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

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- Proprietary Oral NCE Designed to Improve Gastrointestinal Motility in Patients Taking Opioid Analgesics -

- Preclinical Comparisons with Active Agents in this Class Indicate ALKS 37 has Potential to be Efficacious at Lower Doses and for an Extended Period of Time with Low Systemic Exposure -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 27, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of ALKS 37, an orally active, peripherally-restricted opioid antagonist with potential to block the opioid agonist effects on gastrointestinal motility, commonly referred to as opioid-induced constipation (OIC). The randomized, double-blind, placebo-controlled study will assess the safety, tolerability and pharmacokinetic effects of a single oral administration of five doses of ALKS 37 in approximately 40 healthy volunteers. Preclinical studies have shown ALKS 37 targets the gastrointestinal tract following oral administration, with limited systemic exposure. ALKS 37 is a component of ALKS 36, a combination drug candidate for the treatment of pain without the side effects of constipation.

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.

"While opioids are a common and effective treatment for managing chronic pain, the side effects of these medications can be debilitating and may diminish patient adherence to pain medication," stated Daniel Deaver, Ph.D., Vice President, Non-Clinical Development of Alkermes. "We are excited to bring forward ALKS 37 into the clinic as it has the potential to enable the use of pain medications without inhibiting gastrointestinal motility."

“Our unique understanding of opioid biology and pharmacology allowed us to take a very innovative approach to the development of a GI-targeted therapy such as ALKS 37,” said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. “Today’s announcement is a testament to our advancing proprietary pipeline.”

ALKS 37 Study Design

The phase 1 study of ALKS 37 is a randomized, double-blind, placebo-controlled study designed to assess the safety, tolerability and pharmacokinetic effects of a single oral administration of five doses of ALKS 37 in approximately 40 healthy volunteers. Initiation of this trial is based on preclinical studies that showed ALKS 37 demonstrated the potential to reverse opioid agonist effects on gastrointestinal motility with low systemic exposure and little or no CNS penetration. Preclinical data also showed that oral administration of ALKS 37 had greater efficacy at a lower dose and for an extended period of time compared to an active comparator, methylnaltrexone. The company expects to report top-line results from the study in the first half of calendar 2010.

In addition to ALKS 37, Alkermes is developing ALKS 36, an oral co-formulation of an opioid analgesic and ALKS 37. A pain medication that does not inhibit gastrointestinal motility, such as ALKS 36, may provide a unique advantage over current therapies.

About Opioid Modulators

Opioid modulators can act as antagonists, agonists 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 receptors and could ultimately lead to improved therapeutics.

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 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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