Alkermes Announces Completion of Patient Enrollment in Pivotal Phase 3 Study of Aripiprazole Lauroxil

October 8, 2013

- Prespecified Interim Analysis of Sample Size Indicates Study Well-Powered to Evaluate Primary Endpoint –

DUBLIN--(BUSINESS WIRE)--Oct. 8, 2013-- Alkermes plc (NASDAQ: ALKS) today announced completion of patient enrollment in the pivotal, multinational phase 3 study evaluating aripiprazole lauroxil in patients with schizophrenia. Aripiprazole lauroxil 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®. Alkermes continues to expect topline results from the phase 3 study in the first half of 2014.

Enrollment was completed following a prespecified interim analysis of sample size. This analysis, designed to preserve the integrity of the final efficacy analysis and performed by an independent statistical center, indicated that a sample size of 540 patients or more would have sufficient statistical power to evaluate the primary endpoint. The study continues to be blinded until completion.

“There is a clear and compelling need for long-acting injectable medicines for patients with schizophrenia,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “We are excited to complete enrollment in this carefully conducted, multinational study and look forward to reporting the results in the first half of 2014.”

The phase 3 pivotal clinical trial of aripiprazole lauroxil is a 12-week, multicenter, double-blind, placebo-controlled study designed to assess the efficacy, safety and tolerability of aripiprazole lauroxil in patients experiencing acute exacerbation of schizophrenia. The primary endpoint is the change from baseline in Positive and Negative Syndrome Scale (PANSS) total score, which is a standard outcome measure in the evaluation of schizophrenia treatment. The clinical data from this study will form the basis of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for aripiprazole lauroxil for the treatment of schizophrenia.

About Aripiprazole Lauroxil and LinkeRx®

LinkeRx is a novel, proprietary technology platform developed by Alkermes that enables the creation of injectable extended-release atypical antipsychotics and other central nervous system therapies. Aripiprazole lauroxil, which utilizes the LinkeRx technology, is a once-monthly, injectable atypical antipsychotic in phase 3 clinical development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts to aripiprazole, which is commercially available under the name ABILIFY. Aripiprazole lauroxil was formerly referred to as ALKS 9070.

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[1], 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 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; a research and manufacturing facility in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio. For more information, please visit Alkermes’ website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning the sufficiency of the prespecified interim analysis and sample size to evaluate the primary endpoint; the timing of receipt and disclosure of topline phase 3 study results; and that the phase 3 results will form the basis of an NDA to the FDA. The company cautions 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: the phase 3 study of aripiprazole lauroxil may be unsuccessful or not completed in a timely manner; regulatory submissions may not occur or be submitted in a timely manner; the company’s products may not show sufficient therapeutic effects or acceptable safety profiles; adverse decisions by regulatory authorities may occur; existing clinical and preclinical data with respect to our products may not be indicative of future clinical results; the company may be unable to manufacture successfully our products; and those risks described in the Alkermes plc Annual Report on Form 10-K and Form 10-K/A for the year ended March 31, 2013, and in other filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available at the SEC’s website at 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.

[1]National Institutes of Health. Accessed on Oct. 7, 2013 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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

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