Alkermes Presents Phase 3 Data From Successful Pivotal Study of Aripiprazole Lauroxil for Treatment of Schizophrenia at ASCP Annual Meeting

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— Both Doses of Once-Monthly Aripiprazole Lauroxil Met Primary Endpoint With Statistically and Clinically Significant Reductions in PANSS Scores and Met All Secondary Endpoints —

— Company On Track to Submit New Drug Application in Third Quarter of 2014 —

HOLLYWOOD, Fla. & DUBLIN--(BUSINESS WIRE)--Jun. 18, 2014-- Alkermes plc (NASDAQ: ALKS) today announced the presentation of data from its phase 3 clinical trial of aripiprazole lauroxil, an investigational drug candidate in development for schizophrenia, at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in Hollywood, Fla. In the pivotal study, both doses of aripiprazole lauroxil tested, 441 mg and 882 mg administered once-monthly, met the primary endpoint with statistically and clinically significant reductions in Positive and Negative Syndrome Scale (PANSS) scores, met all secondary endpoints and demonstrated significant improvements in schizophrenia symptoms versus placebo. This is the first demonstration of the efficacy of a range of doses of a long-acting injectable form of aripiprazole in a randomized clinical trial. The company remains on track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2014.

"With these compelling phase 3 data in hand, we are moving forward expeditiously to bring aripiprazole lauroxil to patients with schizophrenia and their families," said Serge Stankovic, M.D., MSPH, Senior Vice President, Clinical Development and Medical Affairs of Alkermes. "With a deep background in the development of long-acting injectable antipsychotic medicines, our scientists designed aripiprazole lauroxil rationally, in a ready-to-use format with multiple dosing options, to meet the individual needs of patients and the physicians and nurses who treat them."

Data from the full analysis set of the phase 3 study showed:

- During the 12-week, double-blind treatment period, patients treated once-monthly with either 441 mg or 882 mg of aripiprazole lauroxil demonstrated statistically and clinically significant placebo-adjusted mean reductions from baseline in PANSS total scores (-10.9 points, $p<0.001$ for aripiprazole lauroxil 441 mg; and -11.9 points, $p<0.001$ for aripiprazole lauroxil 882 mg).
- In addition to meeting the prespecified primary efficacy endpoint of PANSS total score reduction, the study also met the prespecified key secondary endpoint of improvement on the Clinical Global Impression – Improvement (CGI-I) scale for each aripiprazole lauroxil group versus placebo at Week 12 ($p<0.001$). Both of the aripiprazole lauroxil dosing groups demonstrated significant improvement at all post-baseline visits.
- Additionally, all other secondary endpoints were found to be statistically significant across both doses.
- Overall, 64% of patients who received aripiprazole lauroxil completed the study, compared to 46% of patients who received 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.

Study Design
The phase 3, randomized, multicenter, double-blind, placebo-controlled study was designed to assess the efficacy, safety and tolerability of aripiprazole lauroxil in patients experiencing acute exacerbation of schizophrenia. The trial included adult patients who met the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (*DSM-IV-TR*®) criteria for schizophrenia and had a PANSS total score of 70 or higher at study baseline.

A total of 623 patients were randomized to receive once-monthly intramuscular injections of aripiprazole lauroxil 441 mg, aripiprazole lauroxil 882 mg or a matching placebo injection of either high volume or low volume for 12 weeks. Following randomization, patients received their first injection along with daily oral study drug for the first three weeks. Patients randomized to the two aripiprazole lauroxil treatment groups received oral aripiprazole for those initial three weeks, while patients randomized to the placebo group received matching oral placebo for three weeks. A total of 596 patients were included in the full analysis set, as defined by those who received at least one dose of study drug and had at least one primary efficacy assessment following administration of study drug.

The primary efficacy endpoint of the study was the mean change from baseline at Week 12 in PANSS total score, using an analysis of covariance (ANCOVA) with a last observation carried forward (LOCF) approach. The Hommel procedure was used for multiple hypothesis testing. Efficacy was also analyzed using a mixed model for repeated measures (MMRM) as a sensitivity analysis.

All participants in the double-blind portion of the study were eligible to continue in an open-label phase and receive aripiprazole lauroxil 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 aripiprazole lauroxil.

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, prefilled 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, 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 therapeutic value, development plans 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: regulatory submissions may not occur or be submitted in a timely manner; adverse decisions by regulatory authorities may occur; the company may be unable to commercially manufacture aripiprazole lauroxil successfully; and those risks described in the Alkermes plc Transition Report on Form 10-K for the fiscal period ended December 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 publicly updating or revising any forward-looking information contained in this press release.

[1]National Institutes of Health. Accessed on June 17, 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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