Alkermes Announces FDA Acceptance for Review of New Drug Application for ALKS 5461 for the Adjunctive Treatment of Major Depressive Disorder

April 16, 2018

-- FDA Action Expected by Jan. 31, 2019 --
-- Conference Call Scheduled for Today at 8:30 a.m. ET --

DUBLIN, April 16, 2018 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ALKS 5461, a novel, once-daily, oral investigational medicine for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressant therapies. FDA's target action date for the ALKS 5461 NDA is Jan. 31, 2019.

FDA's acceptance of the ALKS 5461 NDA and rescission of the Refusal to File letter issued March 30, 2018 follows productive interactions with the Agency in which Alkermes clarified certain aspects of the NDA submission. No additional data or analyses were submitted by Alkermes to FDA.

"FDA's filing of the ALKS 5461 application is a positive step forward for patients suffering from major depressive disorder, a serious disease where inadequate response to existing antidepressants remains a well-known and significant treatment limitation, and where there have been no new pharmacological treatment approaches in 30 years," stated Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "We will continue to engage with the FDA throughout the review process, as we work to bring this important medicine to patients."

The NDA filing for ALKS 5461 is based on results from a 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.

Conference Call Information
Alkermes will host a conference call at 8:30 a.m. ET (1:30 p.m. BST) on Monday, April 16, 2018, to discuss this update. The conference call may be accessed by visiting Alkermes' website or by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Monday, April 16, 2018, through 5:00 p.m. ET (10:00 p.m. BST) on Monday, April 23, 2018, and may be accessed by visiting Alkermes' website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

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) in patients with an inadequate response to standard antidepressant therapies. 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.

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 16.2 million people in the U.S. suffered from MDD in 2016,[1] the majority of whom may not adequately respond to initial antidepressant therapy.[2]

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: potential approval by the FDA of ALKS 5461 and the anticipated timing of such approval; and the therapeutic value and commercial potential of ALKS 5461. 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 the preclinical and clinical results of ALKS 5461 will meet the regulatory requirements for approval by the FDA; whether the FDA's bases for the rescinded Refusal to File letter or other bases will cause the FDA to require more data or information prior to approval; whether ALKS 5461 will be approved by the FDA in a timely manner or at all; if approved, whether ALKS 5461 will be commercialized successfully; whether the preclinical and clinical results for ALKS 5461 will be predictive of commercial potential of ALKS 5461; whether future clinical trials for ALKS 5461, if any, 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; 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, 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] National Institutes of Mental Health: Major Depression. Accessed on April 15, 2018 from https://www.nimh.nih.gov/health/statistics/major-depression.shtml.

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

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