Alkermes Announces Initiation of Phase 2b Clinical Study of ALKS 37 for the Treatment of Opioid-Induced Constipation

October 3, 2011

- Novel, Orally Active Compound Targets Gastrointestinal Tract With Limited Systemic Exposure, Without Affecting Pain Relief From Opioids -

- Topline Results From Phase 2b Studies of ALKS 37 Expected in Mid-Calendar Year 2012 -

DUBLIN, Oct 03, 2011 (BUSINESS WIRE) -- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a phase 2b study of ALKS 37, an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced constipation (OIC). This multicenter, randomized, double-blind, placebo-controlled, fixed-dose study is designed to assess the safety and efficacy of daily administration of a 100 mg dose of ALKS 37 versus placebo for 12 weeks in approximately 80 patients with OIC. The results of this phase 2b study, along with those from the dose-ranging, four-week phase 2b study initiated earlier this year, are expected to be part of the End-of-Phase 2 submission package to the U.S. Food and Drug Administration (FDA).

"We believe ALKS 37 has the potential to normalize bowel function in patients being treated with opioids for chronic pain, without affecting their analgesic effects, and we are excited to initiate this phase 2b study of ALKS 37 for OIC," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "OIC is a significant and growing clinical condition because of widespread use of opioids to treat chronic pain, and we look forward to seeing the results of both phase 2b studies of ALKS 37 in mid-2012."

In February 2011, Alkermes announced data from its first phase 2 double-blind, randomized, placebo-controlled clinical study of ALKS 37, which showed that it significantly improved gastrointestinal motility and increased the frequency of bowel movements in patients with OIC, while simultaneously preserving the analgesic effects of opioid treatment. The study also demonstrated that ALKS 37 was generally well tolerated with limited systemic exposure and bioavailability. In July 2011, Alkermes announced the initiation of a dose-ranging phase 2b study of ALKS 37 for the treatment of OIC. The multicenter, randomized, double-blind, placebo-controlled, repeat-dose study is designed to assess the safety, tolerability, pharmacokinetic profile and efficacy of ALKS 37 in approximately 150 patients.

Phase 2b Study Design

Alkermes' second phase 2b study of ALKS 37 is a multicenter, randomized, double-blind, placebo-controlled, fixed-dose study that will evaluate the safety and efficacy of once-daily administration of ALKS 37 versus placebo for 12 weeks in approximately 80 patients experiencing OIC during treatment with opioids for chronic, non-cancer pain. Under the study protocol, patients will be randomly assigned to placebo or 100 mg of oral ALKS 37 once daily. The primary efficacy endpoint of the study is the change from baseline in the frequency of weekly complete spontaneous bowel movements (CSBMs) during the initial four weeks of the treatment period. A CSBM is defined as a bowel movement that occurs in the absence of laxative usage within the preceding 24 hours accompanied by a patient's self-reporting of a feeling of complete evacuation. Additional endpoints of the study include the change from baseline in the frequency of weekly spontaneous bowel movements (SBMs), a responder analysis and the median time to first SBM and CSBM following the first dose of ALKS 37.

About Opioid-Induced Constipation

According to IMS Health, an estimated 266 million prescriptions were written for opioids in the United States during 2010, and up to 90% of those treated with prescription opioids experience constipation.[1] OIC can be severe and adversely impact quality of life, compromising a patient's compliance with opioid therapy for pain management.

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 http://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 planned future development of ALKS 37, including the expected timing of the results from the phase 2b studies; and the therapeutic value of the company's products. 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 37 will be predictive of future clinical study results; whether future clinical trials for ALKS 37 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 37 clinical trials; whether ALKS 37 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 37; and those risks described in the Alkermes, Inc. Annual Report on Form 10-K, as amended, for the year ended March 31, 2011, subsequent Quarterly Reports on Form 10-Q, recent Current Reports on Form 8-K, the definitive proxy statement/prospectus (commission file number 333- 175078) with respect to the merger of Alkermes, Inc. and Elan Drug Technologies, and in other filings made by the company with the Securities and Exchange Commission ("SEC"), which are available at the SEC's website at

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.

[1] Panchal SJ, Müller-Schwefe P, Wurzelmann JI. Opioid-induced bowel dysfunction: prevalence, pathophysiology and burden. *Int J Clin Pract*. 2007;61(7):1181-1187.

SOURCE: Alkermes plc

Alkermes plc
For Investors:
Rebecca Peterson, +1-781-609-6378
or
For Media:
Jennifer Snyder, +1-781-609-6166