Alkermes Announces Results from Phase 2 Study of ALKS 33 for Treatment of Binge Eating Disorder

July 7, 2011

WALTHAM, Mass., Jul 07, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced topline results from a phase 2 clinical study of ALKS 33 in the treatment of binge eating disorder. This randomized, double-blind, placebo-controlled, 12-week study was designed to assess the safety and efficacy of daily oral administration of ALKS 33 or placebo in 68 patients with binge eating disorder. While ALKS 33 demonstrated a significant reduction from baseline in the efficacy endpoint of self-reported weekly binge eating episodes, the reduction was not significantly different from that observed with placebo. Based on these results, the company has determined that future studies in the binge eating indication are less attractive than other potential alternatives and will not pursue further development of ALKS 33 in this area.

ALKS 33 remains in development for other central nervous system indications based on the compound's favorable characteristics of once-daily dosing, limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 is currently being evaluated as a potential treatment for alcohol dependence and, in combination with buprenorphine as ALKS 5461, for cocaine addiction and treatment-resistant depression (TRD).

"The advantage of our R&D approach is that we are able to quickly determine a candidate's therapeutic viability for a particular indication in order to focus our resources on clinical candidates that show the most promise," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "Based on the results of this study, we will focus our future clinical development efforts on the other ALKS 33 development programs, including ALKS 5461 for TRD and cocaine addiction and ALKS 33 for alcohol dependence, as well as our other promising pipeline candidates including ALKS 9070 for schizophrenia and ALKS 37 for opioid-induced constipation."

Study Details

The phase 2, randomized, double-blind, placebo-controlled, 12-week study was designed to assess the safety and efficacy of daily oral administration of ALKS 33 in 68 patients with binge eating disorder. Binge eating episodes were defined using DSM-IV-TR[1] criteria and assessed based on interviews and review of take-home diaries at weekly physician visits.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol and opioid dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in Ohio. For more information, please visit Alkermes' website at http://www.alkermes.com/.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: the planned future development of ALKS 5461 for treatment-resistant depression and cocaine addiction, ALKS 9070 for schizophrenia, ALKS 33 for alcohol dependence and ALKS 37 for opioid-induced constipation; and the therapeutic value of the company's products. 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 early clinical results for ALKS 33 and ALKS 5461 will be predictive of future clinical study results; whether future clinical trials for ALKS 33, ALKS 5461, ALKS 9070 and ALKS 37 will be completed on time or at all; whether there will occur potential changes in cost, scope and duration of the ALKS 33, ALKS 5461, ALKS 9070 and ALKS 37 clinical trials; whether ALKS 33, ALKS 5461, ALKS 9070 or ALKS 37 could be shown ineffective or unsafe during clinical studies, resulting in regulatory authorities not permitting the continued development of such development candidates; and those risks described in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2011. 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]*Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*

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