



Alkermes Initiates Clinical Trial for ALKS 33, a Novel Oral Molecule with Potential Benefits in Addiction and Other CNS Disorders

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-- ALKS 33 is the Company's First New Small Molecule Drug Candidate to Enter the Clinic --

-- Company Continues Progress with Addiction Programs, Including ALKS 29 --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 4, 2008--Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 1 study of ALKS 33, an oral opioid modulator for the potential treatment of addiction and other central nervous system (CNS) disorders. ALKS 33 is the company's first novel, small molecule drug candidate to enter the clinic. The molecule builds on Alkermes' scientific expertise in brain reward pathways as well as the company's clinical and commercial knowledge in the field of addiction. In addition, Alkermes initiated a clinical pharmacokinetic study to further explore ALKS 29, a potential oral treatment for alcohol dependence.

"The progress of these two candidates clearly demonstrates our commitment to building a commercial enterprise with promising prospects for growth," said David Broecker, president and CEO of Alkermes. "The combination of our strong financial health, the success of two commercial products and our proven science puts Alkermes in a unique position to create new proprietary product opportunities that have the potential to help address the needs of a broad range of patients."

The phase 1 randomized, double-blind, placebo-controlled study for ALKS 33 will enroll 16 healthy volunteers and is designed to assess the pharmacokinetics, safety and tolerability of ALKS 33 following single oral administration at escalating dose levels. The company expects to report top-line results from the study in the first half of calendar 2009. Initiation of this trial is based on recent data from preclinical studies that showed ALKS 33 demonstrated statistically superior oral efficacy compared to naltrexone. The studies also suggested that ALKS 33 is not readily metabolized by the liver, a unique advantage over existing oral therapies for addiction.

"There are few medications available to help patients struggling to overcome addictions and new treatment options are desperately needed," said Elliot Ehrich, M.D., chief medical officer of Alkermes. "We believe that the addiction field will evolve in a similar way to other CNS markets, such as mental illnesses, where treatments include both oral and injectable medications. This flexible approach offers patients and doctors the option to build the most appropriate therapies into treatment programs and fit the needs of individual patients."

As part of the company's strategy, Alkermes is planning additional preclinical studies of ALKS 33 for other CNS disorders and has also initiated a phase 1 study of ALKS 29, a potential oral treatment for alcohol dependence. The open-label crossover study is designed to assess the pharmacokinetics, safety and tolerability of ALKS 29 compared to an oral control. The company expects to report top-line results from the study in the first half of calendar 2009.

The development of these two candidates further underscores the significant expertise in and commitment to the area of addiction at Alkermes. VIVITROL(R), the company's first commercial product in addiction, is currently approved for the treatment of alcohol dependence in the U.S. and Russia. VIVITROL is the only once-monthly injectable medication approved for the treatment of alcohol dependence.

About Opioid Modulators

Opioid modulators can act as agonists, antagonists or partial agonists at opioid receptors in the brain. In addition to the treatment of alcohol dependence, opioid dependence and other addictions, opioid modulators are thought to have a number of clinical applications, including the treatment of CNS disorders and impulse-control disorders.

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(R) for alcohol dependence and manufactures RISPERDAL(R) CONSTA(R) for schizophrenia. 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 value of Alkermes' proprietary molecules targeting opioid receptors 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 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: whether the clinical trials discussed in this release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trials; whether the company's product candidates will demonstrate sufficient efficacy and safety; and decisions by the FDA regarding such product candidates. 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.

VIVITROL(R) is a registered trademark of Cephalon, Inc. RISPERDAL(R) CONSTA(R) is a registered trademark of Janssen-Cilag group of companies.

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