Alkermes Announces Initiation of Clinical Study of Extended Durations of Aripiprazole Lauroxil for Treatment of Schizophrenia

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— Potential To Give Patients and Physicians a New, Long-Acting Injectable Medicine With More Flexibility in Dosing Intervals, Beyond Once-Monthly Aripiprazole Lauroxil —

DUBLIN--(BUSINESS WIRE)--Dec. 15, 2014-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil, the company's investigational, novel, long-acting injectable atypical antipsychotic for the treatment of schizophrenia. The randomized, open-label study of approximately 140 patients with schizophrenia will evaluate the pharmacokinetics, safety and tolerability of aripiprazole lauroxil administered over two new extended durations – once every six weeks, and once every two months. A New Drug Application (NDA) for aripiprazole lauroxil one-month is currently under review with the U.S. Food and Drug Administration (FDA) and has been assigned a Prescription Drug User Fee Act (PDUFA) date of Aug. 22, 2015.

"Building upon our longstanding expertise with multiple long-acting atypical antipsychotics available today, Alkermes recognizes the value of flexibility of dosing for both patients and healthcare providers. Our goal is to continue to move the frontier by creating the first long-acting atypical antipsychotic designed to be dosed every six weeks or every two months," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "We believe there are compelling needs in the mental illness community to improve treatment outcomes for patients, and our aim is to continue to apply our innovative technology to bring forward options for the treatment of schizophrenia."

The phase 1, randomized, open-label study will evaluate the pharmacokinetics, safety and tolerability of aripiprazole lauroxil when administered at one-month, six-week and two-month intervals. Following a 30-day screening period, approximately 140 patients with stable schizophrenia will be randomized to receive one of four different dosing regimens of aripiprazole lauroxil (441 mg once per month, 882 mg every six weeks, or one of two formulations of 1064 mg every two months) for a total of six treatment months. Results from this phase 1 study are expected mid 2016.

About Aripiprazole Lauroxil

Aripiprazole lauroxil is an injectable atypical antipsychotic with one-month and extended-duration formulations in development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts to aripiprazole, which is commercially available under the name ABILIFY®. As a long-acting investigational medication based on Alkermes' proprietary LinkeRx ® technology, aripiprazole lauroxil is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format.

About Schizophrenia and Long-Acting Medicines

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 American adults have schizophrenia,[1] with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, which is one of the most serious types of mental illness. Long-acting injectable antipsychotics provide patients with blood concentrations of active drug that remain within a therapeutic range for an extended period of time[2] and allow healthcare providers to track patient adherence.[3]

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, as amended, including, but not limited to, statements concerning: the company's expectations and timeline for regulatory action by the FDA relating to the NDA for aripiprazole lauroxil one-month for the treatment of schizophrenia; the potential therapeutic value, attributes and commercial potential of aripiprazole lauroxil one-month and extended-duration formulations of aripiprazole lauroxil; and the clinical development timelines of extended-duration formulations of aripiprazole lauroxil. 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: whether preclinical and early clinical results for aripiprazole lauroxil will be predictive of future clinical study results; whether future clinical trials for aripiprazole lauroxil will be completed on time or at all; changes in the cost, scope and duration of the aripiprazole lauroxil clinical trials; whether aripiprazole lauroxil could be shown ineffective or unsafe; whether aripiprazole lauroxil one-month will be approved by regulatory authorities for the treatment of schizophrenia by Aug. 22, 2015 or at all; if approved, whether aripiprazole lauroxil will be commercialized successfully; and those risks described in the Alkermes plc Transition Report on Form 10-K for the fiscal period ended Dec. 31, 2013, and in other subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which

are available on 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 or revising any forward-looking information contained in this press release.

LinkeRx® is a registered trademark of Alkermes Pharma Ireland Limited. ABILIFY® is a registered trademark of Otsuka Pharmaceutical Co., Ltd.

[1]National Institutes of Health. Accessed on Dec. 12, 2014 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

[2]Patel MX and David AS. Why aren't depot antipsychotics prescribed more often and what can be done about it? *Adv Psychiatr Treat*, 2005; 11: 203-213.

[3]Kane JM et al. Guidelines for depot antipsychotic treatment in schizophrenia. *Eur Neuropsychopharmacol*, 1998; 8(1): 55-66.

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