Indivior Announces NDA Acceptance of RBP-7000 Risperidone Monthly Depot

A Novel Sustained-Release Candidate for Treatment of Schizophrenia

Slough, UK and Richmond, VA, 12 December 2017 – Indivior PLC (LON: INDV) (the 'Company') today announces that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for RBP-7000, an investigational, once-monthly injectable risperidone in the ATRIGEL® delivery system for the treatment of schizophrenia. The NDA, which was submitted on September 28, 2017, is based on data from the pivotal Phase 3 study assessing clinical efficacy and safety and from the long-term safety study of RBP-7000. The FDA has set a PDUFA (Prescription Drug User Fee Act) target action date of July 28, 2018.

"FDA acceptance of our RBP-7000 NDA is a significant milestone for Indivior as we expand our treatment portfolio to offer a meaningful therapeutic option to help address non-compliance with medication administration in the treatment of schizophrenia," said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior. "We look forward to closely working with the Agency during the review process to support the approval of RBP-7000 and to provide both physicians and patients this innovative treatment option."

This NDA submission includes the results from the pivotal Phase 3 study (RB-US-09-0010) assessing the efficacy and safety of RBP-7000 and an open-label, long-term safety study (RB-US-13-0005). In the pivotal randomized, double-blind, placebo-controlled study, RBP-7000 demonstrated statistically significant clinical improvement compared to placebo based on changes in mean Positive and Negative Syndrome Scale (PANSS) total and Clinical Global Impression-Severity of Illness (CGI-S) scores at 8 weeks.

About RBP-7000

RBP-7000 IS AN INVESTIGATIONAL PRODUCT WHOSE SAFETY AND EFFICACY IS CURRENTLY UNDER REVIEW BY THE U.S. FOOD AND DRUG ADMINISTRATION.

RBP-7000 is a novel extended-release product using the ATRIGEL® delivery system for the subcutaneous (SC) administration of risperidone once monthly for the treatment of schizophrenia.

The results of the pivotal Phase 3 studies to assess the efficacy, safety and tolerability of RBP-7000 in subjects with acute schizophrenia were recently published.[1,2]

The most common adverse reactions in clinical trials (reported in ≥ 5% and greater than placebo group) were weight increase, constipation, sedation/somnolence, pain in extremity, back pain, akathisia, anxiety and musculoskeletal pain. The most common injection site reactions (≥ 5%) were injection site pain, erythema and induration/nodule.

About Schizophrenia

Schizophrenia is a chronic disorder characterized by a life-long pattern of acute psychotic episodes superimposed upon chronically poor psychosocial adjustment. The symptoms can be grouped into four domains: positive (for example, delusions, hallucinations, disorganized speech and behavior); negative (for example, social withdrawal, avolition, blunted effect); cognitive (for example, impaired sustained attention, executive function and working memory) and affective (for example, anxiety and depression, hostility and aggression, increased risk of suicide) symptoms. These occur in different combinations and to a different degree in each patient. Given the extensive heterogeneity of symptoms among individual patients, schizophrenia can be considered a clinical syndrome rather than a single disease entity. An estimated 23 million people worldwide in 2015 were affected with schizophrenia.[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 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.

Media Contacts
US
IndiviorMediaContacts@indivior.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

REFERENCES

1. Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C. Efficacy, safety and tolerability of RBP-7000 once monthly risperidone for the treatment of acute schizophrenia: An 8-week, randomized, double-blind, placebo-controlled, multicenter Phase 3 study. *J. Clin. Psychopharmacology*, 2016, 36(2): 130-140.
2. Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C. Health-related quality of life in acute schizophrenia patients treated with RBP-7000 once monthly risperidone: An 8-week, randomized, double-blind, placebo-controlled, multicenter phase 3 study. *Schizophr Res*., 2016, 174(1-3): 126-131.
3. GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet, 2016, 388:1545-602