Alkermes Initiates Rolling Submission of ALKS 5461 New Drug Application for Major Depressive Disorder

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— Company Expects to Complete Submission for Fast Track Designated Medicine by Year-End 2017 —

DUBLIN--(BUSINESS WIRE)--Aug. 21, 2017-- Alkermes plc (NASDAQ:ALKS) today announced the initiation of its rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), seeking marketing approval of ALKS 5461, a once-daily, oral investigational medicine with a novel mechanism of action, for the adjunctive treatment of major depressive disorder (MDD). The company expects to complete the submission of the NDA for this Fast Track designated medicine by year-end 2017.

"The initiation of the rolling submission for ALKS 5461 is an important first step in the registration process for ALKS 5461, as we work to bring this potential new medicine to patients suffering from major depressive disorder. ALKS 5461 represents a novel mechanism of action for the treatment of MDD, a condition for which millions of patients in the U.S. do not achieve an adequate response to standard antidepressant therapies," stated Elliot Ehrich, M.D., Executive Vice President, Research and Development of Alkermes. "We expect to complete the submission of the NDA by year-end 2017 and will continue to collaborate closely with the FDA as we work expeditiously toward making ALKS 5461 available to patients and their healthcare providers."

The FDA Fast Track designation is designed to facilitate the development and expedite the review of medicines that are intended to treat serious conditions and address unmet medical needs. Fast Track designation allows for the submission of completed portions of the NDA on a rolling basis as well as eligibility for Priority Review. At a pre-NDA interaction with FDA in July, the company and FDA agreed upon the proposed content and timing of the ALKS 5461 NDA submission.

About ALKS 5461

ALKS 5461 is a proprietary, investigational, once-daily oral medicine that acts as a balanced neuromodulator in the brain and represents a novel mechanism of action for the adjunctive treatment of MDD. ALKS 5461 consists of samidorphan and buprenorphine, and is designed to rebalance brain function that is dysregulated in the state of depression. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies.

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 17 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 plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in 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 and commercial potential of ALKS 5461, and the development and regulatory plans and timelines for ALKS 5461, including the timing of submission of the NDA and whether it will receive Priority Review designation from FDA. You are cautioned 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 expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and clinical results for ALKS 5461 will be predictive of future clinical study results and commercial potential of ALKS 5461; whether future clinical trials for ALKS 5461 will be completed on time or at all; potential changes in cost, scope and duration of the ALKS 5461 clinical development program; whether ALKS 5461 could be shown ineffective or unsafe during clinical studies; whether the preclinical and clinical results of ALKS 5461 will meet the regulatory requirements for approval; whether regulatory submissions may occur or be submitted in a timely manner; whether the company will receive Priority Review designation from FDA; and those risks and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2016 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017 and in 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. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

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

[1] Kessler RC et al (2005) *Archives of General Psychiatry*, Jun; 62 (6), pp. 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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