suboxone[®] Film business in the US based on industry analogs in the near-term. As such, the Company has prepared contingency plans based on various potential generic film launch scenarios.

The Company remains confident in its long-term prospects in view of the progress it continues to make with its innovative product pipeline, in particular buprenorphine monthly depot ("RBP-6000"). On July 31, 2017, the U.S. Food and Drug Administration (FDA) accepted with a Priority Review designation the New Drug Application (NDA) for RBP-6000. The FDA has set a PDUFA target action date of November 30, 2017. The Company continues to believe that RBP-6000 has the potential to generate at least \$1 billion in annual net revenue at peak sales levels.

The financial guidance for FY 2017, updated by Indivior on July 27, 2017 in its H1 2017 results, assumed no generic film launch. Clearly, as a result of the Court ruling, the risk to the guidance related to the launch of a generic Suboxone[®] Film has significantly increased. The Company will continue to monitor market conditions and will update its financial guidance if appropriate.

Commenting today, Shaun Thaxter, CEO, said:

"Today's news is disappointing to Indivior, given the belief that the Company has in its intellectual property for Suboxone[®] Film. We will appeal the ruling and defend our intellectual property.

We remain confident in Indivior's long-term outlook and vision. Our confidence is based on our market leading position in the addiction disease space forged over the past 20 years that has created unrivalled relationships with healthcare professionals, medical societies, regulators, payors and policymakers to expand access to opioid dependence treatment. Our focus and dedication continue to drive our innovative pipeline, particularly RBP-6000, which we expect will be a potentially transformational new option for the treatment of opioid use disorder.

As always, our unwavering focus is on addressing the unmet needs of opioid dependent patients. On behalf of the millions of patients who struggle to overcome opioid addiction, the majority of whom need help but go untreated, we remain relentless in our pursuit to transform addiction from a global human crisis to a recognized and treated disease."

¹ IMS Institute Report, January 2016: "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

Webcast and Conference Call Details

There will be a call at 2:00 pm UK time (9am Eastern in the USA) hosted by Shaun Thaxter, CEO. This presentation will also be webcast live. The details are below and are available on the Company's website at www.indivior.com.

Webcast link: <http://edge.media-server.com/m/p/ekkqtus7>

Confirmation Code:	1978790
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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 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 harbour 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 2017 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; 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](#) 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.

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