



Alkermes Announces Plan to Initiate Second Clinical Trial of ALKS 7119 Based on Preliminary Phase 1 Results

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—Novel Candidate for Treatment of Agitation in Alzheimer's Disease Demonstrated Favorable Profile in First Clinical Trial —

—Company Accelerates Plans to Initiate Multiple-Dose Study —

DUBLIN--(BUSINESS WIRE)--Apr. 28, 2016-- [Alkermes plc](#) (NASDAQ: ALKS) today announced preliminary findings from a phase 1 clinical trial of ALKS 7119, an oral, novel small molecule that acts on multiple key receptor systems in the brain. ALKS 7119 is being developed for the treatment of agitation in patients with Alzheimer's disease and other central nervous system (CNS) indications. Based on initial blinded data from the ongoing single-ascending-dose study, Alkermes has accelerated the decision to advance ALKS 7119 into a multiple-ascending-dose phase 1 study. The study is planned to commence in the third quarter of 2016 and results are expected around year-end.

Initiated in January 2016, the double-blind, placebo-controlled single-ascending-dose study was designed to evaluate the safety and tolerability, as well as the pharmacokinetic properties of ALKS 7119 in healthy volunteers. Preliminary data from the first six escalating dose cohorts demonstrated a favorable tolerability profile for ALKS 7119 and pharmacokinetic properties consistent with potential once-daily dosing. Full results from the ongoing single-ascending-dose phase 1 study, including unblinded safety data, are expected in the second half of 2016.

"ALKS 7119 is an example of a promising new investigational medicine that has emerged from our R&D engine into early clinical studies for an important, chronic CNS disease. Based on the early data from this single dose escalation study, we are excited to accelerate the development program for ALKS 7119 into the multiple-ascending-dose study in healthy volunteers which will begin in the third quarter," commented Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "ALKS 7119's multivalent mechanism has promising potential to address the significant unmet needs of patients and caregivers by treating the debilitating condition of agitation associated with Alzheimer's disease."

About ALKS 7119

ALKS 7119 is an oral, novel, proprietary investigational medicine that has a multivalent mechanism of action and acts on key receptors in the brain involved in several central nervous system (CNS) diseases. In addition to the potential treatment of agitation in patients with Alzheimer's disease, ALKS 7119 may be investigated for the treatment of major depressive disorder and other psychiatric conditions. ALKS 7119 is a N-methyl-D-aspartate (NMDA) receptor antagonist and a serotonin reuptake inhibitor. It also binds to other targets, which may contribute to its pharmacodynamic effects.

About Alzheimer's Disease

Alzheimer's disease (AD) is a progressive brain disorder that slowly destroys memory and thinking skills and, eventually, the ability to carry out the simplest tasks.¹ While cognitive decline is a central feature of the disease, psychiatric symptoms, such as agitation, are the leading source of morbidity and caregiver burden.² There are currently no approved medications in the U.S. for the treatment of Alzheimer's agitation. Approximately 5.3 million individuals in the U.S. had AD in 2015, and this number is expected to nearly triple by 2050.³

About Alkermes

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, development plans and commercial potential of ALKS 7119. 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 preclinical and early clinical results for ALKS 7119 will be predictive of future clinical study results; whether future clinical trials for ALKS 7119 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 7119 clinical trials; whether ALKS 7119 could be ineffective or unsafe during clinical studies, and whether, in such instances, Alkermes may not be permitted by regulatory authorities to undertake new or additional clinical studies for ALKS 7119; and those risks described in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in other 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. 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 or revising any forward-looking information contained in this press release.

¹ National Institute on Aging. About Alzheimer's Disease: Alzheimer's Basics. Accessed from <https://www.nia.nih.gov/alzheimers/topics/alzheimers-basics> on April 27, 2016.

² Wadsworth LP et al. Neuropsychiatric Symptoms and Global Functional Impairment along the Alzheimer's Continuum. *Dement Geriatr Cogn Disord*.

2012; 34:96-111.

³Alzheimer's Association. Alzheimer's Facts and Figures. Accessed from http://www.alz.org/alzheimers_disease_facts_and_figures.asp#quickFacts on April 27, 2016.



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