Alkermes Announces Positive Results from Phase 1 Study of ALKS 33 in Combination with Buprenorphine for Treatment of Cocaine Addiction

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-- Unique Pharmacologic Properties of ALKS 33 Allow for Non-Addictive Oral Therapy --

-- National Institute on Drug Abuse Grants Up to $2.4 Million to Alkermes to Accelerate the Clinical Development of Combination Therapy --

WALTHAM, Mass., Oct 25, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced positive topline results from a phase 1 clinical study of an investigational combination of ALKS 33, one of Alkermes' proprietary candidates, and buprenorphine, an existing medication for the treatment of opioid addiction, for the treatment of cocaine addiction. Data from the study showed that the combination therapy was generally well tolerated and sublingual administration of ALKS 33 effectively blocked the agonist effects of buprenorphine. Based on these positive results, Alkermes expects to initiate a phase 2a study of the combination therapy in the first half of calendar year 2011. The phase 2a study will be funded through a grant from the National Institute on Drug Abuse (NIDA). NIDA has granted Alkermes up to $2.4 million to accelerate the clinical development of the ALKS 33 and buprenorphine combination therapy. Currently, there are no medications approved for the treatment of cocaine addiction.

"We are excited to collaborate with NIDA and leverage our ongoing clinical and preclinical work with ALKS 33 to explore a potential new non-addictive therapy for cocaine addiction," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "We look forward to continuing the recent momentum in our research and development efforts by initiating a phase 2a clinical trial to generate further data, as we advance the ALKS 33 and buprenorphine combination therapy as part of Alkermes' growing pipeline of proprietary product candidates."

Buprenorphine is widely used for the treatment of opioid addiction, despite its own potential for abuse. Combining ALKS 33, an opioid modulator, with buprenorphine, a partial opioid agonist, may block the agonist effects of buprenorphine thereby reducing the potential for the development of opioid dependence while still maintaining effective therapeutic action. Furthermore, the unique pharmacologic properties and low dose of ALKS 33 required to effectively block mu opioid receptors may allow for a co-formulation with buprenorphine as a single sublingual tablet.

The phase 1 study was a randomized, double-blind, multi-dose, placebo-controlled clinical trial that assessed the safety, tolerability and pharmacodynamic effects of the combination of ALKS 33 and buprenorphine when administered alone and in combination to 12 opioid-experienced users. Sublingual administration of ALKS 33 effectively blocked the objective and subjective measures of opioid agonism of co-administered buprenorphine in a dose-related manner. The combination therapy was generally well tolerated in the phase 1 study and Alkermes plans to present the full results of the phase 1 study at a future 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. 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 supports once daily dosing. Previous findings have also shown that ALKS 33 has limited or no metabolism by the liver, a unique advantage over existing oral therapies for 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.

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, alone and in combination with buprenorphine; whether Alkermes and NIDA will continue development of the ALKS 33 and buprenorphine compound; 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 and 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: the investigational combination therapy of ALKS 33 and buprenorphine may not demonstrate sufficient efficacy and safety in subsequent trials; clinical trials may take more time or consume more resources than initially envisioned and they may not be completed on time or at all; the results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results of larger clinical trials; and NIDA may not continue to fund ongoing research of the combination of ALKS 33 and buprenorphine. 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 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 release.

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