Alkermes Announces Initiation of Clinical Study Evaluating Metabolic Profile of ALKS 3831 for Treatment of Schizophrenia

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— Study Designed to Characterize Potential Metabolic Benefits of ALKS 3831 Compared to Olanzapine —

— Metabolic Study is a Supportive Study in the ENLIGHTEN Pivotal Program for ALKS 3831, a Novel, Once-Daily, Oral Antipsychotic in Development for the Treatment of Schizophrenia —

DUBLIN--(BUSINESS WIRE)--Oct. 3, 2016-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a clinical study designed to evaluate the metabolic profile of ALKS 3831, an investigational, novel, oral atypical antipsychotic drug candidate, compared to olanzapine, an established atypical antipsychotic agent with proven efficacy but also metabolic liabilities, including significant weight gain. The randomized, double-blind, parallel-group study will characterize metabolic parameters, including insulin sensitivity and lipid metabolism, in response to treatment with ALKS 3831 and olanzapine. This exploratory metabolic study in healthy subjects is a supportive study in the ENLIGHTEN pivotal program of ALKS 3831 for the treatment of schizophrenia. The two key phase 3 studies, ENLIGHTEN-1 and ENLIGHTEN-2, have been enrolling patients since December 2015 and February 2016, respectively.

The objective of the newly-initiated metabolic study is to more fully characterize the comparative metabolic effects of ALKS 3831 and olanzapine, in order to understand the potential metabolic benefits of ALKS 3831 and to build on the findings from previously conducted preclinical and clinical studies that suggest treatment with ALKS 3831 is associated with less weight gain compared to olanzapine. ALKS 3831 is designed to provide patients with the strong efficacy of olanzapine with favorable weight and metabolic properties.

“With the ENLIGHTEN clinical program, we are assessing the potential for ALKS 3831 to address the compelling opportunity to develop an antipsychotic with the efficacy of olanzapine and a safety profile that addresses the negative health impact of significant weight gain and metabolic consequences associated with olanzapine,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “The initiation of this metabolic study represents our continued progress in advancing ALKS 3831 through pivotal development. As a novel, oral antipsychotic created based on the real-world needs of patients, ALKS 3831 has the potential to offer a meaningful new treatment option for schizophrenia.”

The phase 1 metabolic study will assess the effects of ALKS 3831 on whole body insulin sensitivity, lipid metabolism and other important metabolic parameters compared to olanzapine. Approximately 50 healthy subjects will be randomized to receive ALKS 3831, olanzapine or placebo for 21 days. Results from the study are expected in the first half of 2017.

About the ENLIGHTEN Clinical Program

The ENLIGHTEN pivotal program for ALKS 3831 is comprised of two key studies: a study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks and a study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over six months. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile of ALKS 3831, as well as long-term safety. Alkermes expects to use safety and efficacy data from the ENLIGHTEN pivotal program to serve as the basis for a New Drug Application (NDA) to be submitted to the U.S. Food and Drug Administration (FDA), pending study results.

Further information about the ENLIGHTEN studies can be found at www.clinicaltrials.gov.

About ALKS 3831

ALKS 3831 is a proprietary, investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan, a novel, new molecular entity co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

Weight gain is a common and clinically relevant metabolic side effect of atypical antipsychotic medications, and olanzapine, commercially available as ZYPREXA®, has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs.[1] ALKS 3831 is designed to provide the strong efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

ALKS 3831 is also being evaluated for the treatment of schizophrenia in patients with co-occurring alcohol use disorder. A phase 2 study, initiated in June 2014, is investigating the potential utility of ALKS 3831 for the large number of patients with schizophrenia whose disease is exacerbated by alcohol use disorders – a group representing more than one-third of patients with schizophrenia.[2]

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million American adults have schizophrenia,[3] with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, which is one of the most serious types of mental illness.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more

information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the therapeutic value, development plans and commercial potential of ALKS 3831; the adequacy of the phase 1 metabolic study to assess the metabolic parameters and comparative metabolic effect of ALKS 3831 and olanzapine; and the adequacy of the ENLIGHTEN pivotal program for ALKS 3831 to serve as the basis for an NDA. You are cautioned that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and clinical results for ALKS 3831 will be predictive of future clinical study results; whether the ongoing phase 2 trial, the phase 1 metabolic study and the ENLIGHTEN pivotal trials for ALKS 3831 will be completed on time or at all; if the results of the phase 1 metabolic study will show favorable metabolic effects of ALKS 3831 compared to olanzapine; potential changes in cost, scope and duration of the ALKS 3831 clinical development program; whether ALKS 3831 could be shown ineffective or unsafe during clinical studies; and those risks and uncertainties described in Item 1A under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in any other subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

ZYPREXA® is a registered trademark of Eli Lilly & Company.

[1]Komossa, K. et al. Olanzapine versus other atypical antipsychotics for schizophrenia. *Cochrane Database of Systematic Reviews*. 2010, Issue 3. Art. No.: CD006654.

[2]Regier, D. et al. Comorbidity of Mental Disorders With Alcohol and Other Drug Abuse. *JAMA*. 1990, 264: 2511-2518.

[3]National Institutes of Health. *Schizophrenia*. Accessed on Sept. 30, 2016 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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