Data on VIVITROL®, the New FDA-Approved Medication for Prevention of Relapse to Opioid Dependence, Published in The Lancet

April 27, 2011

- Study Results Showed Non-Addictive, Non-Narcotic, Once-Monthly VIVITROL Effective for Treating Opioid Dependence -

WALTHAM, Mass., Apr 27, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced that results from the phase 3 clinical study of VIVITROL® (naltrexone for extended-release injectable suspension) in opioid dependence have been published by *The Lancet*. The six-month, phase 3 trial met its primary endpoint and showed significantly greater opioid-free weeks among patients treated with VIVITROL, compared to placebo. VIVITROL is the first and only non-addictive, non-narcotic, once-monthly medication approved by the U.S. Food and Drug Administration (FDA) for the prevention of relapse to opioiddependence, following opioid detoxification. VIVITROL should be used along with psychosocial support such as counseling. In contrast to conventional agonist therapies that maintain stimulation of opioid receptors, VIVITROL is an opioid-blocking antagonist that, when administered once per month, occupies the opioid receptor, thereby helping to prevent patients from relapsing to opioid dependence.

"There has been a dramatic increase in the prevalence of opioid dependence, which is a serious, life-threatening disease characterized by high rates of relapse, yet there are so few medications available to treat opioid dependence," stated Evgeny Krupitsky, M.D., Ph.D., Professor of Psychiatry, St. Petersburg State Pavlov Medical University and Head of the Department of Addictions at the Bekhterev Research Psychoneurological Institute. "The robust data from this phase 3 clinical trial showed that treatment with VIVITROL helped opioid-dependent patients remain drug-free with just one injection per month. VIVITROL is the only once-monthly medication that offers patients and physicians a non-narcotic treatment option to help fight this challenging disease."

The pivotal study also met all secondary endpoints, including opioid craving, self-reported opioid use, study retention rate and incidence of physical opioid dependence. Patients in both the VIVITROL and placebo groups received counseling.

"To date, there has been strong recognition from addiction experts and the treatment community that VIVITROL is an important new treatment option for opioid dependence, and the publication of the phase 3 data is an opportunity for us to more broadly share the comprehensive clinical results demonstrating VIVITROL's safety and efficacy with the addiction treatment community," said Richard Pops, Chief Executive Officer of Alkermes. "Alkermes is committed to advancing the field of addiction treatment through the development of new medications that help patients better manage their disease."

In the phase 3 study, patients treated once-monthly with VIVITROL demonstrated statistically significant higher rates of opioid-free urine tests during the evaluation phase, compared to patients treated with placebo, as measured by the cumulative distribution of opioid-free urine tests ($p<0.0002$). Data showed that the median patient taking VIVITROL had 90% opioid-free urine tests. A greater percentage of patients in the VIVITROL group remained in the study compared to the placebo group. Safety was assessed through monitoring of treatment-emergent adverse events, vital signs, biochemistry and hematology urine/blood tests including liver function tests, physical examination of injection sites, and baseline and endpoint electrocardiograms. VIVITROL was generally well tolerated in the study; two patients in each treatment arm discontinued due to adverse events. The most common clinical adverse events experienced by patients receiving VIVITROL during the study were hepatic enzyme elevations, nasopharyngitis and insomnia.

VIVITROL Phase 3 Study Design

The phase 3 randomized, multi-center study was designed to assess the efficacy and safety of VIVITROL compared to placebo treatment in opioid-dependent subjects who had 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 VIVITROL 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 tests 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 opioid-free urine tests. 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 were eligible to continue in an open-label extension phase and receive VIVITROL once-monthly in combination with counseling for an additional thirteen months.

About Opioid Dependence

In addition to the use of heroin, opioid dependence 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 2009 U.S. National Survey on Drug Use and Health, an estimated 1.6 million people aged 18 or older were dependent on pain relievers or heroin.[1] 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.[2]

About VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) 380 mg/vial is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and opioid dependence. 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. Treatment with VIVITROL should be part of a comprehensive treatment program that includes psychosocial support. VIVITROL has been studied in more than 1,000 patients and has been used to treat more than 45,000 people for alcohol and opioid dependence in the U.S. The VIVITROL clinical development program was funded in part with a Small Business Innovation Research Program grant from the National Institute on Drug Abuse (NIDA). For a copy of the VIVITROL full prescribing information, please visit www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876). Please see below for important safety information,

including boxed warning.

VIVITROL IMPORTANT SAFETY INFORMATION

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

WARNING: HEPATOTOXICITY

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 an intramuscular (IM) gluteal injection. Inadvertent subcutaneous injection of VIVITROL may increase the likelihood of severe injection site reactions. VIVITROL must be injected using one of the customized needles 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 IM administration. VIVITROL injections 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. Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis. Opioid-dependent patients including those being treated for alcohol dependence, must be opioid-free for a minimum of 7-10 days before VIVITROL treatment. Attempts to overcome opioid blockade due to VIVITROL may result in a fatal overdose. After opioid detoxification, patients are likely to have reduced tolerance to opioids. Use of lower doses of opioids after VIVITROL is discontinued, at the end of a dosing interval or after missing a dose could result in life threatening opioid intoxication. Alcohol- and opioid-dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thoughts. As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder. In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by appropriately trained personnel in a setting equipped for cardiopulmonary resuscitation. Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

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 and opioid 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. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

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 successful commercialization of VIVITROL; the potential therapeutic and commercial value of VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification; and the growth of opioid dependence as a disease and public health problem. 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. 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 therapeutic results demonstrated in our clinical study of VIVITROL for opioid dependence will be predictive of future therapeutic results; whether VIVITROL will be commercialized successfully; and whether third party payors will cover or reimburse VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification. 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.

VIVITROL® and Medisorb® are trademarks of Alkermes, Inc. RISPERDAL® CONSTA® is a trademark of Janssen-Cilag group of companies.

[1] SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2009. Accessed from www.oas.samhsa.gov/NSDUH/2k9NSDUH/tabs/Sect5peTabs1to56.htm on March 11, 2010.

[2] TL, Woody GE, Juday T, Kleber HD. The economic costs of heroin addiction in the United States. Drug Alcohol Depend. 2001 Jan;61(2): 195-206.

SOURCE: Alkermes, Inc.

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