Alkermes Announces Positive Results from Clinical Study of ALKS 9070 For Treatment of Schizophrenia

June 30, 2011

- Company Plans to Initiate Pivotal Development Program by End of Calendar 2011 -

WALTHAM, Mass., Jun 30, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced positive topline results from a phase 1b, double-blind, randomized, placebo-controlled study of ALKS 9070 in patients with schizophrenia. ALKS 9070, a proprietary Alkermes molecule for the treatment of schizophrenia, is designed to provide patients with once-monthly dosing of a medication that, once in the body, converts into aripiprazole, a molecule that is commercially available under the name ABILIFY® for the treatment of a number of central nervous system (CNS) disorders. Data from the study showed that ALKS 9070 was generally well tolerated, achieved therapeutically relevant plasma concentrations of aripiprazole with a pharmacokinetic profile that supports once-monthly dosing. Based on these results, Alkermes plans to advance ALKS 9070 into pivotal development by the end of calendar 2011.

"We are extremely encouraged by these positive results for ALKS 9070 as a potential treatment for schizophrenia. Alkermes' expertise in developing safe and effective long-acting therapeutics uniquely positions us to develop a once-monthly atypical antipsychotic medication that delivers aripiprazole, a widely prescribed oral product with an established safety and proven efficacy profile," stated Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "Based on these results, we look forward to advancing ALKS 9070 into pivotal studies."

The study was a randomized, multicenter, double-blind, placebo-controlled, 20-week study that assessed the safety, tolerability and pharmacokinetics of a single administration of three ascending doses of ALKS 9070 in 32 patients with chronic, stable schizophrenia. Dose proportionality was achieved across all three dose levels. ALKS 9070 was generally well tolerated at all three dose levels and there were no serious adverse events related to study drug. The company will meet with the U.S. Food and Drug Administration (FDA) for an end of phase 2 meeting and full results from the trial will be submitted to an upcoming medical meeting.

About LinkeRx(TM) and ALKS 9070

LinkeRx is a novel, proprietary technology platform that enables the creation of injectable extended-release atypical antipsychotics and other CNS therapies. ALKS 9070, which leverages the LinkeRx technology, is a once-monthly, injectable atypical antipsychotic in development for the treatment of schizophrenia. Once in the body, ALKS 9070 converts to aripiprazole. Aripiprazole is commercially available under the name ABILIFY® for the treatment of a number of CNS disorders.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans have schizophrenia, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness.

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 and opioid dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable 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. For more information, please visit Alkermes' website at http://www.alkermes.com/.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: statements concerning the planned future development of ALKS 9070, including the expected timing of the pivotal development program; and the therapeutic value of the company's products. You are cautioned that forward-looking statements are inherently uncertain.

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 they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and early clinical results for ALKS 9070 will be predictive of future clinical study results; whether the company will initiate a pivotal development program for ALKS 9070 by the end of calendar 2011; whether future clinical trials for ALKS 9070 will be completed on time or at all; potential changes in cost, scope and duration of the ALKS 9070 clinical trials; whether ALKS 9070 is shown to be ineffective or unsafe during clinical studies; and those risks described in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2011. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained in this press release.

ABILIFY® is a registered trademark of Otsuka Pharmaceutical Co., Ltd.

SOURCE: Alkermes, Inc.

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