



**Indivior PLC Research & Development Day in New York;
Preliminary financial guidance FY 2016.**

Slough, UK, 9th December 2015 – 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 and its preliminary financial guidance for 2016. Highlights of the day’s presentations include the following: -

- Development of Monthly Depot Buprenorphine on track for approval in H2 2017.
 - Last patient dosed in Phase III efficacy trial in November.
 - Publication of Phase II “opioid blockade” data announced.
- Role of Opioid blockade effect in Monthly Depot Buprenorphine Phase II data is presented.
- Potential changes to timelines on two projects – Monthly Depot Buprenorphine in Europe only, and Oral Swallowable tablet for Buprenorphine Hemiadipate, both for treatment of opioid dependence – is presented confirming guidance issued with Q3 results. Revised timelines will follow in 2016 based on the outcome of existing clinical studies.
- Monthly Depot of Risperidone for treatment of schizophrenia on track for approval in 2017. Two patents have been granted. Indivior is examining options for commercialising this product.
- Investment in R&D and pre-commercialisation is planned to increase by more than \$35m in 2016 for new products, funded by resilience of existing business.
- Preliminary financial guidance for 2016 issued with net revenue in a range of \$945m-\$975m, an operating margin above 30%, and net income in a range of \$155m-\$180m, on the assumption of no material change to current market conditions, excluding exceptionals and at constant exchange.
- Indivior has agreed to buy back and retire \$75m of debt reflecting strong cashflow in 2015, the encouraging financial outlook and the relatively high cost of the debt.

Commenting on the outlook for 2016, **Shaun Thaxter, CEO, said:** -

“Our performance in 2015 continues to run well ahead of our plan, which anticipated a more challenging market environment driven by competitive activity. We see no imminent change in conditions, so we have based our preliminary guidance for 2016 on the assumption that these relatively benign market conditions will continue. This over-delivery against our original planning assumptions allows us both to reward shareholders with higher than expected profits, while using a proportion of the over-delivery to reinvest in the long-term organic growth drivers of our business.”

“Accordingly we are consciously stepping up our investment in R&D projects and pre-commercialisation, and particularly in preparation for the launch of our Monthly Depot of Buprenorphine, with a projected investment increase of more than \$35m in 2016. Although these investments will have no impact on sales in 2016, they will help drive long-term value for shareholders by ensuring pipeline projects get off to the best possible start in the market.”

1. Research & Development Highlights

- Monthly Depot Buprenorphine. Much of the day's presentation is devoted to the science of addiction, and the potential role of monthly depot of Buprenorphine in addressing unmet patient needs. In updating the market on progress of this project, the following information is being disclosed:
 - The Phase III trial (RB-US-13-0001) is on track, with last patient in achieved in November 2015.
 - Publication of Phase II "opioid blockade" data announced in the *Journal of Clinical Psychopharmacology*.

Nasser AF, Greenwald MK, Vince B, Fudala PJ, Twumasi-Ankrah P, Liu Y, Jones JP III, Heidbreder C (2015) Sustained-Release Buprenorphine (RBP-6000) Blocks the Effects of opioid Challenge with Hydromorphone in Subjects with Opioid Use Disorder. *J.Clin.Psychopharmacology*, in Press
 - A presentation is being given focused on the importance of the mu-opioid receptor blockade effect achieved by RBP-6000 in Phase II trials, guiding selection of dosing strengths of RBP-6000 in pivotal Phase III efficacy and safety trials.
- Potentially revised timing of two projects confirmed guidance issued at the Q3 results. The revised timing for the clinical development of the Monthly Depot Buprenorphine for Europe only, and for the Oral Swallowable Tablet of Buprenorphine Hemiadipate globally will be confirmed in 2016 based on the outcome of ongoing clinical studies.
- Monthly Depot of Risperidone for treatment of schizophrenia is on track for approval in 2017.
 - The Company confirms that the Phase III long-term safety study (RB-US-13-0005) is on track, with the data cut for interim analysis by end 2015.
 - Phase III efficacy data (RB-US-09-0010) preliminary data from this pivotal efficacy study were published on May 5th 2015. www.indivior.com.
 - Two patents have recently been granted – *US Applications No. 14/490,034 & 14/490,082* – and will be listable in the Orange Book on NDA approval. Filing of the NDA is expected in 2016.

Indivior is currently evaluating alternatives for the commercialisation of this product, recognising that psychiatry is not its core business and more value may be realised by partnering, licensing or out-sourcing this business.

Commenting today on the pipeline, Christian Heidbreder, Chief Scientific Officer, said: -

"We very much enjoy our first opportunity to share with investors the complex science of addiction and how we are developing our industry-leading pipeline to address various aspects of addiction and related co-morbidities. This event gives us a chance to increase understanding of addiction in pursuit of our vision of pioneering life transforming treatments."

2. Preliminary financial guidance for 2016

- Net Revenue in a range of \$945m to \$975m, an operating margin maintained at or above 30%, and net income in a range of \$155m to \$180m all at constant exchange.

- This guidance is based on the assumption of no material change to current US market conditions - no disruption to US generic tablet pricing, no generic film entry, and limited impact of branded competition in 2016. The net income guidance excludes exceptional items.
- The guidance also reflects a strategic decision to reinvest an increased portion (currently expected to be at least an additional \$35m) of the profit generated in excess of original assumptions; this will be invested in pre-commercialisation activity in preparation for the launch of Buprenorphine Monthly Depot for opioid dependence; and in additional R&D activity to support the existing pipeline including additional clinical trials.
- This additional investment is designed to give pipeline projects a strong start on launch as Indivior will be better prepared in terms of training, market access and sales capability.
- The Company has reached agreement to buy back a total of \$75m of its syndicated debt in the market at a discount, retiring this debt early over the coming days. This reflects the Company's strong cashflow in 2015, the encouraging financial outlook for 2016, and the relatively high cost of the debt. As a result of the programme, the debt at the year-end is expected to be of the order of \$635m – \$645m, offset by cash of \$415m – \$425m.

The presentations are being webcast. An archive of the presentations will be available at the Company's website at www.indivior.com.

Suboxone

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

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy in patient advocacy, health policy and evidence-based best practice models that have helped to advance modern addiction treatment. The name is the fusion of the words individual and endeavor, 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 global opioid dependence portfolio including SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet, and SUBUTEX® (buprenorphine) Sublingual Tablet, Indivior has a 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 to learn more.

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 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 two 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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