

28<sup>th</sup> April 2016

## Result of Phase 1 trial of RBP-6300 Buprenorphine Hemiadipate

RBP-6300, the oral swallowable capsule of Buprenorphine Hemiadipate for the treatment of opioid dependence, completed its Phase I clinical PK study (RB-EU-14-0001). The drug did not achieve the anticipated PK profile in humans to justify proceeding further with this technology. Alternative options for the development of an orally bioavailable buprenorphine-based product with abuse deterrent properties are currently being thoroughly evaluated.

Separately, Indivior announces that an external manufacturing issue was identified with one out of six stability batches required for the NDA submission of RBP-7000, the Risperidone Monthly Depot. We believe this issue is now rectified and additional batches will be manufactured to provide the required data. This will result in a delay to the likely approval date until mid-2018. However, the clinical program, currently concluding its Phase III long-term safety trial, is still on track with its original timeline.

### Conference Call

There will be a conference call for investors and analysts, hosted by Shaun Thaxter, CEO and Christian Heidbreder, Chief Scientific Officer, at 1500 hours UK time (10.00am Eastern US time) to discuss this announcement only. Given the proximity of the Q1 Financial Results announcement, due on Tuesday May 3<sup>rd</sup>, there will be no discussion of any other items on this call.

Dial In Details are as follows: -

US Phone Number: 646-838-1622  
UK Phone Number: 44 20 33215268  
Conference ID: 1062584

### For Further Information

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

### **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 700 individuals globally and its portfolio 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 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® Tablet, Suboxone® 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® 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.*