Alkermes Announces Initiation of Second Phase 3 Study of ALKS 3831 for Schizophrenia

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— ENLIGHTEN-2 Will Evaluate Weight Gain Profile of Novel, Once-Daily, Oral Investigational Medicine Compared to Olanzapine —

DUBLIN--(BUSINESS WIRE)--Feb. 10, 2016-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of ENLIGHTEN-2, the second of two core phase 3 studies for ALKS 3831, an investigational, novel, oral atypical antipsychotic drug candidate designed to be a broad-spectrum treatment for schizophrenia. ENLIGHTEN-2 will evaluate the weight gain profile of ALKS 3831 in patients with schizophrenia over a six-month treatment period compared to olanzapine, an established atypical antipsychotic agent with proven efficacy but also metabolic liabilities, including significant weight gain. ALKS 3831 is designed to provide patients with the strong efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

“There is a clear and compelling clinical rationale for developing an antipsychotic with the efficacy of olanzapine and a safety profile that addresses the substantial negative health impact of weight gain and metabolic consequences associated with olanzapine,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “We are excited to continue to progress ALKS 3831 through pivotal development as a new, oral antipsychotic designed with the real-world needs of patients in mind and the potential to be a meaningful new treatment option for patients suffering with schizophrenia.”

ENLIGHTEN-2 is a multicenter, randomized, double-blind phase 3 study comparing weight gain of ALKS 3831 to olanzapine in approximately 540 patients with stable schizophrenia over six months. Safety and tolerability will also be evaluated in the study. All participants in the double-blind portion of the study will be eligible to continue in an open-label safety study of ALKS 3831 for an additional 12 months. The objective of the extension phase of the study is to assess the safety and long-term tolerability of once-daily, oral ALKS 3831.

About the ENLIGHTEN Clinical Program

The ENLIGHTEN pivotal program for ALKS 3831 is comprised of two key studies: a study evaluating ALKS 3831’s antipsychotic efficacy 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; 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 and the ENLIGHTEN pivotal trials for ALKS 3831 will be initiated or completed on time or at all; 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 described in the Alkermes plc Quarterly Report on Form 10-Q for the period ended Sept. 30, 2015 and Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, and in 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. 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 Feb. 9, 2016 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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