



## Alkermes Announces Initiation of Phase 1 Clinical Study of New CNS Drug Candidate ALKS 7119

January 25, 2016

—*Novel, Oral, Investigational Medicine for the Treatment of Agitation in Alzheimer's Disease and Other Psychiatric Indications*—

DUBLIN--(BUSINESS WIRE)--Jan. 25, 2016-- [Alkermes plc](http://www.alkermes.com) (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of ALKS 7119, an oral, investigational drug candidate being developed for the treatment of agitation in patients with Alzheimer's disease (AD) and other central nervous system (CNS) indications. The double-blind, placebo-controlled study will evaluate the safety and tolerability of single ascending doses of ALKS 7119 in approximately 60 healthy subjects. ALKS 7119 is a novel small molecule that acts on multiple key receptor systems in the brain.

"Agitation is a common and debilitating psychiatric symptom of Alzheimer's disease that currently has no approved medicines, and causes significant burden on patients and their caregivers," commented Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "We believe that the multivalent mechanism of ALKS 7119 has promising potential to treat agitation associated with Alzheimer's disease and other important psychiatric indications. With the successful completion of a thorough preclinical development phase, we are excited to launch our clinical program and look forward to seeing the results from this phase 1 study later this year."

The randomized, double-blind, placebo-controlled, multi-cohort, phase 1 study will investigate the safety and tolerability of single ascending doses of ALKS 7119 following oral administration in approximately 60 healthy male adults. The study will also include a battery of psychometric assessments, which are intended to provide preliminary insight into the potential human pharmacodynamic response. Results from this phase 1 study are expected in the second half of 2016.

### **About ALKS 7119**

ALKS 7119 is a novel chemical entity 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.<sup>1</sup> While cognitive decline is a central feature of the disease, psychiatric symptoms, such as agitation, are the leading source of morbidity and caregiver burden.<sup>2</sup> 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.<sup>3</sup>

### **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](http://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 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 Quarterly Report on Form 10-Q for the period ended Sept. 30, 2015 and Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, 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](http://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.

<sup>1</sup> National Institute on Aging. About Alzheimer's Disease: Alzheimer's Basics. Accessed from <https://www.nia.nih.gov/alzheimers/topics/alzheimers-basics> on Jan. 22, 2016.

<sup>2</sup> Wadsworth LP et al. Neuropsychiatric Symptoms and Global Functional Impairment along the Alzheimer's Continuum. *Dement Geriatr Cogn Disord*. 2012; 34:96-111.

<sup>3</sup> Alzheimer's Association. Alzheimer's Facts and Figures. Accessed from [http://www.alz.org/alzheimers\\_disease\\_facts\\_and\\_figures.asp#quickFacts](http://www.alz.org/alzheimers_disease_facts_and_figures.asp#quickFacts) on Jan. 22, 2016.



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