



Data on VIVITROL® to be Presented at Upcoming American Psychiatric Association Annual Meeting

May 19, 2010

WALTHAM, Mass., May 19, 2010 (BUSINESS WIRE) --Alkermes, Inc. (NASDAQ: ALKS) today announced that new data from several company-sponsored studies of naltrexone for extended-release injectable suspension (XR-NTX) are scheduled to be presented at the 2010 American Psychiatric Association (APA) Annual Meeting in New Orleans, May 22-26, 2010.

XR-NTX is marketed by Alkermes as VIVITROL® and is approved in the U.S. for the treatment of alcohol dependence. The company recently submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for the treatment of opioid dependence and, if approved, XR-NTX has the potential to be the first and only non-narcotic, non-addictive drug agent available in a once-monthly formulation.

Presentations to be featured at the 2010 APA Annual Meeting include data on the use of XR-NTX in both alcohol dependence and opioid dependence. The following four studies will be available at the meeting on Wednesday, May 26, 2010 at 3:00 PM CDT:

Characteristics, Persistence and Outcomes of Insured Patients Treated with Extended-Release Naltrexone (XR-NTX) or Oral Medications

Lead Investigator: Henry R. Kranzler, M.D., University of Connecticut School of Medicine, Farmington, CT
Poster # NR7-3

Efficacy and Safety of Extended-Release Injectable Naltrexone (XR-NTX) for the Treatment of Opioid Dependence

Lead Investigator: Evgeny M. Krupitsky, M.D., St. Petersburg Regional Center of Addictions, Novodeviatkino 19/1, Leningrad Region 188661, Russia
Poster # NR7-6

Preliminary Evaluation of Extended-Release Naltrexone (XR-NTX) in Michigan and Missouri Drug Courts

Lead Investigator: Michael Finigan, Ph.D., Northwest Professional Consortium, Inc., Portland, OR
Poster # NR7-12

Extended Release Injectable Naltrexone (XR-NTX) Reduces Brain Response to Alcohol Cues in Alcohol Dependent Volunteers: A BOLD fMRI Study

Lead Investigator: Scott E. Lukas, Ph.D., Brain Imaging Center, McLean Hospital, Belmont, MA
Poster # NR7-16

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://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.vivitrol.com&esheet=6296199&lan=en_US&anchor=www.vivitrol.com&index=1&md5=5d6305fe9b92ee174251f053471747f3 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, decisions by the FDA relating to the sNDA submission for VIVITROL for the treatment of opioid dependence and 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 VIVITROL will be approved by regulatory authorities for the treatment of opioid dependence; 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.

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SOURCE: Alkermes, Inc.

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