Alkermes Completes Enrollment for Registration Study of VIVITROL(R) in Patients with Opioid Dependence

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- VIVITROL Clinical Development Program Expanded with Phase 3b Study in Healthcare Professionals -

CAMBRIDGE, Mass., Apr 21, 2009 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced that it has completed patient enrollment for the registration study of VIVITROL(R) (naltrexone for extended-release injectable suspension) for the treatment of opioid dependence, a chronic brain disease. The data from this study will form the basis of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for VIVITROL for this indication. VIVITROL is a once-monthly, intramuscular injection approved in the U.S. and Russia for the treatment of alcohol dependence and is not currently approved for the treatment of opioid dependence. Alkermes expects to report topline results from this registration study in late calendar 2009 and anticipates a sNDA submission in calendar 2010.

Alkermes also announced today that the company is expanding its VIVITROL clinical development program for the treatment of opioid dependence and will initiate a phase 3b study in healthcare professionals, such as physicians, nurses or pharmacists. The multi-center study will assess the safety and tolerability of VIVITROL in healthcare professionals with a history of opioid dependence who are enrolled in an extended outpatient treatment program that includes psychosocial support, such as counseling. Data from the study will be used to help further demonstrate the value of VIVITROL to patients, physicians and payors.

"The completion of patient enrollment in this registration study of VIVITROL for the treatment of opioid dependence is an important milestone, as there are few approved medications available for these patients and no approved long-acting antagonist therapies," stated Dr. Elliot Ehrich, chief medical officer of Alkermes. "Beyond the registration study, we are expanding the VIVITROL development program with a new study of VIVITROL in healthcare professionals. This study reflects our ongoing commitment to fully elucidate the potential of VIVITROL in different patient populations and to further evolve the treatment paradigm for all individuals suffering from opioid dependence. We very much look forward to the results of both studies."

While opioid dependence affects approximately 1.3 million adults in the U.S., the rate of prescription opioid misuse is estimated to be five times higher among physicians than the general population.[1,2] Physician impairment is a major public health issue, as it affects not only these individuals but also their patients, colleagues and families. For physicians, a long-acting antagonist therapy such as VIVITROL could be an important treatment option as part of recovery.

"Unfortunately, stressors related to working in healthcare, along with easier access to opioids, can put healthcare professionals at an increased risk for addiction to prescription-based therapeutics, such as pain medications. For the well-being of healthcare professionals and for the safety of patients, it's important to get healthcare professionals on the road to recovery," stated Dr. Greg Skipper, medical director, Alabama Physician Health Program. "A long-acting antagonist therapy, such as VIVITROL, could provide an important approach to long-term recovery and potentially help reduce the risk of relapse."

Registration Study Design

The phase 3 randomized, multi-center study is designed to assess the efficacy and safety of VIVITROL 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. More than 250 subjects have been randomized to receive once-monthly intramuscular injections of either VIVITROL or placebo in combination with counseling for six months. The primary efficacy endpoint is the response profile based on the rate of positive urine drug test results. All participants who complete the randomized portion of the study will be eligible to continue in an open-label phase and receive VIVITROL once-monthly in combination with counseling for an additional seven months. The objective of the extension phase of the study is to assess the long-term durability of effect, health economics and quality of life outcomes with once-monthly VIVITROL injections.

Phase 3b Study Design

The phase 3b, open-label, multi-center study will assess the long-term safety and tolerability of VIVITROL administered to healthcare professionals with a history of opioid dependence who are actively enrolled in an extended outpatient treatment program. Approximately 50 subjects will receive once-monthly intramuscular injections of VIVITROL in combination with psychosocial support for 24 months. The primary safety endpoint will be measured by the incidence of adverse events. The efficacy of VIVITROL and its effect on quality of life will also be evaluated.

About Opioid Dependence

In addition to the use of heroin, an illegal opioid, 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 2006 U.S. National Survey on Drug Use and Health, an estimated 1.3 million people aged 18 or older were dependent on or abused pain relievers or heroin.[1] Researchers have found that the cost of prescription opioid abuse in the U.S. in 2001 was $9.2 billion.[3]

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(R) for alcohol dependence and manufactures RISPERDAL(R) CONSTA(R) for schizophrenia. 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.

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 U.S. Food and Drug Administration in April 2006. The proprietary Medisorb(R) 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 more information about VIVITROL, please visit www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876).

Important Safety Information
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 contraindicated in patients receiving or dependent on opioids, in acute opioid withdrawal, and in those who have failed the naloxone challenge test or have a positive urine screen for opioids; and in those with previous hypersensitivity to naltrexone, PLG, carboxymethylcelluose, or any other components of the diluent.

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 fatal overdose. In prior opioid users, use of opioids after discontinuing VIVITROL may result in 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.

Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia. Injection site reactions not improving may require prompt medical attention. Alcohol-dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thinking. 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. For full prescribing information, please visit www.vivitrol.com or call 1-800-VIVITROL.

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 VIVITROL for the treatment of opioid dependence and the potential therapeutic value of VIVITROL for the treatment of opioid dependence in healthcare professionals or other individuals. 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 ongoing registration study will be sufficient to form the basis of a sNDA for VIVITROL for the treatment of opioid dependence; the results of the clinical trial of VIVITROL for the treatment of opioid dependence in healthcare professionals; decisions by the FDA or foreign regulatory authorities regarding VIVITROL for the treatment of opioid dependence; and potential changes in cost, scope and duration of the registration study and the phase 3b clinical trial of VIVITROL for the treatment of opioid dependence. 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, 2006 and 2007.

[2] Merlo MJ and Gold MS. Prescription Opioid Abuse and Dependence Among Physicians: Hypotheses and Treatment. *Harv Rev Psychiatry*. 2008 16(3):181-94.

[3] 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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Alkermes
For Investors:
Rebecca Peterson, 617-583-6378
or
For Media:
Jennifer Snyder, 617-583-6166