Alkermes Announces Positive Preliminary Results from Phase 2 Study of ALKS 37 for Treatment of Opioid-Induced Bowel Dysfunction

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- Novel Orally Active Compound Targets Gastrointestinal Tract with Limited Systemic Exposure without Affecting Pain Relief from Opioids -

- Company Intends to Proceed into Pivotal Development Program in Mid Calendar 2011 -

WALTHAM, Mass., Feb 15, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced positive preliminary results from a phase 2, double-blind, randomized, placebo-controlled clinical study of ALKS 37, an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced bowel dysfunction (OBD), which includes constipation and associated gastrointestinal (GI) abnormalities resulting from chronic use of opioid pain medications. Data from the study showed that ALKS 37 significantly improved GI motility and increased the frequency of bowel movements in patients with OBD, 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. Based on these results, Alkermes plans to advance ALKS 37 into a pivotal development program in mid calendar 2011.

"OBD is one of the most prevalent side effects of prescription opioid use and a major clinical issue given the widespread utilization of opioids in the treatment of chronic pain," said Anthony Lembo, M.D., Associate Professor of Medicine at Harvard Medical School. "There is significant need for a well tolerated, orally active treatment that enables patients to maintain pain relief without having to experience the debilitating effects of OBD."

In this multi-center, multi-dose study, 87 patients diagnosed with OBD during treatment with opioids for chronic, non-cancer pain were randomized to receive escalating doses of ALKS 37 or placebo pursuant to a pre-defined dose escalation schedule. There was a clear dose-response relationship, with the two highest doses tested (30 mg and 100 mg once daily) demonstrating a statistically significant increase in the pre-specified primary endpoint of change from baseline in the average number of spontaneous bowel movements (SBMs), compared to placebo. Patients receiving 100 mg ALKS 37 once daily had a mean change from baseline in the average number of SBMs per week of 4.6 versus 0.7 in the placebo group (p=0.003), or a net increase of 3.9 SBMs over placebo.

The study also demonstrated a clinically meaningful and statistically significant increase in the average number of complete spontaneous bowel movements (CSBMs) per week from baseline at the 100 mg dose, as compared to placebo. The mean change from baseline in the average number of CSBMs per week for patients receiving 100 mg ALKS 37 was 3.6 versus 0.8 in the placebo group (p=0.006), or a net increase of 2.8 CSBMs over placebo. Importantly, there was no reversal of analgesia as measured by a change in Numerical Pain Rating Scale (NPRS) scores and no increase in opioid use.

"We set out to design a metabolically stable molecule to target the GI tract with limited systemic exposure to address the medically important condition of opioid-induced bowel dysfunction. We have done just that, and are extremely encouraged by the safety, tolerability and efficacy results seen in this phase 2 study of ALKS 37," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Our goal is to develop an oral drug that can normalize bowel function in patients being treated with opioids for chronic pain, without affecting the analgesic effects of prescription opioid medications. Based on these results, we are looking forward to initiating an aggressive pivotal development program in mid calendar 2011."

Study Design

The phase 2, multi-center, randomized, double-blind, placebo-controlled, multi-dose study of ALKS 37 was designed to evaluate the efficacy, safety and tolerability of ALKS 37 in 87 patients experiencing OBD during treatment with opioids for chronic, non-cancer pain. Patients were eligible to enroll in the study if they experienced fewer than three CSBMs per week during the baseline period. An SBM is defined as a bowel movement that occurs in the absence of laxative usage within the preceding 24 hours. A CSBM is defined as an SBM that is accompanied by the patient self-reporting a feeling of complete evacuation.

Patients in the study were being treated for moderate to severe pain with opioid analgesics at doses of 30 or more morphine equivalent units. Under the study protocol, patients were randomly assigned to placebo or escalating doses of oral ALKS 37 once daily (1-100 mg) for a treatment exposure period of two weeks. The primary efficacy endpoint of the study was the change in average number of SBMs per week from baseline. The study also evaluated the change in average number of CSBMs per week from baseline. Secondary endpoints included reversal of analgesia as measured by a change in NPRS scores as well as increase in opioid use during the two-week treatment period.

ALKS 37 was generally well tolerated in the study with no serious adverse events. The most commonly reported clinical side effects at efficacious doses were GI-related, including abdominal pain (25%) and diarrhea (22%). Full results from the study will be submitted to an upcoming medical meeting.

About Opioid-Induced Bowel Dysfunction

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

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol and opioid dependence and manufactures RISPERDAL® CONSTA® for

schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in 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 Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: statements concerning the planned future development of ALKS 37, including the expected timing of the pivotal development program; and the therapeutic value of the company's products. 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 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 37 will be predictive of future clinical study results; whether future clinical trials for ALKS 37 will be completed on time or at all; potential changes in cost, scope and duration of the ALKS 37 clinical trials; ALKS 37 could be ineffective or unsafe during clinical studies, and we may not be permitted by regulatory authorities to undertake new or additional clinical studies for ALKS 37; and those risks described in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2010. 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, Inc.

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