



**FDA Posts Federal Register Notice for an Advisory Committee Meeting to Review  
New Drug Application for RBP-6000**

**Slough, UK, 3 October 2017** – Indivior PLC (LON: INDV) (the ‘Company’) today announces the U.S. Food and Drug Administration (FDA) published notice, via the Federal Register, that a joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will review Indivior’s New Drug Application (NDA) for RBP-6000 on October 31, 2017.

RBP-6000 is an investigational once-monthly injectable buprenorphine in the ATRIGEL<sup>®</sup> delivery system for the treatment of adults with moderate-to-severe opioid use disorder (OUD). Indivior submitted the NDA for RBP-6000 in May 2017, following which the FDA granted Priority Review Designation and set a PDUFA (Prescription Drug User Fee Act) date of November 30, 2017. As part of the routine NDA review process, the FDA convenes an Advisory Committee for all new chemical entities, unless the reviewing division can provide adequate justification for not holding a meeting. The role of an Advisory Committee is to provide the FDA with independent advice from outside experts. The FDA will consider the Advisory Committee recommendation and will make the final decision.

“The Advisory Committee meeting moves us one step closer to potentially bringing a critical new treatment option to patients with opioid use disorder,” said Christian Heidbreder, Chief Scientific Officer at Indivior. “We are looking forward to the opportunity to share our data with the Advisory Committee.”

Notice of the meeting and a proposed agenda can be found on the Federal Register at:  
<https://www.federalregister.gov/documents/2017/10/03/2017-21170/meetings-psychopharmacologic-drugs-advisory-committee-and-the-drug-safety-and-risk-management>.



### **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 1,000 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://www.indivior.com) to learn more.

### **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 may or may not 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 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.

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