



Indivior PLC Research & Development Day in New York

Slough, UK, 9th December 2016 – Indivior PLC is today presenting its R&D Day in New York at which it is updating investors on its pipeline of products under development.

Highlights of the day's presentations include the following:

- **Monthly Depot Buprenorphine** (RBP-6000) seeking approval for treatment of Opioid Use Disorder, estimated approval from the FDA in the U.S. in Q4 2017 under the assumption of a priority review.
 - Phase III efficacy and safety trial: Top Line Results published August 17th, 2016.
 - Phase III long-term safety trial: Database lock achieved October 31st, 2016.
 - Fast Track Designation granted May 23rd, 2016. Pre-NDA meeting in December 2016.
 - Planned NDA submission (pending outcome of pre-NDA meeting) Q2 2017.
 - Presentation of Phase III efficacy & safety plus Phase III HEOR data planned for College on Problems of Drug Dependence (CPDD) conference in June 2017.
- **Monthly Depot of Risperidone** seeking approval for treatment of schizophrenia (RBP-7000), estimated approval by the FDA in the U.S. in 2018.
 - Phase III efficacy and safety trial: Top line results released May 5th, 2015.
 - Phase III long-term safety extension trial: Database lock achieved October 21st, 2016.
 - Pre-NDA meeting held August 2016. FDA agreement with proposed stability testing timelines & NDA submission strategy.
 - Planned NDA submission Q4 2017.
- **Investment Priorities for 2017** will focus on organic growth, and in particular on:
 - Pre-Commercialisation for RBP-6000.
 - Accelerating growth in treatment of opioid use disorder in the U.S.
 - Pre-Commercialisation for RBP-7000.
 - Pre-Commercial infrastructure in China following submission of the NDA for SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII) in late 2016.

Following the previously announced <\$35m additional investment in 2016 in pre-commercialisation activities primarily for RBP-6000, most of which is being incurred in SD&A, we expect to increase our investment in pre-commercialisation in 2017. The quantum of additional investment for 2017 will be

confirmed in February, but such cost increases will be offset in part by our previously announced cost optimisation initiative both in respect of indirect costs and in contained cost inflation on the base business.

Commenting on the key messages of the day, **Shaun Thaxter, CEO, said: -**

“Indivior PLC is focused on empowering patients and striving to improve their quality of life by pioneering innovative, high-quality, accessible and cost effective treatments.”

“Our performance in 2016 has run well ahead of our plan. As with last year, this outperformance against our original planning assumptions allows us to reinvest in the long-term organic growth drivers of our business.”

“Accordingly we are consciously stepping up our investment in driving long-term growth opportunities for the business. At a time when there is intensified focus by the U.S. government and regulators to address the public health epidemic of opioid abuse, addiction and overdose, it is an appropriate time to accelerate our investment and dedicate additional resources towards expanding treatment access. At the same time, we recognize that many patients and physicians continue to face unmet treatment needs. We believe that RBP-6000 buprenorphine monthly depot can potentially transform the treatment of opioid use disorder, if approved, by possibly reducing patients’ treatment administration days. Additionally, RBP-6000 was designed to offer physicians the potential for increased certainty of treatment adherence, and developed with the desire to help mitigate abuse, misuse and diversion of medication. Early investment in pre-commercialisation educational initiatives related to need for diagnosis and treatment of Opioid Use Disorder will help ensure that appropriate patients have access to this potentially transformational treatment as soon as possible, once approved. These investments will help drive long-term value for shareholders and ensure that we are well prepared for a successful launch and the best possible start in the market considering an approval is possible as soon as end 2017, assuming an accelerated review.”

The presentations are being webcast. An archive of the presentations will be available at the Company’s website at www.indivior.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® (buprenorphine and naloxone) Sublingual Tablets (CIII), SUBOXONE® Film (buprenorphine and naloxone) Sublingual Film (CIII), SUBUTEX® (buprenorphine) Sublingual Tablets (CIII) 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.

For Further Information

Investor Enquiries	Tom Corran	IR Director, Indivior PLC	+44 1753 423965 tom.corran@indivior.com
Media Enquiries	Stephen Malthouse Jonathan Sibun Kathy Vincent	Tulchan Communications Biosector 2	+44 207 353 4200 +1 310 403 8951

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. 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, Indivior has a strong pipeline of product candidates designed to both expand treatments in opioid dependence and address other chronic diseases 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 is available in over 40 countries worldwide. Its name is a fusion of the words individual and endeavor and its logo radiates the company’s patient-centered holistic focus on expanding access to high-quality treatment services for addiction worldwide. For additional product information, please visit www.indivior.com

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 (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 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 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.