Alkermes Announces FDA Approval of VIVITROL® for Prevention of Relapse to Opioid Dependence

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-- First Once-Monthly Medication for Opioid Dependence --

WALTHAM, Mass., Oct 12, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has approved VIVITROL® (naltrexone for extended-release injectable suspension) for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL is now the first and only non-narcotic, non-addictive, once-monthly medication approved for the treatment of opioid dependence. VIVITROL was approved by the FDA in 2006 for the treatment of alcohol dependence and should be used as part of a comprehensive management program that includes psychosocial support.

"Opioid dependence is a serious and chronic illness characterized by high rates of relapse," stated Dr. Marc Fishman, Assistant Professor of Psychiatry, Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine. "VIVITROL is an opioid-blocking medication that offers patients and physicians a once-monthly medication to prevent relapse to opioid addiction."

"As an organization that helps families find treatment and offers support for loved ones with addiction, we see firsthand that opioid dependence is one of the most significant health issues facing our nation. This new indication for Alkermes' product as a non-addictive approach to prevent relapse to opioid dependence brings new hope to the families we serve," said Steve Pasierb, President and Chief Executive of The Partnership at Drugfree.org.

"Opioid dependence is a growing disease and we believe that VIVITROL offers physicians and their patients a whole new approach, as the only long-acting, non-addictive treatment for opioid dependence," stated Richard Pops, Chief Executive Officer of Alkermes. "We look forward to helping to improve the lives of patients with this chronic and debilitating condition."

The FDA approval of VIVITROL for the prevention of relapse to opioid dependence was based on data from a six-month, multi-center, randomized phase 3 study which met its primary efficacy endpoint and all secondary efficacy endpoints. Data from the intent-to-treat analysis showed that patients treated once a month with VIVITROL demonstrated statistically significant higher rates of opioid-free urine screens compared to patients treated with placebo ($p<0.0002$). VIVITROL was generally well tolerated in the study. The most common clinical adverse events experienced by patients receiving VIVITROL during the study were hepatic enzyme elevations, nasopharyngitis and insomnia.

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).

Conference Call

Alkermes will hold a conference call at 8:00 a.m. ET on Wednesday, October 13, 2010. The conference call may be accessed by dialing 1-888-517-2470 for domestic callers and 1-630-827-6818 for international callers. The conference call ID number is 7124150. In addition, a replay of the conference call will be available from 10:30 a.m. ET on Wednesday, October 13, 2010, through 5:00 p.m. ET on Saturday, October 23, 2010, and may be accessed by visiting Alkermes' website or by dialing 1-888-843-7419 for domestic callers and 1-630-652-3042 for international callers. The replay access code is 7124150. The archived webcast will be available on the Alkermes website at http://www.alkermes.com.

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 oneself 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 dependence 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 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.[3] 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.[4]

About VIVITROL

VIVITROL 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. The VIVITROL clinical development program was funded in part with a Small Business Innovation Research Program grant from the National Institute of Drug Abuse (NIDA). 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

VIVITROL is contraindicated in patients with acute hepatitis or liver failure, patients receiving opioid analgesics, patients 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, and in patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose or any other components of the diluent.

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.

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 and the potential therapeutic and commercial value of VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification. 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 therapeutic results when commercialized; 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.

[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): 817-21.

[3]SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2009. Accessed from http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/tabs/Sect5peTabs1to56.htm#Tab5.14A on October 7, 2010.

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

Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6464874&lang=en

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