Alkermes' New Drug Application for Aripiprazole Lauroxil for Treatment of Schizophrenia Accepted for Filing by U.S. FDA

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— New Once-Monthly Product Candidate for Treatment of Schizophrenia, in a Ready-to-Use Format With Multiple Dose Strengths —

— FDA Action Expected by Aug. 22, 2015 —

DUBLIN--(BUSINESS WIRE)--Oct. 22, 2014-- Alkermes plc (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for aripiprazole lauroxil, the company's investigational, novel, once-monthly injectable atypical antipsychotic for the treatment of schizophrenia. Under the Prescription Drug User Fee Act (PDUFA), the FDA's target action date for the aripiprazole lauroxil NDA is Aug. 22, 2015.

"The FDA acceptance of the aripiprazole lauroxil NDA marks the achievement of an important milestone for this program and brings us another step closer to offering patients and physicians a new treatment option for schizophrenia with distinctive features, including a range of doses and ready-to-use format," stated Richard Pops, Chief Executive Officer of Alkermes. "If approved, aripiprazole lauroxil could be a significant new entrant in the increasingly important category of long-acting injectable medicines for schizophrenia."

The NDA filing included the positive results from the pivotal phase 3 study assessing the efficacy and safety of aripiprazole lauroxil, in which aripiprazole lauroxil demonstrated significant improvements in schizophrenia symptoms, compared to placebo. In the randomized, multicenter, double-blind, placebo-controlled study, both doses of aripiprazole lauroxil tested, 441 mg and 882 mg administered once monthly, met the primary endpoint with statistically significant and clinically meaningful reductions in Positive and Negative Syndrome Scale (PANSS) scores, met all secondary endpoints and demonstrated significant improvements in schizophrenia symptoms versus placebo. Aripiprazole lauroxil was generally well tolerated in the study, and the observed safety profile of aripiprazole lauroxil was similar to that reported with oral aripiprazole. The most common adverse events in the study were insomnia, akathisia and headache.

About Aripiprazole Lauroxil

Aripiprazole lauroxil is an injectable atypical antipsychotic with one-month and two-month 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 submission for aripiprazole lauroxil for the treatment of schizophrenia; and the potential therapeutic value, attributes, and commercial potential 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 aripiprazole lauroxil 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; whether aripiprazole lauroxil could be shown ineffective or unsafe; 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 Alliance on Mental Illness. Accessed on Oct. 21, 2014 from http://www.nami.org/Template.cfm?Section=schizophrenia9.

[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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