Alkermes Initiates Two New Clinical Trials Of ALKS 33

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May. 13, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of two new clinical trials of ALKS 33, an oral opioid modulator for the potential treatment of addiction and other nervous system disorders. Study ALK33-004 is a phase 1 clinical trial designed to examine the ability of ALKS 33 to block the effects of an opioid following a single oral dose of ALKS 33 in healthy, non-dependent, opioid-experienced subjects. Study ALK33-003 is a phase 1 clinical trial designed to evaluate the pharmacokinetics, safety and tolerability of multiple doses of ALKS 33 in healthy volunteers.

The initiation of these studies follows the successful completion of a phase 1 dose escalation study of ALKS 33 in healthy volunteers. Alkermes expects to report data from both ALK33-004 and ALK33-003 in the second half of calendar 2009.

“ALKS 33 is an excellent example of how Alkermes is leveraging its new insights about opioid receptor pathways to develop medications with unique advantages over currently available therapies,” stated Elliot Ehrich, M.D., chief medical officer at Alkermes. “We expect to use the data from these additional phase 1 studies to shape our plans for phase 2 clinical development.”

ALKS 33 Study Designs

ALK33-004 is a phase 1, randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the effects of an opioid agonist, remifentanil, a commercially available analgesic. Approximately 24 healthy, non-dependent, opioid-experienced subjects will be randomized to receive a placebo dose as well as one of two dose levels of ALKS 33. The ability of ALKS 33 to block the effects of remifentanil will be measured by pupillometry assessments and subjective measures of opioid effects. The pharmacokinetics and safety of ALKS 33 will also be evaluated.

ALK33-003 is a phase 1 randomized, double-blind, placebo-controlled, multi-dose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33. Approximately 30 healthy subjects will be randomized to receive seven consecutive, daily oral doses of one of two dose levels of ALKS 33 or placebo.

About ALKS 33

ALKS 33 is an oral opioid modulator that 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 April 2009, Alkermes presented topline data from a phase 1 randomized, double-blind, placebo-controlled study of ALKS 33 in 16 healthy volunteers. Data from the study showed that ALKS 33 was generally well tolerated and demonstrated rapid oral absorption, high plasma concentrations and duration of action that supports once daily dosing. The study results are consistent with previous findings that ALKS 33 is not metabolized by the liver, a unique advantage over existing oral therapies for addiction.

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. 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 the phase 1 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 U.S. Food and Drug Administration 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® is a registered trademark of Alkermes, Inc. RISPERDAL® CONSTA® is a registered trademark of Janssen-Cilag group of companies.

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