



FDA Advisory Committees Recommend Approval of Indivior's RBP-6000 for the Treatment of Opioid Use Disorder

Slough, UK and Richmond, VA, 31 October 2017– Indivior PLC (LON: INDV) announced today that the Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 18 to 1 to recommend approval of RBP-6000 for the treatment of opioid use disorder (OUD). RBP-6000 is an investigational once-monthly injectable buprenorphine formulation in the ATRIGEL[®] delivery system for the treatment of adults with moderate-to-severe OUD, as part of a complete treatment plan to include counseling and psychosocial support.

“The Advisory Committees’ favorable recommendation of RBP-6000 moves us one step closer to potentially bringing this once-monthly injectable buprenorphine treatment option to patients struggling with opioid use disorder,” said Shaun Thaxter, Chief Executive Officer of Indivior. “We are committed to pioneering new options for patients living with this chronic, yet treatable disease to help address the nation’s growing opioid epidemic.”

The FDA will consider the Advisory Committees’ non-binding recommendation in its review of the New Drug Application for RBP-6000 that was submitted by Indivior on May 30, 2017. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2017.

About RBP-6000

RBP-6000 IS AN INVESTIGATIONAL PRODUCT WHOSE SAFETY AND EFFICACY ARE BEING EVALUATED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

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.

The Phase 3 study met its primary efficacy endpoint, with both RBP-6000 dosage regimens demonstrating abstinence rates that were significantly higher versus placebo (300 mg/300 mg: 41.3%; 300 mg/100 mg: 42.7%; placebo: 5.0%, $p < 0.0001$). RBP-6000 was generally well tolerated and had a safety profile consistent with that of transmucosal buprenorphine except for injection site reactions. Injection site reactions were not treatment-limiting and resulted in less than 1% of subjects discontinuing treatment. The most common (reported in $\geq 5\%$ of subjects) adverse reactions reported in the active total group were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzyme, fatigue and injection site pain.

About Opioid Use Disorder

According to the DSM-5¹, 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 2016 data from the most recent National Survey on Drug Use and Health report, 11.8 million Americans engaged in misuse of opioids in the last year. Approximately 2 million American adults (age 12+ years old) met criteria for opioid use disorder in the past year. The same report suggested that 935,000 adults have used heroin in the past year and 471,000 used in the past month. There were approximately 625,000 adults who had a heroin use disorder in the past year².

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.

References

1. American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.
2. Substance Abuse and Mental Health Services Administration. (2017). *Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm>.

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