Alkermes Initiates Phase 2 Clinical Study of ALKS 33 for the Treatment of Alcohol Dependence

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— Company Continues to Advance Clinical Pipeline —

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 17, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 2 clinical study of ALKS 33, an investigational oral opioid modulator for the potential treatment of alcohol dependence and other central nervous system disorders. The study will assess the safety and efficacy of multiple doses of ALKS 33 in patients with alcohol dependence and is designed to further define the clinical profile of ALKS 33.

“The advancement of ALKS 33 in the clinic is an important step as we continue to build our proprietary pipeline, which is based on drugs that we believe have a high likelihood of clinical and commercial success,” stated Elliot Ehrich, M.D., Chief Medical Officer at Alkermes. “We expect to use the results from this phase 2 study to shape our plans for phase 3 clinical development.”

The phase 2 study is designed to assess the safety and efficacy of ALKS 33 in patients with alcohol dependence. In this multi-center, double-blind, placebo-controlled study, up to 440 patients will be randomized to receive daily oral administrations of one of three doses of ALKS 33 or placebo for a total of 12 weeks of treatment. The phase 2 study has an adaptive study design which enables an interim analysis after 40 percent of the patients are enrolled and on medication for eight weeks of treatment. The efficacy of ALKS 33 will be evaluated based on the percentage of patients who are abstinent from heavy drinking during the eight-week evaluation phase. Heavy drinking is defined as five or more drinks per day for men and four or more drinks per day for women. The pharmacokinetics and safety of ALKS 33 will also be evaluated.

About ALKS 33

ALKS 33 is an oral opioid modulator that builds on Alkermes’ unique understanding of biological pathways and opioid 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 clinical trials of ALKS 33. Data from the studies showed that ALKS 33 was generally well tolerated and demonstrated rapid oral absorption, high plasma concentrations and duration of action that supports once daily dosing. ALKS 33 was also shown to successfully block the effects of an opioid agonist for more than 24 hours following a single administration.

About Opioid Modulators

Opioid modulators can act as agonists, antagonists or partial agonists at opioid receptors throughout the body. Emerging biological research and new medicinal chemistry insights now allow for the development of novel opioid modulators with the potential to show enhanced activity at opioid receptor sites and could ultimately lead to improved therapeutic options.

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 dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities 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 and commercial value of Alkermes’ proprietary molecules targeting opioid receptors, including ALKS 33; the potential success of the Phase 2 study of ALKS 33 and Alkermes’ plans to continue development of such proprietary molecules. 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 the phase 2 clinical trial discussed in this release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trial; whether ALKS 33 will demonstrate sufficient efficacy and safety; and decisions by the U.S. Food and Drug Administration regarding ALKS 33. 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.

Source: Alkermes, Inc.

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