Alkermes Initiates Open-Label Pilot Study of VIVITROL® to Evaluate Impact on Re-Arrest and Re-Incarceration in Offenders with History of Opioid Dependence

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DUBLIN--(BUSINESS WIRE)--Jan. 31, 2012-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a pilot study of VIVITROL® (naltrexone for extended-release injectable suspension) in prisoners with a pre-incarceration history of opioid dependence. This open-label study is designed to evaluate the feasibility of initiating treatment with VIVITROL in prison and continuing VIVITROL treatment upon release into the community.

"Opioid dependence is a challenging disease that is closely linked to criminal behavior," said Dr. Frank Vocci, President, Friends Research Institute. "For those with a history of opioid dependence prior to incarceration, the likelihood is high for relapse to opioid dependence and resumption of criminal activity upon release from prison. We are interested in evaluating the impact on recidivism with the use of once-monthly, non-narcotic VIVITROL among these high-risk individuals. Less recidivism could potentially ease the burden that state criminal justice systems bear from repeat, opioid-dependent offenders."

This open-label study of VIVITROL will assess the utility of treatment with VIVITROL in reducing incidence of re-arrest among 30 adult criminal offenders with a prior history of opioid dependence who are seeking treatment. Secondary endpoints include incidence of re-incarceration; drug abuse treatment program entry; treatment retention in the community; incidence of opioid use; and opioid overdose. Additional efficacy endpoints will be based on quality of life and HIV risk behaviors. VIVITROL will be administered to subjects approximately one week prior to their release into the community and once monthly for an additional six months, with one month of post-treatment follow-up. Regular assessments will include urine drug screens and routine safety assessments. Results from the study are expected mid-calendar 2013.

Substance Abuse in the Criminal Justice System

Nearly 65% of the 2.3 million inmates crowding U.S. prisons meet the medical criteria for substance abuse or addiction, yet only 11% receive treatment during their incarceration.[1] Substance-involved offenders are more likely to return to prison than those who are not substance-involved, and more than half (52.2%) of substance-involved inmates have one or more previous incarcerations compared with 31.2% of inmates who are not substance-involved.[1] These high rates of recidivism translate into burdensome incarceration costs for society, averaging approximately $29,000 per inmate, per year.[2] Previous research has shown that treatment with oral naltrexone can reduce the rate of recidivism by more than half, compared to patients who only received psychosocial counseling.[3]

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.[4] According to the 2010 U.S. National Survey on Drug Use and Health, an estimated 1.5 million people aged 18 or older were dependent on pain relievers or heroin.[5] 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.[6]

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 http://www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876). Please see below for important safety information, including boxed warning.

Important Safety Information for VIVITROL® (naltrexone for extended-release injectable suspension) 380 mg/vial

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 plc

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. For more information, please visit Alkermes' website at http://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 potential therapeutic and commercial value of VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification; the potential for VIVITROL to reduce the incidence of re-arrest and re-incarceration among previously incarcerated subjects with a history of opioid dependence and the potential corresponding beneficial impact of such reductions on state criminal justice systems; and the growth of opioid dependence as a disease and public health problem closely linked to criminal behavior. 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 in clinical studies and in real-world use of the product, including in this study; whether third-party payors will cover or reimburse VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification; and those risks described in our Registration Statement on Form S-4 (commission file number 333- 175078), which was declared effective by the Securities and Exchange Commission ("SEC") on August 4, 2011; and in other filings made by the company with the SEC, which are available at the SEC's website at http://www.sec.gov. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained in this press release.

VIVITROL® and Medisorb® are trademarks of Alkermes, Inc.

[1] The National Center on Addiction and Substance Abuse at Columbia University (CASA). *Behind Bars II: Substance Abuse and America's Prison Population*. February 2010.

[2] The PEW Center on the States. *1 in 31: The Long Reach of American Corrections.* March 2009.

[3] Cornish JW, Metzger D, Woody GE, et al. Naltrexone pharmacotherapy for opioid dependent federal probationers. *J Subst Abuse Treat*. 1997; 14:529-534.

[4]DSM-IV-TR, American Psychiatric Association.

[5]SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2010. Accessed from http://oas.samhsa.gov/NSDUH/2k10NSDUH/tabs/Sect5peTabs1to56.htm#Tab5.14A.

[6]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.

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