

## **INDIVIOR WELCOMES COURT RULING ON ANDA LITIGATION**

Indivior PLC (LON:INDV) (“Indivior” or the “Company”) welcomes today’s favourable ruling in the District Court of Delaware in the ANDA litigation against Actavis Laboratories Inc. (“Actavis”) and Par Pharmaceutical Companies, Inc. (“Par”). The ruling confirms Indivior’s belief in the validity and enforceability of its Suboxone® Film patent portfolio and provides the business with substantially greater certainty about the nearer-term outlook.

The U.S. District Court for the District of Delaware has ruled that Actavis and Par’s ANDA Products infringe the asserted claims of U.S. Patent No. 8,603,514, one of Company’s Orange Book listed patents for Suboxone® Film, and that the asserted claims of US Patent No. 8,603,514 are valid and enforceable. The ’514 Patent does not expire until April 3, 2024.

The Court also ruled that the asserted claims of U.S. Patent No. 8,017,150, which is set to expire in 2023, are valid, but that they are not infringed by Watson or Par’s ANDA Product. The Court found that the asserted claims of U.S. Patent No. 8,475,832 are invalid, but that certain of claims of this patent would be infringed by Watson and Par’s ANDA Products if they were valid.

While today’s ruling marks a very important milestone, investors should remain mindful that the Company has ongoing litigation against four other ANDA filers in which it has also asserted its Orange Book listed patents covering Suboxone® Film. Full details of the forthcoming trial dates in these other ANDA litigations were disclosed in the Company’s full year 2015 press release on 18 February 2016. Indivior intends to continue working to achieve the best outcome for its shareholders in pursuing resolution of these other ANDA litigations.

The clarification provided by today’s ruling means that the threat of early generic film entry has receded significantly and Indivior can continue with planning and executing its strategy, with increased confidence that its business model is not going to be structurally undermined in the immediate future. That strategy for an interesting future for Indivior is based on: -

- A sustainable base with Suboxone® Film, supported by patient and physician preference for the film technology, and increased confidence in the sustainability and enforceability of its patent portfolio for Suboxone® Film.
- A pipeline of interesting and potentially transformative technologies in addiction, including the Buprenorphine Monthly Depot.
- Global expansion of treatment opportunities into new geographies and new areas of addiction.
- Business development and M&A to expand the business into adjacencies, diversifying the business risks of dependence on one product, and opening up new treatment areas for growth.

Indivior will continue to focus on paying down its debt as a necessary pre-cursor to giving the business much greater flexibility in addressing any future business development and M&A activity.

The financial guidance for 2016, issued on 9 December 2015 and confirmed with full year 2015 results on 18 February 2016 remains in force. This guidance was reconfirmed with Q1 results on 3 May 2016.

Commenting today, Shaun Thaxter, CEO of Indivior, said:

“We are pleased that the court has ratified our confidence in the Suboxone Film patent portfolio. This confirmation gives our business the degree of certainty that we need to allow us to continue with our strategy to develop Indivior as the leading addiction treatment company. While welcoming this good news, we recognise that Indivior still needs long-term certainty, so we will leverage this outcome to seek a positive resolution of all the outstanding ANDA litigation involving Suboxone® Film. Our confidence in the long-term future of Indivior has received a good boost today, and we look forward to the next chapter in our development.”

### 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, health policy and evidence-based best practice 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 robust, global opioid dependence portfolio featuring SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet, and SUBUTEX® (buprenorphine) Sublingual Tablet, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic diseases of addiction – including alcohol use disorders and cocaine intoxication. It also is pursuing novel product candidates in related mental health disorders such as schizophrenia. Headquartered in the United States in Richmond, VA., Indivior employs more than 850 individuals globally and its portfolio is available in over 40 countries worldwide. Visit [www.Indivior.com](http://www.Indivior.com) to learn more.

### 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 physicians 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 doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE Film suddenly without talking to your doctor. 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 (i.e., 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 doctor 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 (e.g., heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

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

Before taking SUBOXONE Film, tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant or become pregnant while taking SUBOXONE Film, alert your doctor immediately and you should report it using the contact information provided below.\*

Neonatal withdrawal has been reported following the use of buprenorphine by the mother during pregnancy.

Before taking SUBOXONE Film, talk to your doctor if you are breastfeeding or plan to breastfeed your baby. SUBOXONE can pass into your breast milk. You and your doctor 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 negative 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<sup>®</sup> (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX<sup>®</sup> (buprenorphine) Sublingual Tablets (CIII), please see the respective full Prescribing Information and Medication Guide at [www.IndiviorREMS.com](http://www.IndiviorREMS.com).

#### **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 will or may 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 2016 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 Suboxone<sup>®</sup> Tablet, Suboxone<sup>®</sup> Film, Subutex Tablet and any future 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 the Suboxone<sup>®</sup> Film patent litigation relating to 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.*

