Alkermes Expands CNS Pipeline and Announces Positive Results from Phase 1 Study of ALKS 3831, a Novel Antipsychotic Therapy for the Treatment of Schizophrenia

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—Data Showed ALKS 3831 Significantly Attenuated Antipsychotic-Related Weight Gain —

—Alkermes Plans to Initiate Phase 2 Study in Mid Calendar 2013 —

DUBLIN--(BUSINESS WIRE)--Jan. 3, 2013-- Alkermes plc (NASDAQ: ALKS) today announced positive topline results from a phase 1 study of its new antipsychotic candidate, ALKS 3831, a combination of a proprietary drug molecule, ALKS 33, and olanzapine, a molecule that is commercially available under the name ZYPREXA®. ALKS 3831 is in development for the treatment of schizophrenia, a central nervous system (CNS) disease, and is designed to attenuate the antipsychotic-related metabolic side effect of weight gain.

The multicenter, randomized, double-blind, placebo- and active-controlled study was designed to compare the mean change from baseline in body weight in 106 healthy volunteers following three weeks of once-daily, oral administration of ALKS 3831, compared to olanzapine alone or placebo. Data from the study showed that patients administered ALKS 3831 demonstrated significantly less weight gain compared to patients taking olanzapine. Weight gain is a common and clinically relevant 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]

Based on the positive results of the phase 1 study, Alkermes plans to meet with the U.S. Food and Drug Administration (FDA) and initiate a phase 2 study of ALKS 3831 in mid calendar 2013. The company expects to present comprehensive data from the phase 1 study at an upcoming medical meeting.

“Based on these encouraging results, we are very excited to advance ALKS 3831 as one of our proprietary clinical candidates as we continue to expand Alkermes’ strength as a developer of novel CNS medications for unmet patient needs,” said Richard Pops, Chief Executive Officer of Alkermes. “ALKS 3831 is a prime example of the productivity of our R&D efforts that leverage Alkermes’ scientific expertise in opioid biology and pharmacology as well as the company’s clinical and commercial knowledge in the field of CNS disorders.”

“Antipsychotic-induced weight gain is a common side effect and area of medical concern in the treatment of patients with schizophrenia. We believe a combination therapy that could reduce the metabolic side effects of olanzapine, without inhibiting olanzapine’s antipsychotic activity, would provide significant value to physicians and patients,” stated Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “We are encouraged by these data showing statistically significant results with ALKS 3831 during a three-week study, and since weight gain continues to increase with ongoing use of antipsychotics, we look forward to evaluating ALKS 3831 in our longer-duration phase 2 clinical study, which we plan to initiate in mid calendar 2013.”

The phase 1, 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. ALKS 3831 was generally well tolerated in the study, and the safety and tolerability results for ALKS 3831 were similar to those observed with olanzapine alone. 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, a proprietary drug compound for the treatment of schizophrenia, is the combination of ALKS 33, a potent opioid modulator, and the established antipsychotic agent, olanzapine. Weight gain is a common and clinically relevant 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 weight gain side effect from atypical antipsychotics may be associated with the onset or exacerbation of diabetes and dyslipidemia, which are known risk factors for cardiovascular disease and mortality.[2]

In preclinical models, an ALKS 3831 regimen was shown to mitigate olanzapine-induced weight gain without affecting olanzapine’s ability to demonstrate efficacy in a standard preclinical model used to assess antipsychotic activity. In another preclinical study, ALKS 3831 was shown to attenuate olanzapine-induced weight gain and abdominal adipose accretion.

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 above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning the planned future development of ALKS 3831, including the expected timing of the phase 2 study; and the therapeutic value of ALKS 3831 and ALKS 33. 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; the company's business is subject to significant risk and uncertainties, and there can be no assurance that its actual results will not differ materially from its expectations.

These risks and uncertainties include, among others: whether preclinical and early clinical results for ALKS 3831 and ALKS 33 will be predictive of future clinical study results; whether future clinical trials for ALKS 3831 will be completed on time or at all; whether there will occur potential changes in cost, scope and duration of the ALKS 3831 clinical development program; whether ALKS 3831 or ALKS 33 could be shown ineffective or unsafe during clinical studies, and the company may not be permitted by regulatory authorities to undertake new or additional clinical studies for ALKS 3831 or ALKS 33; and those risks described in the company's Annual Report on Form 10-K for the year ended March 31, 2012, and in other filings made by the company with the Securities and Exchange Commission ("SEC") and 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]American Diabetes Association; American Psychiatric Association; American Association of Clinical Endocrinologists; North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care*. 2004;27:596-601.

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Alkermes Contacts:
For Investors:
Rebecca Peterson, +1 781 609 6378
or
For Media:
Jennifer Snyder, +1 781 609 6166