Alkermes Announces Results from Phase 2 Study of ALKS 33 in Alcohol Dependence

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-- Safety, Dose Response and Efficacy of ALKS 33 in Alcohol Study Support Unique Pharmacologic Properties of Novel Oral Opioid Receptor Modulator --

WALTHAM, Mass., Dec 08, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced preliminary results from a phase 2 clinical study of ALKS 33, one of Alkermes' proprietary candidates for the treatment of reward disorders and other central nervous system (CNS) disorders. The 12-week study was designed to assess the safety and efficacy of daily oral administration of three different dose levels of ALKS 33 compared to placebo in 400 alcohol dependent patients. In addition to more traditional measurements of efficacy, the study also tested a new efficacy endpoint previously untested in a clinical trial, which was a measurement of complete abstinence from heavy drinking. The preliminary results of the study showed that once daily administration of ALKS 33 was generally well tolerated at all three dose levels. While the difference in complete abstinence from heavy drinking between treatment groups did not reach statistical significance, patients treated with all three doses of ALKS 33 demonstrated a significant reduction in heavy drinking days in a dose dependent manner compared to placebo. Patients on the highest dose of ALKS 33 showed the greatest relative reduction in heavy drinking days of 41% compared to placebo.

"ALKS 33 was well tolerated and showed a clear effect in reducing heavy drinking in this clinical trial. This study provides a large data set, which reinforces the potential clinical attributes of ALKS 33 and supports its expanded clinical development as an oral opioid modulator with potential utility in the treatment of a wide range of CNS disorders," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes.

ALKS 33 is characterized by its potential for daily dosing, non-hepatic metabolism, extended pharmacologic benefit in the event of missed doses and pharmacologic activity in modulating brain opioid receptors. ALKS 33 is currently being evaluated in clinical trials as a potential treatment for binge eating disorder and, in combination with buprenorphine, for cocaine addiction and potentially other disorders. Alkermes plans to meet with the U.S. Food and Drug Administration (FDA) to discuss the results of this phase 2 study and the potential endpoints for a phase 3 clinical study.

Study Details

The phase 2 study was designed to assess the safety, dose response and efficacy of daily oral administration of ALKS 33 in patients with alcohol dependence. In this multi-center, double-blind, placebo-controlled study, approximately 400 patients were randomized to receive daily oral administration of one of three doses of ALKS 33 or placebo for a total of 12 weeks of treatment. All subjects received psychosocial counseling. A number of efficacy assessments of drinking patterns were employed. The pre-specified primary endpoint was a novel endpoint not previously used in any clinical trial, which measured the percentage of patients who were completely abstinent from heavy drinking during the evaluation phase of weeks 5-12. Heavy drinking is defined as five or more drinks per day for men and four or more drinks per day for women. Percent of subjects who did not have any heavy drinking days during the evaluation phase were: placebo 13.9%, 1 mg 13.5%, 2.5 mg 17%, 10 mg 15.8%; p = NS. This complete abstinence from heavy drinking endpoint was not sensitive enough to capture the differences in drinking behavior observed in the study. In order to more fully evaluate drinking behavior over the course of the 12-week study, Alkermes also analyzed the data by the method employed in the VIVITROL® (naltrexone for extended-release injectable suspension) phase 3 clinical trial for alcohol dependence. This recurrent event analysis captures the cumulative rate of heavy drinking over the course of the 12-week study and incorporates all available drinking data. Using this methodology, all three doses showed statistically significant differences in heavy drinking compared to placebo. Subjects on the 10 mg dose showed a relative reduction in heavy drinking days of 41% compared to placebo (p=0.0006). The safety of ALKS 33 was also evaluated. ALKS 33 was generally well tolerated at all three dose levels with a clear dose response. Alkermes plans to present the full data set at an upcoming medical meeting.

About ALKS 33

ALKS 33 is an oral opioid modulator that builds on Alkermes' scientific expertise in opioid biology and pharmacology, as well as the company's clinical and commercial knowledge in the field of addiction and CNS disorders. In October 2009, Alkermes presented topline data from two phase 1 studies of ALKS 33. Data from the studies showed that ALKS 33 was generally well tolerated and successfully blocked the effects of an opioid, with a duration of action that supported once daily dosing. Previous findings also showed limited or no metabolism of ALKS 33 by the liver and extended pharmacological activity beyond one day. ALKS 33 is in clinical development for the treatment of alcohol dependence, binge eating disorder and as a combination therapy with buprenorphine for the treatment of cocaine addiction.

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 www.alkermes.com.

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, the potential therapeutic value of ALKS 33; whether the company will continue development of ALKS 33 for the treatment of alcohol dependence; and the timing, feasibility and completion of the company's clinical trials of 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 ALKS 33

will demonstrate sufficient efficacy and safety in subsequent trials; whether the company will continue to develop ALKS 33 for alcohol dependence; whether the FDA will require the company to use abstinence from heavy drinking as a primary endpoint for future clinical studies; potential changes in cost, scope and duration of the clinical trials; and whether ALKS 33 will be approved by regulatory authorities and subsequently commercialized. For further information with respect to factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports the company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this press release are made only as of the date hereof and the company disclaims any intention or responsibility for updating predictions or financial expectations contained in this press release.

VIVITROL® is a trademark of Alkermes, Inc. and RISPERDAL® CONSTA® is a trademark of Janssen-Cilag group of companies.

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