Alkermes Announces Alignment with FDA on Plans for Pivotal Program for ALKS 5461 for Major Depressive Disorder

October 9, 2013

- Program to Begin in Early 2014 –

DUBLIN--(BUSINESS WIRE)--Oct. 9, 2013-- Alkermes plc (NASDAQ: ALKS) today announced that it has successfully completed its End-of-Phase 2 interactions with the U.S. Food and Drug Administration (FDA), and the company plans to advance ALKS 5461 into phase 3 development in early 2014. Alkermes is developing ALKS 5461 for the treatment of patients with major depressive disorder (MDD) who have inadequate response to standard therapies.

The company and the FDA agreed on key elements of the development program, including preclinical and clinical requirements for the New Drug Application, the confirmatory study plans, the incorporation of innovative study designs that include the use of sequential parallel comparison design (SPCD), the primary endpoint and the statistical methodology. In September 2013, in advance of a planned End-of-Phase 2 meeting, Alkermes submitted a written briefing document detailing design elements of the proposed development program. The FDA's written responses aligned with the company's proposals such that the End-of-Phase 2 meeting was deemed unnecessary.

"We prepared a robust and innovative clinical trial plan and are pleased with the FDA's positive feedback that enables us to move directly into the ALKS 5461 phase 3 program in early 2014," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "There is a clear and compelling need for a novel mechanism for the treatment of depression, and ALKS 5461 reflects a new approach based on modulation of the opioid system in the brain."

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.

About MDD

According to the *DSM-5*® (*Diagnostic and Statistical Manual of Mental Disorders*, *Fifth Edition*), major depressive disorder (MDD) is a condition in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. An estimated 16.1 million people in the U.S. suffer from MDD in a given year,[1,2] the majority of whom may not adequately respond to initial antidepressant therapy.[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 timing of the phase 3 development program for ALKS 5461. 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: phase 3 development of ALKS 5461 may not be commenced or completed in a timely manner or at all, due to factors including, but not limited to, protocol design, regulatory and institutional review board approval, the rate of patient enrollment and compliance with good clinical practices; adverse decisions by regulatory authorities may occur; the company may be unable to manufacture successfully ALKS 5461; 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 at 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.

DSM-5® is a registered trademark of the American Psychiatric Association.

[1] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun; 62 (6): 617-27.

[2] U.S. Census.

[3] Rush AJ et al (2007) *Am J. Psychiatry* 163:11, pp. 1905-1917 (STAR*D Study).

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