



## Alkermes Announces Advances With Its Late-Stage CNS Pipeline

January 8, 2014

*– Company Unveils New Aripiprazole Lauroxil Two-Month Product Candidate for Treatment of Schizophrenia; Clinical Testing to Begin in 2014 –*

*– Details Provided for ALKS 5461 Pivotal Program in Major Depressive Disorder; Program to Begin in First Quarter 2014 –*

DUBLIN--(BUSINESS WIRE)--Jan. 8, 2014-- [Alkermes plc](#) (NASDAQ: ALKS) today announced new developments related to its late-stage product candidates in its proprietary central nervous system (CNS) pipeline. The company unveiled aripiprazole lauroxil two-month, a new product candidate addition to its portfolio of atypical antipsychotics for the treatment of schizophrenia. If approved, aripiprazole lauroxil two-month would be the first and only long-acting atypical antipsychotic medication dosed every two months. This new two-month product candidate is designed to provide physicians and patients with an even longer dosing option than the once-monthly formulation of aripiprazole lauroxil, which is currently completing the phase 3 study, with topline results expected in the first half of 2014. In addition, Alkermes provided details regarding its pivotal phase 3 program for ALKS 5461, a Fast Track-designated new medicine being evaluated for the treatment of major depressive disorder (MDD) in patients who have had an inadequate response to standard therapies. The phase 3 trials for ALKS 5461 will incorporate state-of-the-art study designs, and the pivotal program is expected to begin in the first quarter of 2014.

"As we begin 2014, Alkermes is aggressively executing on our strategy of building and advancing one of the most exciting CNS pipelines in the industry; one characterized by its potential value to patients and treatment systems," said Richard Pops, Chief Executive Officer of Alkermes.

"Schizophrenia and major depressive disorder are chronic diseases that affect the daily lives of millions of patients and are conditions where new treatment options with novel mechanisms of action and new dosing regimens are needed," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Clinicians who treat patients with schizophrenia and major depression need better treatment options to achieve stable remission in these serious, chronic conditions. Our goal is to advance clinical care by addressing unmet medical needs with aripiprazole lauroxil and ALKS 5461."

The aripiprazole lauroxil two-month product candidate is designed to offer physicians and patients a dosing option that is not currently available, and Alkermes plans to begin clinical testing in 2014. Both the one-month and two-month forms of aripiprazole lauroxil are long-acting injectable medications that, once in the body, convert into aripiprazole, a molecule that is commercially available under the name ABILIFY®, and both utilize the company's proprietary LinkeRx® technology.

Alkermes also today announced details regarding the pivotal program and innovative phase 3 clinical trial design for ALKS 5461, a proprietary drug candidate with a novel mechanism for the treatment of MDD. The pivotal clinical program will include three core phase 3 efficacy studies and is expected to enroll a total of approximately 1,500 patients with MDD who have had an inadequate response to standard therapies. The three core efficacy studies will utilize sequential parallel comparison design (SPCD) to reduce the impact of clinically meaningful placebo response. The primary efficacy endpoint for all phase 3 studies will be the change in Montgomery-Åsberg Depression Rating Scale (MADRS) scores from baseline. The pivotal program will also evaluate remission as a secondary endpoint, following the recently reported remission data from the phase 2 study of ALKS 5461, in which 35-50% of patients in the study achieved remission, as evaluated by MADRS scores, across the two stages of the study. In addition to the three core efficacy studies, the pivotal program will also include studies to evaluate the long-term safety, pharmacokinetic profile, titration schedule and human abuse liability of ALKS 5461. The first study to commence in the ALKS 5461 pivotal program will be a study to evaluate onset of clinical effect, safety and tolerability.

### **About Aripiprazole Lauroxil**

Aripiprazole lauroxil, which utilizes the LinkeRx technology, is an injectable atypical antipsychotic, with a once-monthly formulation in phase 3 clinical development for the treatment of schizophrenia. Topline results from the phase 3 study are expected in the first half of 2014. Once in the body, aripiprazole lauroxil converts to aripiprazole, which is commercially available under the name ABILIFY. Aripiprazole lauroxil was formerly referred to as ALKS 9070.

### **About ALKS 5461**

ALKS 5461 is a proprietary investigational medicine with a novel mechanism for the treatment of MDD. The mechanism of action for ALKS 5461 in the treatment of depressive symptoms is based on modulation of the opioid system in the brain, employing a balanced combination of agonism and antagonism of opioid receptors. ALKS 5461 consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist, and is designed to be a once-daily, non-addictive medicine. Early clinical development of ALKS 5461 was funded through a grant from the National Institute on Drug Abuse (NIDA). In October 2013, the U.S. Food and Drug Administration (FDA) granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard therapies.

### **About Alkermes**

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 and depression. 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, including, but not limited to, statements concerning: the therapeutic value, development plans and commercial potential of the company’s product candidates, including aripiprazole lauroxil one-month, aripiprazole lauroxil two-month and 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 projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: clinical trials of the company’s products may be unsuccessful or not initiated or conducted in a timely manner; its products may not show sufficient therapeutic effects or acceptable safety profiles; adverse decisions by regulatory authorities; existing clinical and preclinical data with respect to its products may not be indicative of future clinical or commercial results; intellectual property protection for its products may not be obtained or patents covering the company’s products may be successfully challenged; the company’s inability to manufacture successfully its products; and those risks described in the Alkermes plc Annual Report for the year ended March 31, 2013, and in other 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 any forward-looking information contained in this press release.

LinkeRx® is a registered trademark of Alkermes, Inc. ABILIFY® is a registered trademark of Otsuka Pharmaceutical Co., Ltd.



Source: Alkermes plc

Alkermes plc

For Investors:

Rebecca Peterson, +1-781-609-6378

or

For Media:

Jennifer Snyder, +1-781-609-6166