# Alkermes Initiates Phase 3 Clinical Study of VIVITROL(R) for the Treatment of Opioid Dependence

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--June 26, 2008--Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 3 clinical trial of VIVITROL(R) (naltrexone for extended-release injectable suspension) for the treatment of opioid dependence. The multi-center study is designed to assess the efficacy and safety of VIVITROL in approximately 200 patients diagnosed with opioid dependence. The clinical 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 the treatment of opioid dependence, a chronic brain disease.

"Opioid dependence is a serious disease affecting millions of people yet there are few approved medications available for these patients and no approved long-acting antagonist therapies," stated Dr. Herbert Kleber, Professor of Psychiatry, Director, Division on Substance Abuse, Columbia University. "Naltrexone, the active ingredient in VIVITROL, has been shown to effectively block the effects of opiates but patients have difficulty complying with a daily medication regimen. Therefore, I am pleased to see the development of new therapeutic options, such as VIVITROL, which could provide an important approach to long-term recovery and potentially help reduce the risk of relapse."

In addition to the use of heroin, an illegal opioid, opioid abuse and addiction includes the non-medical use of 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 1.9 million people aged 12 or older were dependent on or abused pain relievers or heroin.(1) In 2005, the European Monitoring Centre for Drugs and Drug Addiction estimated the prevalence of problem opioid use in Europe to be in the range of 1.3 to 1.7 million people.(2) Researchers have found that the cost of prescription opioid abuse in the U.S. in 2001 was $9.2 billion.(3)

"The advancement of VIVITROL into phase 3 development for an indication of opioid dependence marks an important milestone for the program," stated Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "If approved, VIVITROL would be the first and only non-narcotic, non-addictive, long-acting medication for the treatment of opioid dependence."

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. Approximately 200 subjects will be 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.

About Alkermes

Alkermes, Inc., a biotechnology company committed to developing innovative medicines to improve patients' lives, manufactures RISPERDAL(R) CONSTA(R) for schizophrenia and developed and manufactures VIVITROL(R) for alcohol dependence. 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 and manufacturing facilities in Massachusetts and Ohio. For more information about Alkermes, visit http://www.alkermes.com.

About VIVITROL

VIVITROL was approved by the U.S. Food and Drug Administration in April 2006 for the treatment of alcohol dependence. 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 1-800-896-5855.

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. 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: the results of the clinical trial of VIVITROL for the treatment of opioid dependence; 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 phase 3 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) Substance Abuse and Mental Health Services Administration. (2007). Results from the 2006 National Survey on Drug Use and Health: National Findings (Office of Applied Studies, NSDUH Series H-32, DHHS Publication No. SMA 07-4293).

(2) European Monitoring Centre for Drugs and Drug Addiction. Opioid use and drug injection. Retrieved on June 4, 2008 from http://www.emcdda.europa.eu/.

(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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