



## **Indivior Applauds Congressional Passage of Bipartisan Comprehensive Addiction & Recovery Act of 2016 (CARA)**

*– Landmark approval follows promising U.S. Department Health and Human Services  
recent patient cap increase –*

**Richmond, VA, July 13, 2016** – Indivior PLC (LON: INDV) commends the United States Senate and House of Representatives for their leadership in passing the Comprehensive Addiction & Recovery Act of 2016 (CARA), S. 524. This bipartisan legislation signals a strong federal response to the growing public health epidemic of opioid abuse, addiction and overdose. The Company is especially encouraged that this news closely follows the final rule by the U.S. Department of Health and Human Services (HHS) to increase access to medication by raising the number of patients that can be treated by certain qualified physicians to 275 from the current cap of 100. Together, these actions represent a vital step toward addressing the unmet treatment needs of patients living with opioid dependence and the nation's opioid abuse crisis.

“These governmental initiatives show the understanding and engagement of the Administration and Congress in addressing the urgent need of patients suffering from opioid dependence. We also applaud the engagement of so many national and local stakeholders who contributed to this tremendous advancement in patient care,” said Indivior Chief Executive Officer Shaun Thaxter. “For the past 20 years, Indivior has worked alongside governments, policymakers, payers, advocacy groups and healthcare professionals to increase education about the scientific nature of the disease and the value of medication-assisted treatment, and is elated by this much-needed progress.”

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), there were 2.5 million people (aged 12 or older) in the U.S. who abused or were dependent on painkillers or heroin in 2014.<sup>1</sup> According to the Centers for Disease Control and Prevention (CDC), opioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths.<sup>2</sup> Opioid dependence is a complex health condition with many elements to consider – biological, psychological and social. As the industry leader in medication-assisted treatment (MAT), Indivior works to ensure that patients have unrestricted access to high-quality treatment services for the chronic, relapsing condition of addiction and we believe that both CARA and the HHS rule have the capability to increase access to comprehensive treatment for many underserved patients.

“We are pleased that the CARA legislation additionally authorizes nurse practitioners and physician assistants to prescribe treatment for patients in need and are encouraged by the grants provided by CARA that focus on education, treatment and recovery. We look forward to uniting with stakeholders and healthcare professionals across communities to help implement the comprehensive approach outlined by CARA,” added Thaxter.

### **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 portfolio of opioid dependence treatments 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 conditions and co-morbidities of addiction including alcohol use disorder, cocaine intoxication 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.

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

## **Forward-Looking Statements**

This press release contains forward-looking statements. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior products 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 patent litigation relating to 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.

Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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### **REFERENCES**

<sup>1</sup> Substance Abuse and Mental Health Services Administration. SAMHSA Behavioral Health Trends in the United States: Results from the 2014 National survey on Drug Use and Health. HHS Publication No. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

<sup>2</sup> Centers for Disease Control and Prevention MMWR / December 18, 2015 / Vol. 64