Alkermes Submits New Drug Application To U.S. FDA For ALKS 5461 For The Adjunctive Treatment Of Major Depressive Disorder

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- New Medicine for Treating Major Depressive Disorder Supported by Comprehensive Efficacy and Safety Data Package From More Than 1,500 Patients -

DUBLIN, Jan. 31, 2018 /PRNewswire/ -- Alkermes plc (NASDAQ: ALKS) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ALKS 5461, a once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of major depressive disorder (MDD). The NDA submission is based on a comprehensive clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD. Throughout the clinical development program, ALKS 5461 demonstrated a consistent profile of antidepressant activity, safety and tolerability in the adjunctive treatment of MDD. ALKS 5461 was granted Fast Track status by the FDA in October 2013 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies.

"ALKS 5461 represents the first potential treatment option with a novel mechanism of action for the treatment of depression in 30 years. We believe its unique pharmacology may provide distinct clinical benefits for the large number of patients who do not get adequate relief from first-line standard antidepressant therapy," stated Elliot Ehrich, M.D., Executive Vice President, Research and Development at Alkermes. "With this regulatory submission, we are one step closer to our goal of bringing this important new medicine to patients, families and healthcare professionals, who are eager for new treatment options."

"ALKS 5461 has demonstrated consistent safety, tolerability and antidepressant activity for the adjunctive treatment of major depressive disorder throughout its comprehensive clinical development program," stated Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President, Clinical Development and Medical Affairs at Alkermes. "The NDA submission of ALKS 5461 further demonstrates our ongoing commitment to developing innovative, patient-centered treatment options for those afflicted by serious mental illness and chronic CNS disorders."

About ALKS 5461

ALKS 5461 is a proprietary, investigational, once-daily oral medicine that acts as an opioid system modulator and represents a novel mechanism of action for the adjunctive treatment of major depressive disorder (MDD). ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist. 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: approval by the FDA of the NDA for ALKS 5461 and the therapeutic value and commercial 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 expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether the NDA for ALKS 5461 will be accepted and approved by the FDA; if approved, whether ALKS 5461 will be commercialized successfully; 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; 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 Sept. 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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