Alkermes Announces Positive Results From Two Clinical Trials of ALKS 33

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— Novel Oral Molecule Has Potential Benefits in Addiction and Other Central Nervous System Disorders —

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 13, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced positive topline data from two clinical trials of ALKS 33, an investigational oral opioid modulator for the treatment of addiction and other central nervous system disorders. Data from the studies, ALK33-003 and ALK33-004, showed that ALKS 33 was generally well tolerated and successfully blocked the effects of an opioid, with a duration of action that supports once daily dosing. Based on these results, Alkermes expects to initiate a phase 2 study of ALKS 33 by the end of calendar 2009.

“The data for ALKS 33 demonstrate our ability to develop new chemical entities based on our unique understanding of biological pathways and opioid pharmacology and sets the stage for the next phase of growth for our pipeline,” said Elliot Ehrich, M.D., Chief Medical Officer at Alkermes. “We look forward to moving ALKS 33 into phase 2 development.”

Trial Designs and Results

ALK33-003 was a phase 1 randomized, double-blind, placebo-controlled, multi-dose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33. Thirty healthy subjects were randomized to receive seven consecutive, daily oral doses of one of two dose levels of ALKS 33 or placebo. In the study, ALKS 33 demonstrated rapid oral absorption and sustained pharmacologically active plasma levels that support once daily dosing.

ALK33-004 was a phase 1, randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the subjective and objective effects of a potent opioid agonist, remifentanil, a commercially available analgesic. Twenty-four healthy, non-dependent, opioid-experienced subjects were randomized to receive a placebo dose as well as one of two dose levels of ALKS 33, the same doses investigated in ALK33-003. Data showed that the onset of action of ALKS 33 was rapid and observed as early as 15 minutes following oral administration. A full blockade of the opioid agonist was observed and sustained for more than 24 hours following a single administration of ALKS 33. ALKS 33 was generally well tolerated in both studies.

About Opioid Receptor Pathways

Opioid receptor pathways have biological activity throughout the body including the brain, gastrointestinal system, immune system and cardiovascular system. Consequently, opioid receptor pathways play a key role in a broad range of nervous system disorders such as pain, addiction, psychiatric disorders, gastrointestinal disorders and immune disorders. 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 value of Alkermes’ proprietary molecules targeting opioid receptors, including 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 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 ALKS 33 will demonstrate sufficient efficacy and safety in subsequent trials; potential changes in cost, scope and duration of the clinical trials; and whether ALKS 33 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.

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