Alkermes Announces Positive Results for Phase 1 Study of New Drug Candidate for Treatment of Opioid-Induced Constipation

February 16, 2010

- ALKS 37 Targets Gastrointestinal Track with Limited Systemic Exposure-
- Company Plans to Initiate Additional Clinical Studies in First Half of Calendar 2010 -

WALTHAM, Mass., Feb 16, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced positive topline data from a phase 1 clinical study of ALKS 37, an orally active, peripherally-restricted opioid antagonist with potential to block the effects of opioid agonists on gastrointestinal motility, commonly referred to as opioid-induced constipation (OIC). Data from the study showed that ALKS 37 was generally well tolerated and as predicted, demonstrated low systemic exposure across a wide range of doses. Based on these positive results, Alkermes expects to initiate a multi-dose phase 1 study in March 2010 as well as a phase 2 study to assess safety, tolerability and efficacy of ALKS 37 in individuals with OIC by the end of the first half of calendar 2010.

The completed phase 1 study was a randomized, double-blind, placebo-controlled clinical trial that assessed the safety, tolerability and pharmacokinetics of a single oral administration of five ascending doses of ALKS 37, from 1 mg to 100 mg, in 40 healthy volunteers. At doses up to 100 mg there was low systemic exposure, consistent with prior preclinical results indicating that ALKS 37 targets the gastrointestinal tract with limited systemic exposure and little to no central nervous system (CNS) penetration. ALKS 37 was generally well tolerated in the phase 1 study and Alkermes plans to present the full results of the phase 1 study of ALKS 37 at a future medical meeting.

"We believe that these phase 1 data support our view that ALKS 37 may have a unique clinical profile because it targets the gastrointestinal tract and showed low systemic exposure," 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 two additional clinical trials to generate further data, as we advance ALKS 37 as part of Alkermes' growing pipeline of proprietary product candidates."

Upcoming Studies of ALKS 37

Based on these positive phase 1 clinical results, Alkermes plans to initiate a phase 1 multi-dose study of ALKS 37 in March 2010. The study, ALK37-002, is a randomized, double-blind, placebo-controlled repeat dose study designed to assess the safety, tolerability and pharmacokinetics of daily oral administration of two dose levels of ALKS 37 for a seven day period in 24 healthy volunteers. These results will support the phase 2 clinical study, which is expected to begin in the first half of calendar 2010.

About ALKS 37, ALKS 36 and Opioid-Induced Constipation

ALKS 37 is a component of ALKS 36, a combination drug candidate for the treatment of pain without the side effects of constipation. Preclinical studies with ALKS 37 demonstrated the potential to reverse opioid agonist effects on gastrointestinal motility by oral dosing with low systemic exposure and little to no CNS penetration. Preclinical data also showed that oral administration of ALKS 37 had a greater effect on GI motility at a lower dose and for a longer period of time compared to an active comparator, methylnaltrexone. According to IMS Health, over 200 million prescriptions were written for opioids in 2007 in the United States. Many studies indicate that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility.

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 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 Alkermes' proprietary molecules targeting opioid receptors, including ALKS 37 and ALKS 36, 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 preclinical and early clinical results will be predictive of future clinical study results; 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; and whether ALKS 37 and ALKS 36 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 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.

Alkermes
For Investors:
Rebecca Peterson, 781-609-6378
or
For Media:
Eva Stroynowski, 781-609-6823