Alkermes Announces Completion of Patient Enrollment in Phase 2 Study of ALKS 3831, a Novel, Broad-Spectrum Oral Antipsychotic

September 3, 2014

– Study to Evaluate ALKS 3831's Efficacy, Safety and Tolerability in the Treatment of Schizophrenia and Attenuation of Olanzapine-Associated Weight Gain –

– Topline Data From 12-Week, Double-Blind Treatment Period Expected in Early 2015 –

DUBLIN--(BUSINESS WIRE)--Sep. 3, 2014-- Alkermes plc (NASDAQ: ALKS) today announced completion of patient enrollment in a phase 2 study of ALKS 3831, an investigational, novel, oral, broad-spectrum atypical antipsychotic medicine in development for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan, a novel, potent mu-opioid antagonist, in combination with the established antipsychotic drug, olanzapine. The double-blind, active-controlled, dose-ranging study will assess ALKS 3831's efficacy, safety and tolerability in the treatment of schizophrenia and its attenuation of weight gain, compared with olanzapine. Weight gain is a common and clinically relevant metabolic side effect of atypical antipsychotic medications. Clinical studies have demonstrated that olanzapine has one of the highest incidences and greatest amounts of weight gain among widely prescribed atypical antipsychotics.[1]

This double-blind, olanzapine-controlled phase 2 study randomized 309 patients at multiple centers in the U.S. and Europe. Alkermes expects topline results from the 12-week, double-blind treatment period of this phase 2 study in early 2015. The double-blind treatment period will be followed by an additional 12-week period in which all patients will receive ALKS 3831.

"There is a clear and compelling clinical rationale for developing an antipsychotic with the efficacy of olanzapine and a safety profile that addresses the negative health impact of weight gain associated with olanzapine," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "This clinical study of ALKS 3831 is designed to evaluate the efficacy of ALKS 3831 in the treatment of schizophrenia and its ability to attenuate olanzapine-associated weight gain. We are pleased to have now completed enrollment and look forward to reporting the results from this study early next year."

This study is the first of two studies in the ALKS 3831 phase 2 clinical program. The second phase 2 study was initiated in June 2014 and is designed to evaluate ALKS 3831 for the treatment of patients with schizophrenia and alcohol use. Alcohol use complicates the clinical course of more than one-third of patients with schizophrenia,[2] a population that is commonly excluded from clinical trials and is often undertreated.

Phase 2 Study Design

This phase 2, double-blind, active-controlled, dose-ranging study is designed to assess the efficacy, 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 in adult patients with schizophrenia. In the study, following a one-week oral lead-in of olanzapine, patients are 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.

About ALKS 3831

ALKS 3831 is a novel, 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 the treatment of schizophrenia in patients with 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[3], 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 Dec. 31, 2013, 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 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] 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.

[3] National Institutes of Health. Accessed on Sept. 2, 2014 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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