**Indivior PLC Announces FDA Acceptance with Priority Review Designation of RBP-6000 Buprenorphine Monthly Depot New Drug Application (NDA) for the Treatment of Opioid Use Disorder**

FDA Sets a PDUFA target action date of November 30, 2017

**Slough, UK and Richmond, VA, 31 July 2017 –** Indivior PLC (LON: INDV) today announces that the U.S. Food and Drug Administration (FDA) has accepted with a Priority Review designation the New Drug Application (NDA) for RBP-6000, an investigational once-monthly injectable buprenorphine in the ATRIGEL® delivery system for the treatment of adults with moderate-to-severe opioid use disorder (OUD) as part of a complete treatment plan to include counseling and psychosocial support. The NDA, which was submitted on May 30, 2017, is based on data from the pivotal Phase 3 study (RBP-US-13-0001) assessing the efficacy and safety of RBP-6000.

"FDA acceptance with a Priority Review designation of our NDA application for RBP-6000 represents a significant milestone for our Company as well as for the broader field of opioid use disorder treatment. This milestone is the result of our clear focus on developing treatments that deliver on the unmet needs of patients, along with our relentless advocacy for evidence-based medication-assisted treatment (MAT) as a key part of the addiction recovery equation," said Shaun Thaxter, Chief Executive Officer of Indivior.

If approved, RBP-6000 would represent the first once-monthly injectable buprenorphine treatment for OUD. As a depot injectable formulation, RBP-6000 uses a delivery system that is intended to make abuse and diversion difficult. The product is intended to be administered by healthcare professionals only.

"We are excited about FDA's acceptance with Priority Review designation of our NDA application for RBP-6000, which we believe will represent an entirely new treatment paradigm if approved," said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior. "We look forward to continuing to work closely with the Agency as they review our New Drug Application and bring this potential innovative treatment option to patients and physicians. The FDA has set a PDUFA target action date of November 30, 2017."

A Priority Review designation indicates the FDA's goal to take action on a new drug application within six months (compared to 10 months under standard review), and is assigned to medications that may offer significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications.

Additionally, the FDA has notified the Company that they will convene an Advisory Committee meeting to review the NDA for RBP-6000 as it meets the 'new chemical entity/new combination product' criteria established by PDUFA IV (also known as the Food and Drug Administration Amendments Act (FDAAA) of 2007). As part of the NDA review process, FDA is required to convene Advisory Committee meetings for all new chemical entities, unless they can provide adequate justification for not holding a meeting. FDA may need Advisory Committee input to assess the use of novel clinical or surrogate endpoints in the clinical trials or the overall benefit-risk of a new chemical entity. The Advisory Committee meeting for RBP-6000 will likely be convened in Q4 2017, since the NDA has been assigned a Priority Review designation.

**About RBP-6000**

**RBP-6000 IS AN INVESTIGATIONAL PRODUCT. THE SAFETY AND EFFICACY OF RBP-6000 IS BEING EVALUATED BY THE U.S. FOOD AND DRUG ADMINISTRATION AND HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR ANY OTHER HEALTH AUTHORITY.**

RBP-6000 is an investigational buprenorphine sustained-release formulation using the ATRIGEL® delivery system, which 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 subcutaneous injection, NMP diffuses out of the polymer matrix and the polymer precipitates, trapping buprenorphine inside and forming an amorphous solid depot *in situ*. The depot releases buprenorphine over a one-month period by diffusion as the polymer biodegrades.

Buprenorphine, the active ingredient in RBP-6000, is a Schedule III controlled substance that can be abused similar to other opioids.

Significant respiratory depression and death have occurred in association with buprenorphine, particularly when taken intravenously in combination with benzodiazepines or other CNS depressants including alcohol.

Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use.

Chronic administration produces physical dependence of the opioid type. Withdrawal signs and symptoms may be delayed following discontinuation of RBP-6000.

The most common adverse reactions reported with RBP-6000 during the Phase 3 clinical program (in ≥5% of subjects) were constipation, headache, nausea, vomiting, increased hepatic enzymes, fatigue, and injection site pain and pruritus.

**About Opioid Use Disorder**

According to the DSM–5[1], 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.

Based on 2015 data from the most recent National Survey on Drug Use and Health report, 11.5 million American adults (age 18+ years old) engaged in misuse of prescription pain relievers, including opioids, in the last month. Approximately 1.9 million American adults met criteria for prescription pain reliever use disorder in the past year. The same report suggested that 5.1 million adults have used heroin at some point in their lives, with 807,000 using in the past year and 324,000 using in the past month. There were approximately 585,000 adults who had a heroin use disorder in the past year[2].

**About Indivior**

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment 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 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.

**Forward-Looking Statements**

This press release 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 our financial guidance for 2017 and our medium- and long-term growth outlook, our operational goals, our 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 Indivior Group's 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 patent infringement litigation relating to Indivior Group's products, including 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.

This press release does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

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2. "National Survey on Drug Use and Health 2015." *Substance Abuse and Mental Health Data Archive Public Surveys*. https://pdas.samhsa.gov/#/?_k=o2r5ed. Accessed on 02 Mar. 2017.