Indivior Submits New Drug Application to U.S. FDA for RBP-6000 Buprenorphine Monthly Depot

A Potential Novel Long-Acting, Sustained-Release Product Candidate for Treatment of Opioid Use Disorder

Slough, UK, 30 May 2017 – Indivior PLC (LON: INDV) (the 'Company') today announced that the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) to seek marketing approval for RBP-6000, the Company's investigational, once-monthly injectable buprenorphine for the treatment of moderate-to-severe Opioid Use Disorder (OUD) as part of a complete treatment plan to include counseling and psychosocial support. This NDA submission includes the results from the pivotal Phase 3 study assessing the efficacy and safety of RBP-6000 which met both the primary and secondary endpoints.

"As a depot injectable formulation, RBP-6000 uses a delivery system that is intended to make abuse and diversion difficult and provide the potential for increased treatment adherence," stated Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior. "The results observed during our research and development program position RBP-6000 to be a meaningful treatment option for OUD, and we look forward to working with the FDA to bring this innovative medication to patients and physicians as quickly as possible."

The NDA submission follows the completion of the six-month multicenter, randomized, double-blind, placebo-controlled Phase 3 study (RB-US-13-0001), in which RBP-6000 showed statistically significant higher percentage of urine samples negative for opioids combined with self-reports negative for illicit opioid use compared with placebo. At the 79th Annual Scientific Meeting of the College on Problems of Drug Dependence (CPDD) meeting, Indivior will present "late breaking" research findings on Wednesday, June 21st at 5:25pm EDT that will summarize the results of this pivotal Phase 3 trial. The presentation will include a high-level summary of the exposure-response modelling that established a relationship between buprenorphine plasma concentrations as delivered by RBP-6000, predicted whole brain mu-opioid receptor occupancy, abstinence, opioid craving, and withdrawal symptoms. The presentation will be posted on Indivior.com.

RBP-6000 was generally well tolerated in the Phase 3 study. Available safety findings suggest that 2.7% of subjects on RBP-6000 (both dosage regimens combined) experienced a serious treatment-emergent adverse event (TEAE) compared with 5.0% of subjects on placebo. There were no related serious TEAEs across groups. 6.9% of subjects on RBP-6000 (both dosage regimens combined) experienced a severe TEAE compared with 4.0% of subjects on placebo. 4.2 % of subjects on RBP-6000 (both dosage regimens combined) discontinued treatment due to TEAEs compared with 2.0% of subjects on placebo. The most common (reported in ≥ 5% of subjects) TEAEs reported in the active total group were headache, constipation, nausea, injection site pruritus, vomiting, insomnia and upper respiratory tract infection.

Investor Event

Indivior will host a webcast event on June 29th, 2017 for the investment community on RBP-6000, along with a question and answer session. Participation details will be made available shortly.

About RBP-6000

RBP-6000 IS AN INVESTIGATIONAL PRODUCT THAT HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR SAFETY AND EFFICACY.

RBP-6000 is an investigational buprenorphine sustained-release formulation using our 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 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.

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.

In the most recent report from the National Survey on Drug Use and Health (NSDUH, 2014)[2], 4.3 million Americans engaged in non-medical use of prescription painkillers including opioids in the last month. Approximately 1.9 million Americans met criteria for prescription painkillers use disorder based on their use of prescription painkillers in the past year. In addition, 1.4 million people used prescription painkillers non-medically for the first time in the past year. The same report suggested that 4.8 million people have used heroin at some point in their lives with 212,000 people aged 12 or older using heroin for the first time within the past 12 months. Approximately 435,000 people were regular (past-month) users of heroin. Perhaps most concerning, deaths from overdose of opioid analgesics (including opioids, methadone and other synthetic narcotics) showed a 4.7-fold increase from 5,528 to 18,893 deaths between 2001 and 2014. Similarly, heroin-related overdose fatalities showed a 5.4-fold increase during this same period, from 1,779 deaths in 2001 to 10,574 in 2014[3].

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 presentation 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 presentation 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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