



## **Alkermes Announces New Drug Candidate, ALKS 7119, for Treatment of Alzheimer's Agitation, Depression and Other CNS Diseases**

March 2, 2015

— ALKS 7119 to Enter Clinic This Year; Joins Expanding CNS Pipeline Focused on Major Chronic Diseases —

— Company to Provide Update at Analyst and Investor Event and Outline Commercial Potential for Late-Stage CNS Portfolio —

DUBLIN--(BUSINESS WIRE)--Mar. 2, 2015-- [Alkermes plc](#) (NASDAQ: ALKS) today announced a new drug candidate, ALKS 7119, for the treatment of agitation in patients with Alzheimer's disease, major depressive disorder (MDD) and other central nervous system (CNS) indications. Alkermes has successfully completed preclinical development and expects to initiate the first clinical study of ALKS 7119 in the third quarter of 2015. Additional details about ALKS 7119 will be presented at an Analyst and Investor Event hosted by Alkermes this afternoon. At the event, the company will also provide an update and outline the commercial opportunity for four late-stage product candidates in its emerging blockbuster portfolio addressing major chronic CNS diseases — aripiprazole lauroxil for schizophrenia, ALKS 5461 for MDD, ALKS 3831 for schizophrenia and ALKS 8700 for multiple sclerosis.

ALKS 7119 is the newest candidate in Alkermes' pipeline of novel medicines for CNS diseases. ALKS 7119 has a multivalent mechanism of action that acts on key receptors in the brain involved in several CNS diseases, including agitation in patients with Alzheimer's disease, MDD and others. Alkermes intends to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the second quarter and begin clinical trials in the third quarter of 2015. A number of patent applications have been submitted to the U.S. Patent and Trademark Office related to ALKS 7119.

"ALKS 7119 exemplifies the continuing productivity of R&D at Alkermes and our distinctive approach to creating medicines designed to offer meaningful value for patients, their caregivers and the healthcare system," commented Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Based on results and observations to date, we believe that the multivalent mechanism of ALKS 7119 has the potential to impact a range of CNS diseases. We will begin with addressing agitation associated with Alzheimer's disease and look forward to beginning our clinical program later this year."

In addition to presenting information on ALKS 7119, the company will provide details on its late-stage pipeline candidates at the Analyst and Investor Event. Management will also present current epidemiologic data and discuss financial tools that may be useful in analyzing the economic value of the company's late-stage product candidates.

"As we meet with analysts and investors today, our presentations will focus on the potential medical and economic value of our late-stage CNS pipeline, which is one of the most diverse and exciting in the industry," commented Richard Pops, Chief Executive Officer of Alkermes. "In addition to introducing our newest clinical candidate, ALKS 7119, our goal is to provide a more complete picture of the medical need, human proof-of-concept data and economic rationale supporting each of our late-stage drug candidates — new medicines with the potential to impact millions of patients suffering from diseases including schizophrenia, depression, addiction and multiple sclerosis."

### **Webcast**

A live webcast of the company's Analyst and Investor Event will begin today at 4:00 p.m. EST (9:00 p.m. GMT). The webcast will be available on the Investors tab of the company's website at [www.alkermes.com](http://www.alkermes.com). To ensure a timely connection to the webcast, it is recommended that users register 15 minutes prior to the scheduled webcast. This webcast will be archived on Alkermes' website for one month.

### **About Alkermes plc**

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia, depression 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 manufacturing facilities in Gainesville, Georgia and 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, including blockbuster status, of the company's product candidates, including aripiprazole lauroxil, ALKS 5461, ALKS 3831, ALKS 8700 and ALKS 7119; the clinical development success and timelines of our product candidates; and the intellectual property protection of ALKS 7119. 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 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; the company's product candidates may not be approved by regulatory authorities; the company may not be able to successfully commercialize its products; and those risks described in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014 and in

any 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.



Source: Alkermes plc

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