Alkermes Presents Phase 2 Data of ALKS 37 in Late-Breaking Oral Session at Digestive Disease Week Meeting

May 9, 2011

CHICAGO & WALTHAM, Mass., May 09, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today presented positive results from the phase 2 study of ALKS 37 for the treatment of opioid-induced constipation (OIC) in a late-breaking oral session at Digestive Disease Week (DDW) 2011 in Chicago. Data from the study showed that ALKS 37 significantly improved GI motility, demonstrated by increased 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 bioavailability and systemic exposure. The results reported are 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 OIC.

"These positive results show that ALKS 37 offers potential as a treatment for opioid-induced constipation, a serious and debilitating side effect of chronic prescription opioid therapy," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "ALKS 37, one of several proprietary product candidates in our advancing clinical pipeline, is an excellent example of how the company is leveraging its unique understanding of opioid biology and pharmacology to develop medications that address current unmet medical needs."

Study Design and Results

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 escalating doses of ALKS 37 in 87 patients experiencing OIC during treatment with opioids for chronic, non-cancer pain. Patients were eligible to enroll in the study if they experienced fewer than three complete spontaneous bowel movements (CSBMs) per week during the baseline period. A spontaneous bowel movement (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 accompanied by 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 per day. 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 Numerical Pain Rating Scale (NPRS) scores as well as increase in opioid use during the two-week treatment period.

Key results of the ALKS 37 phase 2 study include:

- A clear dose response relationship, with the two highest doses tested (30 mg and 100 mg once daily) demonstrating an increase in the pre-specified primary endpoint of change from baseline in the average number of SBMs, compared to placebo.
- Patients receiving 100 mg ALKS 37 once daily achieved a significantly (p=0.006) greater increase in the mean number of SBMs per week from baseline, as compared to placebo patients (4.5 versus 0.7, net increase of 3.8 SBMs over placebo).
- Patients receiving 100 mg ALKS 37 once daily achieved a significantly (p=0.007) greater increase in the mean number of CSBMs per week from baseline, as compared to placebo patients (3.5 versus 0.8, net increase of 2.7 CSBMs over placebo).
- No reversal of analgesia as measured by a change in NPRS scores and no increase in opioid use.

ALKS 37 was generally well tolerated in the study with no serious adverse events. The most commonly reported clinical side effects at efficacious doses (30 mg and 100 mg) were GI-related, including abdominal pain (25%) and diarrhea (22%).

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, which is a predominant component of OIC.[1] OIC 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® Update Cancel 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.

About Digestive Disease Week (DDW)

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. DDW is jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract. The meeting

showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in gastrointestinal research, medicine and technology. For more information, visit www.ddw.org.

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; whether there will occur potential changes in cost, scope and duration of the ALKS 37 clinical trials; whether ALKS 37 could be shown 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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