New Long-Term Data on VIVITROL® Showed Sustained Efficacy and Safety over 18 Months of Treatment

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- Results from Open-label Extension of Pivotal Trial for VIVITROL Presented at Psych Congress 2011 -

DUBLIN, Nov 09, 2011 (BUSINESS WIRE) -- Alkermes plc (NASDAQ: ALKS) today presented positive results from a long-term study of VIVITROL® (naltrexone for extended-release injectable suspension) at the 24th Annual U.S. Psychiatric and Mental Health Congress in Las Vegas, NV. Results from the one-year, open-label extension of the six-month pivotal study showed sustained efficacy of VIVITROL, as measured by the number of opioid-free urine screens, in patients who received VIVITROL, in combination with psychosocial treatment, for a total of 18 months of treatment. Additionally, all safety events observed during the open-label extension were consistent with those set forth in the approved product labeling.

"The robust data from this extension study confirm VIVITROL's efficacy and safety profile over an 18-month period and support its clinical utility as a treatment option for opioid dependence, following opioid detoxification," 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. "VIVITROL is the first and only once-monthly medication that offers patients and physicians a non-narcotic treatment option to help fight this challenging disease."

During the total observation period of 18 months, improvements during the six-month pivotal trial observed in patients treated with VIVITROL were maintained for the duration of the subsequent one-year, open-label extension study. Half of the patients (49%) who entered the one-year extension study, after receiving six months of VIVITROL in the pivotal study, were completely abstinent for the duration of the extension study, based on opioid-free urine screens. The response profile based on the number of opioid-free urine screens was the primary efficacy endpoint of the six-month pivotal study. The extension study also measured opioid craving, improvements in quality of life measures, self-reported opioid use and incidence of physical opioid dependence, confirming the findings documented in the first phase of the study. All patients received psychosocial counseling.

Treatment with VIVITROL during this study showed a low rate of clinical adverse events, the absence of severe adverse events and a low overall rate (2.6%) of injection site pain, with no serious injection site reactions. All safety events observed during the open-label extension were consistent with those set forth in the approved product labeling. No patients discontinued the open-label extension due to serious adverse events. The most common clinical adverse events listed in the extension study were toothache and influenza.

Overall, nearly 65% of patients completed the open-label study, representing a high completion rate for an addiction study. At the onset of the study, 114 patients from the original six-month pivotal trial continued into the open-label, 52-week extension study. Sixty-seven patients continued treatment with VIVITROL, while 47 patients who had been on placebo crossed over to receive VIVITROL.

About Opioid Dependence

In addition to the use of heroin, an illegal opioid drug, opioid abuse and addiction 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 2010 U.S. National Survey on Drug Use and Health, nearly 2.3 million people aged 12 or older were dependent on or abused pain relievers or heroin.[1] 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.[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 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 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 in clinical studies and in real-world use of the product; whether VIVITROL will be commercialized successfully; 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 the Alkermes, Inc. Annual Report on Form 10-K, as amended, for the year ended March 31, 2011; 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.

[1] SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2010. Accessed on Nov. 8, 2011 from http://www.samhsa.gov/data/NSDUH/2k10Results/Web/HTML/2k10Results.htm#Fig7-2.

[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 plc

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