Alkermes Initiates Phase 3 Clinical Study of ALKS 9070 for Treatment of Schizophrenia

December 19, 2011

-- ALKS 9070 Is Designed to Offer Best-in-Class, Extended-Release, Once-Monthly Version of Aripiprazole --

DUBLIN--(BUSINESS WIRE)--Dec. 19, 2011-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a phase 3 clinical trial of ALKS 9070 for the treatment of schizophrenia. ALKS 9070, a proprietary Alkermes molecule, 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. The multicenter, double-blind, placebo-controlled study is designed to assess the efficacy, safety and tolerability of ALKS 9070 in approximately 690 patients experiencing acute exacerbation of schizophrenia. The clinical data from this study, expected mid-calendar 2013, will form the basis of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ALKS 9070 for the treatment of schizophrenia, a chronic brain disease.

“Multiple studies have shown that long-acting therapies in the treatment of schizophrenia can lead to improved patient outcomes and reduced costs,” stated Dr. Herbert Meltzer, Professor of Psychiatry at Feinberg School of Medicine and Director of the Division of Neuropsychopharmacology at Northwestern University. “An extended-release injectable medication that incorporates the unique clinical properties and established safety and efficacy of aripiprazole would represent a significant treatment advancement for patients and physicians to manage this serious, chronic disease.”

In June 2011, Alkermes announced data from a phase 1b double-blind, randomized, placebo-controlled clinical study of ALKS 9070 in 32 patients with schizophrenia. Data from the study showed that ALKS 9070 was generally well tolerated and achieved therapeutically relevant plasma concentrations of aripiprazole with a pharmacokinetic profile that supports once-monthly dosing.

“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 efficacy profile,” stated Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. “The advancement of ALKS 9070 into pivotal development marks an important milestone for the program, and we look forward to seeing the results in mid-2013.”

Phase 3 Study Design

The phase 3 randomized, multicenter, double-blind study is designed to assess the efficacy, safety and tolerability of ALKS 9070 compared to placebo in patients experiencing acute exacerbation of schizophrenia. Approximately 690 subjects will be randomized to receive once-monthly intramuscular injections of ALKS 9070 300 mg, ALKS 9070 600 mg or placebo for twelve weeks. In addition, subjects will receive oral study drug for the first three weeks after randomization. Subjects randomized to one of the two ALKS 9070 treatment groups will receive oral aripiprazole, while subjects randomized to the placebo group will receive matching oral placebo. The primary efficacy endpoint of the study is the change in Positive and Negative Syndrome Scale (PANSS) total score from baseline. All participants in the double-blind portion of the study will be eligible to continue in an open-label phase and receive ALKS 9070 for an additional 12 months. The objective of the extension phase of the study is to assess the safety and long-term durability of effect of once-monthly ALKS 9070.

About LinkeRx™ 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 plc

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. For more information, please visit Alkermes’ website at http://www.alkermes.com.

Note Regarding Forward-Looking Statements

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 continued clinical development of ALKS 9070 for the treatment of schizophrenia and the therapeutic value and potential of ALKS 9070. 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. 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 and early clinical results for ALKS 9070 will be predictive of future clinical study results; whether ALKS 9070 is shown to be ineffective or unsafe during clinical studies; decisions by the FDA or foreign regulatory authorities regarding ALKS 9070 for the treatment of schizophrenia; potential changes in cost, scope and duration of the phase 3 clinical trial of ALKS 9070 for the treatment of schizophrenia; and those risks described in the Alkermes, Inc. Annual Report on Form 10-K, as amended, for the year ended March 31, 2011; in our Registration Statement on Form S-4 (commission file number 333- 175078) which was declared effective by the Securities and Exchange Commission ("SEC") on August 4, 2011; and in other filings made by the company with the SEC, which are available at the SEC's website at http://www.sec.gov. 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.

Source: Alkermes plc

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