Alkermes Announces Positive Topline Results From Pivotal Phase 3 Study of Aripiprazole Lauroxil for Treatment of Schizophrenia

April 8, 2014

— Once-Monthly Injectable Schizophrenia Medication Achieved Primary and Secondary Endpoints at Both Doses Tested in Pivotal Study —

— Company Plans To Submit New Drug Application in Third Quarter of 2014 —

DUBLIN--(BUSINESS WIRE)--Apr. 8, 2014-- Alkermes plc (NASDAQ: ALKS) today announced positive topline results from a randomized, double-blind, placebo-controlled phase 3 clinical trial of aripiprazole lauroxil in patients with schizophrenia. Patients treated once monthly with either 441 mg or 882 mg of aripiprazole lauroxil demonstrated statistically significant reductions from baseline in Positive and Negative Syndrome Scale (PANSS) total scores at week 12, compared to placebo ($p<0.001$ aripiprazole lauroxil 441 mg, $p<0.001$ aripiprazole lauroxil 882 mg), which was the prespecified primary endpoint in the study. Based on the positive results from this phase 3 study, Alkermes plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2014. Aripiprazole lauroxil is a new, long-acting injectable antipsychotic agent designed to provide patients with once-monthly dosing of a medication that, once in the body, converts to aripiprazole, a molecule that is commercially available under the name ABILIFY®.

“These statistically significant efficacy data demonstrate aripiprazole lauroxil’s ability to provide clinically meaningful symptom control in patients struggling with schizophrenia,” said Henry Nasrallah, M.D., Chair, Department of Neurology and Psychiatry at Saint Louis University School of Medicine. “A once-monthly version of aripiprazole with multiple dose strengths would be a welcome addition since it would enhance current treatment options and provide dosing flexibility. These data come at a time when the treatment landscape for schizophrenia is evolving; more physicians are now recognizing the benefits of long-acting injectable antipsychotics and considering their use earlier in disease progression.”

Data from the full analysis set showed statistically significant improvement in PANSS total scores from baseline in both aripiprazole lauroxil dose groups, relative to the placebo treatment group. In addition to meeting the prespecified primary efficacy endpoint, the study also met the prespecified key secondary endpoint of improvement on the Clinical Global Impression – Improvement scale (CGI-I) versus placebo at week 12 ($p<0.001$).

“Our goal has been to develop a differentiated long-acting injectable product candidate responsive to the real-world needs of patients and healthcare providers, providing the proven efficacy of aripiprazole administered once-monthly in a ready-to-use format with multiple dosage strengths,” stated Richard Pops, Chief Executive Officer of Alkermes. “With these positive data in hand, we will complete the preparation of our NDA, which we plan to submit next quarter, and continue our preparations to bring this important new medicine to patients and healthcare providers.”

Aripiprazole lauroxil was generally well tolerated in the phase 3 study, and the 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.

Alkermes will present comprehensive data from the phase 3 study at an upcoming medical meeting and submit the results for publication in a peer-reviewed journal.

Phase 3 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 placebo 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. The primary efficacy endpoint of the study was the change from baseline at week 12 in PANSS total score, using an analysis of covariance (ANCOVA) with a last observation carried forward (LOCF). The key secondary endpoint was the CGI-I score at week 12.

All participants in the double-blind portion of the study are 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.

Conference Call

Alkermes will host a conference call today, April 8, 2014, at 8:00 a.m. EDT (1:00 p.m. BST), to discuss these topline results. The conference call may be accessed by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. The conference call will also be webcast on the Investors section of Alkermes’ website at www.alkermes.com. In addition, a replay of the conference call will be available from 10:30 a.m. EDT (3:30 p.m. BST) on Tuesday, April 8, 2014, through 5:00 p.m. EDT (10:00 p.m. BST) on Tuesday, April 15, 2014, and may be accessed by visiting Alkermes’ website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

About Aripiprazole Lauroxil

Aripiprazole lauroxil, which utilizes Alkermes' proprietary LinkeRx ® technology, 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.

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 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.

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 when a patient does not return for a scheduled injection.[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, 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 updating any forward-looking information contained in this press release.

[1]National Institutes of Health. Accessed on April 7, 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.

Source: Alkermes plc

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