Alkermes Receives Fast Track Designation for ALKS 5461 for Major Depressive Disorder

October 10, 2013

DUBLIN--(BUSINESS WIRE)--Oct. 10, 2013-- Alkermes plc (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track status for ALKS 5461 for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard therapies. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and with the potential to address an unmet medical need.

“We are extremely pleased to have been conferred Fast Track status for ALKS 5461 as we believe that ALKS 5461 may represent an important option for the treatment of major depressive disorder,” said Elliot Ehrich, Chief Medical Officer of Alkermes. “This designation supports our position that there is a clear and compelling need for a novel mechanism for the treatment of depression.”

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 Fast Track

Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. For more information about Fast Track, please visit www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm.

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 therapeutic value and market potential of 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: the results of ALKS 5461 development activities may not be predictive of real-world results or of results in subsequent clinical trials; ALKS 5461 may have unintended side effects, adverse reactions or incidents of misuse; adverse decisions by regulatory authorities may occur; clinical development activities with respect to ALKS 5461 may not be commenced or completed on time or at all; 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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