Alkermes Presents Positive Results from Phase 1 Study of ALKS 3831 as a Broad Spectrum Treatment for Schizophrenia

May 28, 2013

— Clinical Data Presented at the 53rd Annual NCDEU Meeting —

HOLLYWOOD, Fla. & DUBLIN--(BUSINESS WIRE)--May. 28, 2013-- Alkermes plc (NASDAQ: ALKS) today presented positive results from a phase 1 study of ALKS 3831, a novel drug candidate for the treatment of schizophrenia, in an oral session at the 53rd Annual New Clinical Drug Evaluation Unit (NCDEU) Meeting in Hollywood, Fla. By combining a novel opioid modulator, ALKS 33, and olanzapine, an antipsychotic drug commercially available as ZYPREXA®, ALKS 3831 is designed to be a broad spectrum treatment for schizophrenia with the potential benefits of reduced weight gain associated with olanzapine and expanded utility in patients with schizophrenia and comorbid substance abuse.

In the phase 1 study, subjects who received once-daily, oral administration of ALKS 3831 for three weeks demonstrated significantly less weight gain compared to subjects taking 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] Data from the phase 1 study showed that ALKS 3831 had a safety and tolerability profile similar to that observed in the olanzapine-only treatment group.

Based on the positive results of the phase 1 study, Alkermes plans to initiate a phase 2 dose-ranging study of ALKS 3831 in mid calendar 2013. This study will evaluate ALKS 3831's safety and effects on metabolic outcomes, including weight gain, in patients with schizophrenia. Additional studies will investigate ALKS 3831 for the large number of patients with the dual diagnosis of schizophrenia and substance abuse, a group representing as many as 50% of patients with schizophrenia.[2] A prior 400-patient phase 2 clinical study of ALKS 33, the opioid modulator in ALKS 3831, showed utility in reduction of heavy drinking in patients with alcohol dependence.

Elliot Ehrich, M.D., Chief Medical Officer of Alkermes commented, "We believe that the addition of the opioid modulating properties of ALKS 33 to olanzapine creates the opportunity for a broader spectrum schizophrenia treatment that may be a useful therapeutic option for physicians and patients in two important ways. First, we believe that ALKS 3831 has the potential to attenuate the clinically significant weight gain commonly seen with olanzapine, and diminishing this side effect could open its proven therapeutic benefits to a wider range of patients with schizophrenia. Second, we see potential applicability for the large number of patients with the dual diagnosis of schizophrenia and substance abuse – a group representing as many as half of patients with schizophrenia."

Study Design and Results

The phase 1, multicenter, randomized, double-blind, placebo- and active-controlled study was designed to compare the mean change from baseline in body weight following three weeks of oral administration of ALKS 3831 in a study that included 106 healthy, normal-weight male volunteers. The safety and tolerability results for ALKS 3831 were overall similar to those observed with the olanzapine-only treatment group. Healthy volunteers who received ALKS 3831 gained an average of 2.5 kg (5.5 lbs), while subjects who received olanzapine alone gained an average of 3.4 kg (7.5 lbs). The difference between the ALKS 3831 treatment group and the control group receiving olanzapine alone was statistically significant over the three-week study period (p=0.014), with a trend indicating the potential for even greater differentiation over longer study periods.

About ALKS 3831

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is comprised of ALKS 33, a novel opioid modulator that acts as a 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.

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 a phase 2 study for ALKS 3831; 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 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 at 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.

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

[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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