Alkermes Announces Notification of Tentative FDA Advisory Committee Meeting to Review VIVITROL® for Opioid Dependence

June 17, 2010

WALTHAM, Mass., Jun 17, 2010 (BUSINESS WIRE) --Alkermes, Inc. (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has notified the company of the tentative scheduling of a Psychopharmacologic Drugs Advisory Committee meeting on September 16, 2010, for the review of the company's supplemental New Drug Application (sNDA) for VIVITROL® (naltrexone for extended-release injectable suspension) for opioid dependence. Notification of this potential advisory committee meeting follows a designation in May 2010 by the FDA of priority review of the VIVITROL sNDA, a designation that accelerates the FDA's target review timeline from ten to six months for drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. With priority review, the Prescription Drug User Fee Act (PDUFA) date for the FDA's decision regarding approval of the VIVITROL sNDA for opioid dependence is October 12, 2010.

"The upcoming FDA advisory committee meeting represents progress toward our goal of obtaining approval of VIVITROL for patients with opioid dependence, building on the recent priority review designation by the FDA and our compelling phase 3 pivotal data showing the efficacy of VIVITROL for opioid dependence. We are pleased that the FDA has moved expeditiously to schedule a panel prior to the PDUFA date," stated Richard Pops, Chief Executive Officer of Alkermes. "We are confident in our sNDA submission and look forward to discussing the efficacy and safety data for VIVITROL for opioid dependence with the members of the panel and the FDA review team. If approved, VIVITROL could change the treatment paradigm as the first and only non-narcotic, non-addictive, once-monthly medication for the treatment of opioid dependence."

Alkermes submitted the sNDA for VIVITROL for opioid dependence in April 2010. Confirmation and details of the FDA advisory committee meeting for VIVITROL are expected to be published in the Federal Register about six to eight weeks prior to the scheduled meeting date. The Federal Register notice will be available at the following website: http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm.

The sNDA is based on statistically significant results from a recent phase 3 study assessing the efficacy and safety of VIVITROL for opioid dependence. VIVITROL is an opioid antagonist administered once-monthly by intramuscular injection and is approved in the U.S. for the treatment of alcohol dependence.

About Opioid Dependence

A chronic brain disease, opioid dependence is characterized by cognitive, behavioral and physiological symptoms in which an individual continues to use opioids despite significant harm to himself and others.[1] The misuse of opioids can create euphoria of such intensity that it reinforces drug taking behavior and may lead to opioid dependence or addiction.[2] In addition to the use of heroin, an illegal opioid drug, opioid abuse and addiction includes the non-medical use of 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 1.3 million people aged 18 or older were dependent on pain relievers or heroin.[3] The overall cost of prescription opioid abuse in the U.S. has been estimated at $9.6 billion, including healthcare, criminal justice and workplace costs,[4] and the overall cost of heroin addiction in the U.S. has been estimated to be approximately $22 billion, including productivity losses, criminal activity, healthcare and social welfare costs.[5]

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 http://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 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.

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 occurrence of an advisory committee meeting for the review of the VIVITROL sNDA, the timeline for FDA review and regulatory action relating to the sNDA submission for VIVITROL for the treatment of opioid dependence, and the company's expectations concerning the potential therapeutic and commercial 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: whether the advisory committee, if held, will recommend approving VIVITROL for the treatment of opioid dependence; whether the advisory committee will recommend labeling and, if so, the impact of such recommendations on the potential of VIVITROL; whether VIVITROL will be approved by the FDA for the treatment of opioid dependence by October 12, 2010 or at all; and, if approved, whether VIVITROL will be 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]DSM-IV-TR, American Psychiatric Association

[2]Tomkins DM, Sellers EM. Addiction and the brain: the role of neurotransmitters in the cause and treatment of drug dependence. *CMAJ.* 2001 March;164(6)

[3]SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2008. Accessed from http://www.oas.samhsa.gov/NSDUH/2k8NSDUH/tabs/Sect5peTabs1to56.htm#Tab5.14A on March 11, 2010.

[4]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.

[5]Mark TL, Woody GE, Juday T, Kleber HD. The economic costs of heroin addiction in the United States. *DrugAlcohol Depend.* 2001;61:195-206.

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