Alkermes Announces Initiation of Phase 2 Clinical Study of ALKS 3831, Designed to Be a Broad Spectrum Oral Antipsychotic for the Treatment of Schizophrenia

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– Study Will Evaluate ALKS 3831's Safety, Tolerability and Effect on the Attenuation of Weight Gain Associated With Olanzapine –

DUBLIN--(BUSINESS WIRE)--Jul. 17, 2013-- Alkermes plc (NASDAQ:ALKS) today announced the initiation of a phase 2 study of ALKS 3831, a novel oral atypical antipsychotic drug candidate designed to be a broad spectrum treatment for schizophrenia. The double-blind, active-controlled, dose-ranging study in approximately 400 patients with schizophrenia will assess ALKS 3831, a proprietary combination of a novel opioid modulator, ALKS 33, and olanzapine, an approved atypical antipsychotic medicine, compared to olanzapine alone. In addition to safety and tolerability, the phase 2 study is designed to evaluate the impact of ALKS 3831 on weight and other metabolic factors in patients and confirm the attenuation of olanzapine-induced weight gain observed in the phase 1 study of ALKS 3831.

"We have designed ALKS 3831 as a broad spectrum schizophrenia agent addressing two specific patient subpopulations: patients who may benefit from attenuation of the significant weight gain often associated with olanzapine treatment; and patients with a dual diagnosis of substance abuse disorder, which often exacerbates their schizophrenia," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "This large, well-designed phase 2 study will provide data necessary for us to determine ALKS 3831's ability to attenuate weight gain commonly associated with olanzapine treatment."

The ALKS 3831 comprehensive phase 2 clinical program is comprised of two separate studies, including the study announced today focused on the attenuation of weight gain associated with olanzapine. Weight gain is a common and clinically relevant metabolic side effect of atypical antipsychotic medications, and olanzapine has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs.[1] The second phase 2 study will investigate the potential utility of ALKS 3831 for the large number of patients with the dual diagnosis of schizophrenia and substance abuse disorder, a group representing as many as 50% of patients with schizophrenia.[2]

Phase 2 Study Design

The phase 2, double-blind, active-controlled, dose-ranging study is designed to assess the safety and tolerability of ALKS 3831, as well as evaluate the impact of ALKS 3831 on weight and other metabolic factors in comparison to olanzapine alone in approximately 400 adult patients with schizophrenia. In the study, following a one-week oral lead-in of olanzapine, patients will be randomly assigned to olanzapine or three different doses of ALKS 3831 for a period of 12 weeks, followed by a 12-week period in which all patients will receive ALKS 3831. Alkermes expects to provide topline results from the study in the first half of 2015.

About ALKS 3831

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is composed of ALKS 33, a novel potent mu-opioid antagonist, in combination with the established antipsychotic drug, olanzapine. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in patients with schizophrenia and comorbid substance abuse disorder.

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 Americans have schizophrenia, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and 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, including, but not limited to statements concerning: the therapeutic value of ALKS 3831 and clinical development plans for ALKS 3831. 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 projected or suggested 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 company will initiate studies for ALKS 3831 for dual-diagnosis patients; whether future clinical trials for ALKS 3831 will be 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 Annual Report on Form 10-K and Form 10-K/A for the year ended March 31, 2013, and in other 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 any forward-looking information contained in this press release.

[1]Komossa K, Rummel-Kluge C, Hunger H, Schmid F, Schwarz S, Duggan L, Kissling W, Leucht S. Olanzapine versus other atypical antipsychotics for schizophrenia. *Cochrane Database of Systematic Reviews*. 2010, Issue 3. Art. No.: CD006654.

[2]Koola M, Wehring H, Kelly D. The Potential Role of Long-acting Injectable Antipsychotics in People with Schizophrenia and Comorbid Substance Use. *Journal of Dual Diagnosis*. 2012, 8(1): 50–61.

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