**Indivior PLC Announces Positive Top-line 12-Month Phase 3 Results Confirming Long-Term Safety Profile of RBP-7000 in Patients with Schizophrenia**

*Results represent the first demonstration of safety and durability of effect for a once-monthly injectable form of subcutaneously-administered risperidone in a long-term clinical trial*

**This announcement contains inside information.**

**Slough, UK, 13 March 2017** – Indivior PLC (LON: INDV) today announced positive top-line results from its Phase 3 open-label, long-term safety trial (RB-US-13-0005) of RBP-7000 risperidone monthly depot, an investigational drug candidate in development for the treatment of schizophrenia. No new safety signals or unexpected safety findings were seen in this long-term safety study. The profile of observed adverse events (AEs) was similar to that reported for risperidone and in previous short-term studies with RBP-7000.

Measures of clinical efficacy in the RB-US-13-0005 trial demonstrated that patients remained stable or improved across study visits over 12-months as evidenced by decreases in mean Positive and Negative Syndrome Scale (PANSS) total and Clinical Global Impression-Severity of Illness (CGI-S) scores. Health outcome measures showed no deleterious effect of treatment, high medication satisfaction and preference to treatment, and good long-term prognosis for stability. This is the first demonstration of safety and durability of effect for a once-monthly injectable form of risperidone administered subcutaneously (SC) in a long-term clinical trial.

“Schizophrenia is a chronic, severe and disabling brain disorder that affects an estimated 23 million people worldwide. With these positive preliminary findings, we are expeditiously moving toward filing a New Drug Application, which we target in Q4-2017, to bring RBP-7000 to the patients and physicians who need new treatment options for this serious disease,” said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior PLC.

**About the Study Design**

This was a Phase 3, open-label study designed to evaluate the long-term safety and tolerability of RBP-7000 in patients with schizophrenia. RBP-7000 was administered at a dose of 120 mg via subcutaneous injections once monthly for 12 months, using the ATRIGEL® delivery system. The study was performed at

approximately 50 sites in the U.S. About 500 patients were enrolled into the trial to ensure 300 patients achieved 6 months and 100 patients achieved 1 year of treatment with RBP-7000. The following patients were assessed for participation in this study: rollover patients who completed the Phase 3 double-blind, placebo-controlled, efficacy study of RBP-7000 (Study RB-US-09-0010) conducted in patients with acute schizophrenia and had completed 56 days of double-blind treatment, and patients newly diagnosed with schizophrenia with a PANSS score of ≤70.

The primary objective of this study was to assess the long-term safety and tolerability of RBP-7000 in patients with schizophrenia. The secondary objectives of this study were to continue collecting clinical efficacy measures to assess the durability of effect of RBP-7000 in subjects with schizophrenia using the PANSS and CGI-S scales. Tertiary objectives of this study were to continue collecting the health economics and patient-reported outcome data that were collected in the Phase 3 double-blind study and additionally to collect data on the SF-36 Physical and Mental summary scores and healthcare utilization.

Over the course of the 12-month treatment with RBP-7000, those patients who had been stable at enrollment remained clinically stable. Those patients and those who had been acutely ill in the previous 8 weeks and treated with 2 injections of RBP-7000 prior to "roll-over" enrollment in the long-term trial showed continuous improvement, both as determined by the PANSS and CGI-S scores. In addition, health outcome measures showed no deleterious (harmful or worsening) effect of RBP-7000 treatment (e.g., healthcare utilization, well-being, and quality of life) with high medication satisfaction and preference to treatment. Also, based on SF-36 Physical and Mental summary scores from this trial, patients treated with RBP-7000 have good long-term prognosis for stability in schizophrenia.

**About RBP-7000**

RBP-7000 is a novel sustained-release product using the ATRIGEL® delivery system for the subcutaneous (SC) administration of risperidone once every month. RBP-7000 consists of a two-syringe system, whose contents are mixed immediately prior to administration. One syringe contains the ATRIGEL® delivery system, and the other contains the powder-filled drug substance risperidone. Both syringes are e-beam irradiated to provide a sterile product to the end user.

With its full year 2016 financial results published on February 22, 2017, Indivior PLC raised its guidance for the potential peak net revenues of RBP-7000, if approved, to a range of $200m to $300m on the assumption of no material change in U.S. market circumstances.

**About Schizophrenia and Long-Acting Medicines**

Schizophrenia is a chronic disorder characterized by a life-long pattern of acute psychotic episodes superimposed upon chronically poor psychosocial adjustment. The symptoms can be grouped into four domains: positive (for example, delusions, hallucinations, disorganized speech and behavior); negative (for example, social withdrawal, avolition, blunted effect); cognitive (for example, impaired sustained attention, executive function and working memory) and affective (for example, anxiety and depression, hostility and aggression, increased risk of suicide) symptoms. These occur in different combinations and to a different degree in each patient. Given the extensive heterogeneity of symptoms among individual patients, schizophrenia can be considered a clinical syndrome rather than a single disease entity. An estimated 23 million people worldwide are affected with schizophrenia.[1] The median lifetime prevalence of schizophrenia has been reported to be 4/1,000 people[2] whereas the median incidence of

schizophrenia reported was 15.2 per 100,000 persons.[3] Schizophrenia leads to high direct and indirect costs and accounts for 1.5–3 % of national healthcare expenditures across countries.[4]

Long-acting injectable antipsychotics provide patients with steady-state plasma concentrations of active drug that remain within a therapeutic range for an extended period of time and allow healthcare providers to track patient adherence. Although results cannot be easily generalized, there is common agreement to conclude that long-acting antipsychotics contribute to reduce relapses and hospitalizations, improve compliance, and are cost effective.[4]

**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 2017 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® (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, 13 business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

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**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 global portfolio of opioid dependence treatments, 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-occurring disorders 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 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 healthcare providers 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 healthcare provider can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE Film suddenly without talking to your healthcare provider. 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 healthcare provider 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 healthcare provider if you are pregnant or plan to become pregnant. If you are pregnant, tell your healthcare provider as withdrawal signs and symptoms should be monitored closely and the dose adjusted as necessary. If you are pregnant or become pregnant while taking SUBOXONE Film, alert your healthcare provider immediately and you should report it using the contact information provided below. *

Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

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 healthcare provider 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 healthcare provider 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 pregnancy or 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.

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