Alkermes Announces Initiation of Phase 1 Clinical Study of ALKS 7106 for Treatment of Pain

August 26, 2014

—Novel, Investigational Medicine Designed to Provide Pain Relief With Intrinsically Low Potential for Abuse and Overdose Death —

DUBLIN--(BUSINESS WIRE)--Aug. 26, 2014-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of ALKS 7106, a proprietary, novel, oral, small-molecule drug candidate for the treatment of pain. The randomized, double-blind, placebo-controlled study will evaluate the safety, tolerability and pharmacokinetics of ALKS 7106 in approximately 80 healthy, male adults. ALKS 7106 represents a new class of analgesic agents in development at Alkermes: potent opioid modulators designed for the treatment of pain with intrinsically low potential for abuse and overdose death – two liabilities associated with opioid analgesics. ALKS 7106's potential attributes derive from its intrinsic mechanism of action in the brain rather than through the use of abuse-deterrent technologies or formulations.

"Pain relievers are some of the most prescribed medicines in America, and there is a significant need for new opioid treatment options for pain that can provide analgesic effect with lower abuse potential and risk of overdose, compared to conventional opioid pain medications," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Based on preclinical studies, ALKS 7106 appears to have intrinsic properties that may address these serious risks while maintaining analgesic effect, and we look forward to determining whether these findings are also observed in the clinic."

This phase 1, randomized, double-blind, placebo-controlled, single-ascending-dose, multi-cohort, four-week study will evaluate the safety, tolerability and pharmacokinetics of ALKS 7106 administered orally in approximately 80 healthy, male adults. Results from this phase 1 study are expected in the first half of 2015.

About ALKS 7106

ALKS 7106 is Alkermes' novel, oral opioid analgesic drug candidate designed for the treatment of pain with intrinsically low potential for abuse and overdose death. In preclinical models, ALKS 7106 was shown to be highly potent, with similar efficacy to morphine at a 30-fold lower dose, and was well tolerated at doses far in excess of those required for analgesic action. Additional preclinical data for ALKS 7106 demonstrated a ceiling effect on neurotransmitter release over a broad concentration range, suggesting low potential for abuse and overdose death.

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.

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 7106. 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: whether preclinical and early clinical results for ALKS 7106 will be predictive of future clinical study results; whether future clinical trials for ALKS 7106 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 7106 clinical trials; whether ALKS 7106 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 7106; and those risks described in the Alkermes plc Transition Report on Form 10-K for the fiscal period ended Dec. 31, 2013, 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.

Source: Alkermes plc

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