Alkermes Announces Notice of Allowance of Key U.S. Patent for Aripiprazole Lauroxil, a New Schizophrenia Drug Candidate

January 3, 2013

—Patent Protection Expected Into Late 2030 for Extended-Release, Once-Monthly Prodrug of Aripiprazole —

—Aripiprazole Lauroxil Designated as Generic Name for ALKS 9070 —

DUBLIN--(BUSINESS WIRE)--Jan. 3, 2013-- Alkermes plc (NASDAQ: ALKS) today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application 12/823,007, titled "Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders." The allowed claims will cover a class of compounds that includes aripiprazole lauroxil, a proprietary Alkermes molecule formerly referred to as ALKS 9070, which is in development for the treatment of 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® for the treatment of a number of central nervous system (CNS) disorders.

Given this action, Alkermes expects the patent to issue within the next month and provide a patent term that would expire no earlier than 2030. A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application.

"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 Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "With data from our phase 3 study for aripiprazole lauroxil anticipated in late 2013 and expected patent protection into late 2030, we look forward to advancing aripiprazole lauroxil as a potential new treatment option for patients with schizophrenia."

In December 2011, Alkermes announced the initiation of a phase 3 clinical trial of aripiprazole lauroxil for the treatment of schizophrenia. The 12-week, multicenter, double-blind, placebo-controlled study is designed to assess the efficacy, safety and tolerability of aripiprazole lauroxil in approximately 690 patients experiencing acute exacerbation of schizophrenia. The clinical data from this study, expected in late calendar 2013, 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 CNS therapies. Aripiprazole lauroxil, which leverages the LinkeRx technology, is a once-monthly, injectable atypical antipsychotic in development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts to aripiprazole. Aripiprazole is commercially available under the name ABILIFY® for the treatment of a number of CNS disorders. 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, 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; 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 above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to: whether Patent Application 12/823,007 will issue; whether such patent will adequately protect the pharmaceutical composition of aripiprazole lauroxil against competition; the expiration date and strength of such patent; the timing and successful completion of the phase 3 trial of aripiprazole lauroxil for the treatment of schizophrenia; and the therapeutic value and potential of aripiprazole lauroxil. 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 Patent Application 12/823,007 will issue and, if issued, whether the validity and enforceability of the patent will be challenged by one or more third parties and upheld; whether preclinical and early clinical results for aripiprazole lauroxil will be predictive of future clinical study results; whether aripiprazole lauroxil will be shown to be ineffective or unsafe during clinical studies; decisions by the FDA or foreign regulatory authorities regarding aripiprazole lauroxil for the treatment of schizophrenia; potential changes in cost, scope and duration of the phase 3 clinical trial of aripiprazole lauroxil for the treatment of schizophrenia; and those risks described in the Alkermes plc

Annual Report on Form 10-K for the year ended March 31, 2012, 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.

Source: Alkermes plc

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