Alkermes Announces Positive Results from Phase 3 Clinical Study of Naltrexone for Extended-Release Injectable Suspension for the Treatment of Opioid Dependence

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— Once-Monthly, Non-Addictive Treatment Significantly Reduced Opioid Use in Multicenter, Six-Month Study —

— Company to File for FDA Approval in the First Half of Calendar 2010 —

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 16, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced positive preliminary results from a phase 3 clinical trial of naltrexone for extended-release injectable suspension (XR-NTX) for the treatment of opioid dependence. The six-month phase 3 study met its primary efficacy endpoint and data showed that patients treated once-monthly with XR-NTX demonstrated statistically significant higher rates of clean (opioid-free) urine screens, compared to patients treated with placebo, as measured by the cumulative distribution of clean urine screens ($p<0.0002$). Based on the positive results of this phase 3 study, Alkermes plans to file a supplemental New Drug Application (sNDA) with the U.S. Food and Drug Administration (FDA) in the first half of calendar 2010. XR-NTX, marketed by Alkermes as VIVITROL®, is an opioid antagonist administered once-monthly by intramuscular injection and is approved in the U.S. for the treatment of alcohol dependence. If approved by the FDA for the treatment of opioid dependence, XR-NTX has the potential to be the first and only non-narcotic, non-addictive drug agent available in a once-monthly formulation.

In addition to meeting the primary efficacy endpoint, the six-month phase 3 study met all secondary efficacy endpoints. Data from the intent-to-treat (ITT) analysis show that the median patient taking XR-NTX had 90% opioid-free urine screens during the evaluation phase of the study and patients treated with XR-NTX demonstrated a significant reduction in opioid craving compared to placebo as measured by a visual analog scale. XR-NTX was generally well tolerated in the study and no patients on XR-NTX discontinued the study due to adverse events. The most common adverse events experienced by patients receiving XR-NTX during the study were nasopharyngitis and insomnia.

“These robust data show that XR-NTX helped opioid dependent patients become drug-free with just one injection each month,” stated Dr. Herbert Kleber, Professor of Psychiatry, Director, Division on Substance Abuse, Columbia University. “XR-NTX is a unique formulation that offers patients and physicians a once-monthly, non-addictive medication to help fight this challenging disease.”

“Medical treatment for opioid dependence is an established and growing pharmaceutical market, yet there are limitations with currently available therapies," stated Richard Pops, Chief Executive Officer of Alkermes. “We look forward to expanding our label beyond alcohol dependence to make XR-NTX available as the first and only non-narcotic, non-addictive, once-monthly treatment option for the millions of patients struggling with opioid dependence.”

Alkermes will complete the full analysis of the phase 3 trial data and plans to submit the data for publication in a peer-reviewed journal.

Phase 3 Study Design

The phase 3 randomized, multi-center study was designed to assess the efficacy and safety of XR-NTX compared to placebo treatment in opioid dependent subjects who have been recently detoxified and abstinent from opioids for a minimum of seven days prior to treatment initiation. Two hundred and fifty subjects were randomized to receive once-monthly injections of either XR-NTX 380 mg or placebo in combination with counseling for six months. The primary efficacy endpoint was the response profile based on the rate of urine drug screens that were free of opioids during the last 20 weeks of the 24-week double-blind treatment period, as measured by the cumulative distribution of clean urine screens. The secondary efficacy endpoints in the phase 3 study were the study retention rate, craving scores, self-reported opioid use and the incidence of physiologic opioid dependence. All participants who completed the randomized portion of the study are eligible to continue in an open-label extension phase and receive XR-NTX once-monthly in combination with counseling for an additional thirteen months.

About Opioid Dependence

In addition to the use of heroin, an illegal opioid drug, opioid abuse and addiction includes the non-medical use of FDA-approved opioid analgesics, including prescription pain relievers, and represents a growing public health problem in the U.S. According to the 2008 U.S. National Survey on Drug Use and Health, an estimated two million people aged 12 or older were dependent on or abused pain relievers or heroin.[1] The overall cost of prescription opioid abuse in the U.S. has been estimated at $9.6 billion, including health care, criminal justice, and workplace costs.[2]

About VIVITROL

VIVITROL is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and was approved by the FDA in April 2006. The proprietary Medisorb® drug delivery technology in VIVITROL enables the medication to be gradually released into the body at a controlled rate over a one-month time period. For a copy of the VIVITROL full prescribing information, including boxed warning, please visit www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876).

VIVITROL Important Safety Information in Alcohol Dependence

VIVITROL is contraindicated in patients receiving opioid analgesics or with current physiologic opioid dependence, patients in acute opiate withdrawal, any individual who has failed the naloxone challenge test or has a positive urine screen for opioids, or in patients who have previously exhibited hypersensitivity to naltrexone PLG, carboxymethylcellulose or any other components of the diluent.

VIVITROL patients must be opioid free for a minimum of 7-10 days before treatment. Attempts to overcome opioid blockade due to VIVITROL may result in a fatal overdose. In prior opioid users, use of opioids after discontinuing VIVITROL may result in a fatal overdose because patients may be more sensitive to lower doses of opioids. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by appropriately trained personnel in a setting equipped for cardiopulmonary resuscitation.

Naltrexone has the capacity to cause hepatocellular injury when given in excessive doses.

Naltrexone is contraindicated in acute hepatitis or liver failure, and its use in patients with active liver disease must be carefully considered in light of its hepatotoxic effects.

The margin of separation between the apparently safe dose of naltrexone and the dose causing hepatic injury appears to be only five-fold or less. VIVITROL does not appear to be a hepatotoxin at the recommended doses.

Patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Use of VIVITROL should be discontinued in the event of symptoms and/or signs of acute hepatitis.

VIVITROL is administered as a gluteal intramuscular injection. Inadvertent subcutaneous injection of VIVITROL may increase the likelihood of severe injection site reactions. VIVITROL must be injected using the customized needle provided in the carton. Because needle length may not be adequate due to body habitus, each patient should be assessed prior to each injection to assure that needle length is adequate for intramuscular administration. VIVITROL injection site reactions may be followed by pain, tenderness, induration, swelling, erythema, bruising or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including in some cases surgical intervention.

Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia. In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics. Alcohol dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thoughts. Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The most common adverse events associated with VIVITROL in clinical trials were nausea, vomiting, headache, dizziness, asthenic conditions and injection site reactions.

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 dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

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, the continued development of XR-NTX for the treatment of opioid dependence; our plan to file a sNDA for XR-NTX with FDA in the first half of calendar 2010 and the potential therapeutic and commercial value of XR-NTX for the treatment of opioid dependence. 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 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 data from the phase 3 study will be sufficient to form the basis of a sNDA for XR-NTX for the treatment of opioid dependence; whether XR-NTX will be approved by regulatory authorities for the treatment of opioid dependence; and, if approved, whether XR-NTX will be subsequently commercialized successfully. For further information with respect to factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports the company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and the company disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

[1]SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2008. Accessed from http://oas.samhsa.gov/nsduh/2k8nsduh/AppG.htm#TabG-27 on November 10, 2009.

[2]Birnbaum HG, White AG, Reynolds JL, Greenberg PE, Zhang M, Vallow S, Schein JR, Katz NP. Estimated costs of prescription opioid analgesic abuse in the United States in 2001: A societal perspective. *Clin J Pain*. 2006 Oct;22(8):667-76.

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