

Outcome of Phase 3 Trial of RBP-7000

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Indivior PLC Announces Positive Top-line Results From Pivotal Phase 3 Trial of RBP-7000 in Schizophrenia

Slough, UK, 5 May 2015- Indivior PLC (LON: INDV) today announced top-line results from its phase 3 clinical trial of RBP-7000, an investigational drug in development for the treatment of schizophrenia. In this pivotal study, both doses of RBP-7000 tested, 90 mg and 120 mg administered once-monthly, met the primary endpoint with statistically and clinically significant reductions in the symptoms of acute schizophrenia over an 8-week treatment period. Symptom reduction was measured using the change from baseline to end of treatment in the total Positive and Negative Syndrome Scale (PANSS) scores. RBP-7000 also met the key secondary endpoint with statistically significant improvements in the Clinical Global Impression-Severity of Illness (CGI-S) scale compared with placebo over the 8-week treatment period using change from baseline to end of treatment.

"With these positive phase 3 data in hand, we are moving forward expeditiously to complete the open-label long-term assessment of the safety and tolerability of RBP-7000," said Christian Heidbreder, Ph.D., Chief Scientific Officer of Indivior. "We understand there is a great unmet need among patients living with this chronic disease, and we hope to bring a new, long-acting treatment option to those individuals and the physicians who treat them."

Based on the success of the open-label phase of the trial, Indivior expects to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration for potential approval in 2017.

During the 8-week, double-blind treatment period, patients treated once-monthly with either 90 mg or 120 mg of RBP-7000 demonstrated statistically and clinically significant mean reductions from baseline in PANSS total scores (-9.2 points for placebo; -15.4 points for RBP-7000, 90 mg, $p=0.0004$ vs. placebo; and -16.4 points for RBP-7000, 120 mg, $p<0.0001$ vs. placebo). In addition to meeting the pre-specified primary efficacy endpoint of PANSS total score reduction, the study also met the pre-specified key secondary endpoint of improvement on the CGI-S scale for each RBP-7000 group vs. placebo at Week 8 ($p=0.0002$ vs. placebo for RBP-7000, 90 mg; and $p<0.0001$ vs. placebo for RBP-7000, 120 mg). RBP-7000 was generally well tolerated in the study, and the observed safety profile of RBP-7000 was similar to that reported with oral risperidone.

Schizophrenia is a chronic, severe and disabling brain disorder¹ that affects an estimated 26 million people worldwide.² Treatment is aimed at reducing or eliminating the symptoms of the disease and often includes antipsychotic medications and various psychosocial treatments.¹

About the Study Design

The phase 3, randomized, multicenter, double-blind, placebo-controlled study was designed to assess the efficacy, safety and tolerability of RBP-7000 (90 mg and 120 mg) in patients experiencing acute exacerbation of schizophrenia. The trial included adult male and female patients between the ages of 18 to 55 years who met the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR[®]) criteria for schizophrenia and had a PANSS total score between 80 and 120 at the initial screening visit, and a score of 4 or greater on at least two of the following four items of the PANSS positive subscale: hallucinatory behavior, delusions, conceptual disorganization or suspiciousness.

A total of 354 patients were randomized to receive once-monthly subcutaneous injections of RBP-7000, 90 mg; RBP-7000, 120 mg; or a matching placebo injection for 8 weeks. Following randomization, patients received their first injection of RBP-7000.

The primary efficacy endpoint of the study was the mean change from baseline at Week 8 in PANSS

total score. Statistical analyses of the effect of study treatment vs. placebo on the primary efficacy endpoint were conducted using a mixed effects model for repeated measures taking into account all available observations of the primary efficacy endpoint at various visits, and including terms for treatment (RBP-7000 [90 mg], RBP-7000 [120 mg], placebo), baseline total PANSS score, visit (5, 6, 8, 9) and treatment-by-visit interaction as fixed effects. The unstructured covariance type was used to model the variance-covariance matrix. Dunnett's procedure was used to adjust for the comparison between two levels of study treatment (RBP-7000 [90 mg and 120 mg]) with a single placebo.

All participants who completed the double-blind portion of the study and met some additional inclusionary/exclusionary criteria were eligible to continue in an open-label phase and receive RBP-7000 for a total of 13 injections (2 in the double-blind phase and 11 in the open-label phase). The objective of the extension phase of the study is to assess the safety and long-term tolerability of once-monthly RBP-7000.

About RBP-7000

RBP-7000 is a novel sustained-release product using the Atrigel® delivery system for the subcutaneous administration of risperidone once every month.³ RBP-7000 consists of a two-syringe system, whose contents are mixed immediately prior to administration. One syringe contains the Atrigel® delivery system, and the other contains the powder-filled drug substance risperidone. These phase 3 clinical trial results further emphasize the compatibility of our Atrigel® drug delivery platform with a range of pharmaceutical compounds for their safe, sustained release over targeted time period through an easy biodegradable and biocompatible process.

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 (e.g., delusions, hallucinations, disorganized speech and behavior); negative (e.g., social withdrawal, avolition, blunted affect); cognitive (e.g., impaired sustained attention, executive function and working memory) and affective (e.g., 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. Schizophrenia leads to high direct and indirect costs and accounts for 1.5-3 percent of national healthcare expenditures across countries.³

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy, health policy and evidence-based best practice models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavor, 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 robust, global opioid dependence portfolio featuring SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet, and SUBUTEX® (buprenorphine) Sublingual Tablet, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic diseases of addiction - including opiate overdose, alcohol use disorders and cocaine intoxication. It also is pursuing novel product candidates in related mental health disorders such as schizophrenia. Headquartered in the United States in Richmond, Va., Indivior employs more than 700 individuals globally and its portfolio is available in over 40 countries worldwide. Visit www.Indivior.com to learn more.

Forward-Looking Statements

This press release contains forward-looking statements. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include, among other things, statements regarding our financial guidance for 2015 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 Suboxone Tablet, Suboxone Film, Subutex Tablet and any future 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 the Suboxone Film patent litigation relating to the three 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.

Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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