Alkermes Announces Initiation of Second Phase 2 Clinical Study of ALKS 3831, a Novel Broad-Spectrum Oral Antipsychotic

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– Study Will Evaluate Efficacy, Safety and Tolerability of ALKS 3831 in Patients With Schizophrenia Whose Symptoms Are Exacerbated by Alcohol Use Disorder –

DUBLIN, Ireland--(BUSINESS WIRE)--Jun. 2, 2014-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of the second phase 2 study of ALKS 3831, a novel, oral, broad-spectrum antipsychotic medicine in development for schizophrenia. The randomized, double-blind, active-controlled study will assess ALKS 3831's efficacy, safety and tolerability in treating schizophrenia in patients with co-occurring alcohol use disorder, compared to olanzapine, an approved and widely used atypical antipsychotic medicine. More than one-third of patients with schizophrenia have a co-occurring alcohol use disorder,[1] a population that is commonly excluded from clinical trials and is often undertreated.

"Schizophrenia is a very challenging disease to treat and is frequently complicated by alcohol use, which can exacerbate symptoms and is associated with poor long-term outcomes," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "With this innovative study, we will evaluate whether the uniquely designed attributes of ALKS 3831 improve the treatment of schizophrenia for this subpopulation of patients."

This study is the second in the ALKS 3831 comprehensive phase 2 clinical program; the first phase 2 study was initiated in July 2013 and is designed to evaluate the attenuation of weight gain associated with olanzapine in patients with schizophrenia. 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.[2]

Phase 2 Study Design

This phase 2, randomized, double-blind, active-controlled study is designed to assess the efficacy, safety and tolerability of ALKS 3831 in adult patients with schizophrenia and co-occurring alcohol use disorder over a treatment period of up to 15 months. Approximately 450 patients will be enrolled in the study. The objective of this study is to compare symptom exacerbation between the two treatment groups. Alkermes expects to provide topline results from the study in mid 2017.

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 (formerly referred to as 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 whose disease is exacerbated by alcohol use.

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, 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, as amended, including, but not limited to statements concerning: the therapeutic value of ALKS 3831 and clinical development plans for ALKS 3831. The company cautions 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 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 Transition Report on Form 10-K for the fiscal period ended December 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] Regier D, Farmer M, Rae D, Locke B, Keith S, Judd L, Goodwin F. Comorbidity of Mental Disorders With Alcohol and Other Drug Abuse. *JAMA*. 1990, 264: 2511-2518.

[2] 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.

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