Indivior Announces Additional Results from Clinical Studies Further Supporting the Relationship Between Sustained Plasma Levels of Buprenorphine as Delivered by RBP-6000 Monthly Depot, High Levels of μ-Opioid Receptor Occupancy in the Brain, and Clinical Efficacy

Results also include preliminary health economics and outcomes research findings for RBP-6000

Slough, UK, 28 March 2017 – Indivior PLC (LON: INDV) today announced additional subanalysis results from Phase 2 (RB-US-12-0005) and Phase 3 (RB-US-13-0001) studies that combined more than 17,000 observations from 507 subjects. The objective of this subanalysis was to establish a robust population pharmacokinetics (PK) model and an exposure-response relationship between plasma concentrations of buprenorphine, predicted μ-opioid receptor occupancy (RO) in the brain, and biomarkers of clinical efficacy (PD) against key drivers of relapse and poor treatment outcomes. A separate subanalysis also looked at the effects of RBP-6000 buprenorphine monthly depot on health economics and outcomes research (HEOR) endpoints in the Phase 3 (RB-US-13-0001) study with a main focus on health status, health-related quality of life (HRQoL), and medication satisfaction.

The company is planning to present these results in late June at the 79th Annual Scientific Meeting of the College on Problems of Drug Dependence (CPDD) in Montreal, Quebec, Canada (June 17th-22nd, 2017). The presentation will be followed by a conference call with the investment community (details to be announced).

"*These findings further support our original hypothesis that sustained therapeutic plasma concentrations of buprenorphine as reliably delivered by RBP-6000 across the entire one-month period can suppress withdrawal symptoms and craving, block the subjective effects of opioid agonists, and improve patients' health status. These results also strengthen our belief that RBP-6000 may bring a new pharmacotherapeutic option to healthcare practitioners and patients as they work together towards long-term treatment*" said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior PLC.

About RB-US-13-0001 Phase 3 Study

This was a multicenter, randomized, double-blind, placebo-controlled study, of 489 subjects with moderate or severe opioid use disorder (based on criteria from the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders [DSM–5; American Psychiatric Association, 2013])[i] who were not currently in treatment but seeking medication-assisted treatment for opioid use disorder. Subjects were

initially inducted onto SUBOXONE® (buprenorphine/naloxone) sublingual film for 3 days according to the SUBOXONE® sublingual film prescribing information in order to mitigate opioid withdrawal symptoms and to ensure lack of allergy to buprenorphine. The subjects then completed a 4- to 11-day SUBOXONE® sublingual film dose adjustment (SUBOXONE® doses ranging from 8 mg to 24 mg). Once subjects met the randomization criteria of no significant opioid craving (≤20 mm on an Opioid Craving visual analog scale [VAS]) or withdrawal (a score of ≤ 12 on the Clinical Opiate Withdrawal Scale [COWS]) after at least 7 days of SUBOXONE® sublingual film therapy, they were randomized to either 1 of 2 dose regimens of RBP-6000 or placebo of the equivalent volume in 6 SC injections separated by 28 days. Subjects randomized to receive dose regimen #1 of RBP-6000 received 1 injection of 300 mg RBP-6000 on Day 1 and then every 28 (±2) days thereafter. Subjects randomized to receive dose regimen #2 of RBP-6000 received 1 injection of 300 mg RBP-6000 on Day 1 and Day 29 (±2 days), which were then followed by 4 injections (once every 28 ± 2 days) of 100 mg of RBP-6000.

About RBP-6000

RBP-6000 is an investigational subcutaneous (SC) long-acting monthly depot injection that delivers a sustained-release formulation of buprenorphine through the company's ATRIGEL® delivery system. The ATRIGEL delivery system consists of a polymeric solution of a biodegradable poly-(DL-lactide-co-glycolide) co-polymer dissolved in N-methyl pyrrolidone (NMP), a water-miscible biocompatible solvent. After SC injection, NMP diffuses out of the polymer matrix and the polymer precipitates, trapping the drug inside and forming an amorphous solid depot in situ. The depot releases buprenorphine over a one-month period by diffusion as the polymer biodegrades.

RBP-6000 received Fast Track designation in the U.S. from the Food and Drug Administration (FDA) on May 23rd, 2016. The company anticipates submitting a New Drug Application (NDA) for RBP-6000 in Q2 2017 and, subject to satisfactory completion of the NDA dossier and FDA review and approval, marketing authorization could be achieved in Q4 2017 if Priority Review staus is granted by the FDA.

About Opioid Use Disorder

According to the DSM–5, Opioid Use Disorder is characterized by signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, they are used in doses greatly in excess of the amount needed for that medical condition. The Substance Abuse and Mental Health Services Administration (SAMHSA) 2015 National Survey on Drug Use and Health reports that 2.7 million Americans (aged 12 or older) had a prescription drug use disorder in the past year.[ii] According to the Centers for Disease Control and Prevention (CDC), opioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths.[iii] OUD is a complex health condition with many elements to consider – biological, psychological and social.

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.

Media Contacts
US

IndiviorMediaContacts@indivor.com
+1 804-594-0836

UK

Tulchan Communications

+44 207 353 4200

Investor Contact
Jason Thompson

Indivior

Vice President, Investor Relations

+1 804-423-8916

Jason.thompson@indivior.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 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.

[i] American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing

[ii] Substance Abuse and Mental Health Services Administration. Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health. NSDUH Data Review, September 2016.

[iii] Centers for Disease Control and Prevention MMWR / December 18, 2015 / Vol. 64. American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.