



FOR IMMEDIATE RELEASE

Indivior Receives FDA Fast Track Designation for RBP-6000 Buprenorphine Monthly Depot for the Treatment of Opioid Use Disorder

Slough, UK, May 26, 2016 – Indivior Inc., a subsidiary of Indivior PLC (LON: INDV), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for RBP-6000 buprenorphine monthly depot, an investigational new drug for the treatment of opioid use disorder as part of a complete treatment plan to include counseling and psychosocial support.

Fast Track designation is granted to facilitate and expedite development and review for drugs that are intended to treat a serious condition and with nonclinical or clinical data that demonstrate the potential to address an unmet medical need. By granting this designation, FDA agrees that RBP-6000 meets these criteria.

“This Fast Track designation is an important acknowledgment of the potential that RBP-6000 holds as an innovative treatment option for patients living with opioid use disorder and Indivior looks forward to working closely with the Agency,” said Shaun Thaxter, Chief Executive Officer of Indivior. “We are currently awaiting our top line RBP-6000 Phase 3 efficacy results which are still expected in Q3 2016 and we continue to estimate an approval in 2017 under the assumption of a Priority Review.”

To date, 2 Phase 1, 1 Phase 2 and 1 Phase 2A clinical studies have been completed. The most commonly reported ($\geq 5\%$) TEAEs were constipation, nausea, diarrhea, upper abdominal pain, headache, injection site pain, injection site pruritus and abnormal liver function test.

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 opiate overdose, 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 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 (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 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 (eg, 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 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.IndiviorREMS.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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