Alkermes Announces Results from Phase 2 Study of ALKS 37 for Treatment of Opioid-Induced Constipation

May 30, 2012

DUBLIN--(BUSINESS WIRE)-- Alkermes plc (NASDAQ: ALKS) today announced topline results from a phase 2b dose-ranging clinical study of ALKS 37 in the treatment of opioid-induced constipation. The multicenter, randomized, double-blind, placebo-controlled, repeat-dose study was designed to assess the safety, tolerability, pharmacokinetic profile and efficacy of ALKS 37 in approximately 150 patients. ALKS 37 was generally well tolerated at all dose levels, and while subjects taking ALKS 37 demonstrated an increase in bowel movements compared to baseline, the product profile did not satisfy our pre-specified criteria for advancing into phase 3 clinical trials. Based on this evaluation, Alkermes has decided not to advance ALKS 37 and will consider out-licensing opportunities.

“We had predetermined the product profile we needed to observe in order to continue to advance ALKS 37 into phase 3 clinical studies. Based on the results of this study, we will focus our future clinical development efforts on our other development programs, including ALKS 9070 for schizophrenia and ALKS 5461 for major depressive disorder,” said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. “We will continue to maintain a disciplined approach to R&D and focus our resources on clinical candidates that show the most promise.”

A second phase 2b study of ALKS 37 for the treatment of opioid-induced constipation is concluding, and no additional clinical studies for ALKS 37 are planned.

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 and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; 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 above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning the future development and potential out-licensing of ALKS 37; the focus and nature of the company’s future clinical development efforts, including the development of ALKS 9070 for schizophrenia and ALKS 5461 for major depressive disorder; and the potential promise shown by ALKS 9070 and ALKS 5461. 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. The company’s business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations.

These risks and uncertainties include, among others: whether preclinical and early clinical results for ALKS 9070 and ALKS 5461 will be predictive of future clinical study results; whether clinical trials for ALKS 37, ALKS 9070 and ALKS 5461 will be completed on time or at all; changes in the cost, scope and duration of clinical trials; whether ALKS 37, ALKS 9070 and ALKS 5461 could be ineffective or unsafe during clinical studies; whether a development partner for ALKS 37 will be found; and those risks described in the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2012 and in other filings made by the company with the Securities and Exchange Commission (“SEC”), which are available at 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 any forward-looking information contained in this press release.

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