# Alkermes Announces Initiation of Multidose Phase 1 Clinical Study of ALKS 37 for the Treatment of Opioid-Induced Constipation

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WALTHAM, Mass., Mar 17, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a multidose 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). The randomized, double-blind, placebo-controlled, repeat-dose study will assess the safety, tolerability and pharmacokinetics of daily oral administration of two dose levels of ALKS 37 for a seven day period in approximately 24 healthy volunteers.

"We are pleased to be advancing ALKS 37 quickly through the clinic as it may have the potential to reverse this severe side effect of opioid administration with low systemic exposure and little to no central nervous system penetration," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "ALKS 37, one of several proprietary product candidates in our growing clinical pipeline, is an excellent example of how the company is leveraging its unique understanding of opioid biology and pharmacology to develop medications with potential advantages over currently available therapies."

This phase 1 multidose study follows completion of a previous single dose clinical study in healthy volunteers, which showed that ALKS 37 was generally well tolerated and demonstrated low systemic exposure across a wide range of doses. These results will support a phase 2 clinical study of ALKS 37, which will assess the safety, tolerability and efficacy of ALKS 37 in individuals with OIC. The phase 2 study is expected to begin in the first half of calendar 2010.

**ALKS 37 Phase 1 Study Design**

The phase 1 study of ALKS 37 is a randomized, double-blind, placebo-controlled, repeat-dose study designed to assess the safety, tolerability and pharmacokinetic effects of daily oral administration of ALKS 37 for a seven day period in approximately 24 healthy volunteers. Two dose levels of ALKS 37 will be tested in sequential cohorts.

**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 the effects of opioid agonists on gastrointestinal motility by oral dosing with low systemic exposure and little to no central nervous system penetration, with low systemic exposure confirmed in the clinic. Preclinical data also showed that oral administration of ALKS 37 had a greater effect on gastrointestinal 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 results will be predictive of clinical results; whether the phase 1 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; 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.

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