Alkermes Presents Data on Two Late-Stage Clinical Candidates, Aripiprazole Lauroxil and ALKS 5461, at 52nd Annual ACNP Meeting

December 9, 2013

— Pharmacokinetic Data Support Aripiprazole Lauroxil's Competitive Features as Once-Monthly, Long-Acting Injectable Antipsychotic With Both Deltoid and Gluteal Administration —

— Additional Efficacy Analyses of Phase 2 Study Results for ALKS 5461 Show Significant Responder and Remission Rates in Patients With Inadequate Response to Conventional Antidepressants —

HOLLYWOOD, Fla. & DUBLIN--(BUSINESS WIRE)--Dec. 9, 2013-- Alkermes plc (NASDAQ: ALKS) today announced that data will be presented at the 52nd Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Hollywood, Fla., Dec. 8-12, 2013, related to the company's two most advanced clinical candidates, aripiprazole lauroxil, a long-acting injectable treatment for schizophrenia, and ALKS 5461, a novel oral compound for the treatment of major depressive disorder (MDD). Enrollment in the phase 3 study for aripiprazole lauroxil has been completed, and ALKS 5461 is expected to enter phase 3 clinical trials in 2014.

Details for these presentations at the ACNP meeting include:

Monday, Dec. 9, 2013, 5:30-7:30 p.m. EST

Poster M184: "ALKS 5461, a Novel Opioid Modulator, Produces Remission and Decreases Core Depressive Symptoms and Anhedonia as an Adjunctive Treatment: A Sequential Parallel Comparison Design Trial in Inadequate Responders to Antidepressants" will be presented by Marlene P. Freeman, M.D., Massachusetts General Hospital and Harvard Medical School.

- Alkermes will present additional analyses that build on the previously reported phase 2 primary efficacy results for ALKS 5461 in patients with MDD, showing response rates and remission rates based on Montgomery-Åsberg Depression Rating Scale (MADRS) scores, as well as additional efficacy outcomes on two core depression symptom scales: the Anhedonia subscale of the MADRS and the Bech Melancholia Scale of the Hamilton Depression Rating Scale (HAM-D17). Since depression rating scales capture a range of symptoms, findings on the Anhedonia and Bech scales enable clinicians to evaluate a medication's efficacy for the core features of depression, such as depressed mood and anhedonia, and not only secondary features like sleep problems.
- ALKS 5461 was evaluated in a phase 2, randomized, double-blind, multicenter, placebo-controlled study, utilizing a sequential parallel comparison design (SPCD) to assess the efficacy and safety of once-daily ALKS 5461 as adjunctive treatment in patients with MDD. In October 2013, the U.S. Food and Drug Administration (FDA) granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard therapies, and Alkermes plans to begin the phase 3 program in early 2014.

Tuesday, Dec. 10, 2013, 5:30-7:30 p.m. EST

Poster T137: "Aripiprazole Lauroxil (ALKS 9070), a Novel Once-Monthly Prodrug of Aripiprazole, Achieves Therapeutically Relevant Levels and is Well-Tolerated in Adult Patients With Schizophrenia Following Deltoid Administration" will be presented by Ryan Turncliff, Ph.D., Alkermes, Inc.

- Alkermes will present pharmacokinetic data from a multicenter, randomized, open-label, single-dose study of aripiprazole lauroxil, assessing administration of aripiprazole lauroxil by either deltoid or gluteal injection.
- The clinical data from this pharmacokinetic study will be included in a New Drug Application (NDA) to the FDA for aripiprazole lauroxil 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®. Alkermes continues to expect topline results from the phase 3 study of aripiprazole lauroxil in the first half of 2014.

Further details on the ACNP Annual Meeting are available at: www.acnp.org.

About ALKS 5461

ALKS 5461 is a proprietary investigational medicine with a novel mechanism for the treatment of major depressive disorder (MDD). The mechanism of action for ALKS 5461 in the treatment of depressive symptoms is based on modulation of the opioid system in the brain, employing a balanced combination of agonism and antagonism of opioid receptors. ALKS 5461 consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist, and is designed to be a once-daily, non-addictive medicine. Early clinical development of ALKS 5461 was funded through a grant from the National Institute on Drug Abuse (NIDA).

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 central nervous system therapies. Aripiprazole lauroxil, which utilizes the LinkeRx technology, is a once-monthly, injectable atypical antipsychotic in phase 3 clinical development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts to aripiprazole, which is commercially available under the name ABILIFY. Aripiprazole lauroxil was formerly referred to as ALKS 9070.

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, the clinical development and regulatory plans and timelines with respect to aripiprazole lauroxil and ALKS 5461; and the timing of receipt and disclosure of topline phase 3 study results for 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: the phase 3 study of aripiprazole lauroxil may not be successful and may not be completed in a timely manner; aripiprazole lauroxil may not demonstrate sufficient therapeutic effect or an acceptable safety profile; we plan to rely, to a significant extent, on third-party clinical research organizations, or CROs, to help us conduct clinical trials so the success and timing of the trials is dependent on our ability to work with such CROs and their performance; regulatory submissions may not occur or be submitted in a timely manner; the company may be unable to manufacture successfully our products; and those risks described in the Alkermes plc Annual Report for the year ended March 31, 2013, and in other 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.

Source: Alkermes plc

Alkermes:
For Investors:
Rebecca Peterson, +1 781-609-6378
or
For Media:
Jennifer Snyder, +1 781-609-6166