



VIVITROL(R) Data to be Presented at Upcoming American Psychiatric Association Annual Meeting

May 3, 2012

-- Highlighted Data Include Long-Term Safety, Efficacy and Cost-Effectiveness Analyses of VIVITROL in Treatment of Alcohol and Opioid Dependence --

DUBLIN, May 03, 2012 (BUSINESS WIRE) --[Alkermes plc](#) (NASDAQ: ALKS) today announced that data from several company-sponsored studies of naltrexone for extended-release injectable suspension (XR-NTX) are scheduled to be presented at the 2012 American Psychiatric Association (APA) Annual Meeting in Philadelphia, May 5-9, 2012. XR-NTX is marketed by Alkermes as VIVITROL^(R) and is approved in the U.S. for the treatment of alcohol dependence and opioid dependence, following opioid detoxification.

Presentations to be featured at the 2012 APA Annual Meeting include data on the use of XR-NTX in both alcohol dependence and opioid dependence. Key presentations include:

[Sunday, May 6, 2012 at 8:00 a.m. EDT](#)

The oral presentation, "Extended-Release Naltrexone for the Treatment of Alcohol Dependence," will be given by David Gastfriend, M.D., Alkermes, Inc., during a symposium sponsored by the U.S. National Institute on Alcohol Abuse and Alcoholism (NIAAA), entitled "Medication Use for Treating Alcohol Dependence."

[Monday, May 7, 2012 at 2:00 p.m. EDT](#)

Poster NR7-09: "The Cost Effectiveness of Treatment With Extended-Release Naltrexone: A Structured Review Across Four Studies" will be presented by Dennis McCarty, Ph.D., Department of Public Health and Preventive Medicine, Oregon Health Sciences University.

Poster NR7-10: "Safety and Effectiveness of Treatment With a Once-Monthly, Injectable Formulation of Naltrexone in a Real-World Clinical Practice Setting" will be presented by Rochelle Wagner, Ph.D., Alkermes, Inc.

Poster NR7-11: "Open-Label Study of Extended-Release Injectable Naltrexone (XR-NTX) in Healthcare Professionals With Opioid Dependence" will be presented by Paul Earley, M.D., Member of the Board of the American Society of Addiction Medicine (ASAM).

Poster NR7-12: "Injectable Extended-Release Naltrexone (XR-NTX) for Opioid Dependence: Long-Term Safety and Effectiveness" will be presented by David Gastfriend, M.D., Alkermes, Inc.

A full list of all Alkermes abstracts being presented at the APA meeting is available at: <http://www.psychiatry.org/learn/2012-annual-meeting>.

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^(R) 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^(R) (naltrexone for extended-release injectable suspension) 380 mg/vial

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 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.

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. 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 and the other matters discussed by such forward-looking statements are subject to significant risk and uncertainties, and there can be no assurance that actual results or events will not differ materially from its expectations.

These risks and uncertainties include the risks described in the company's filings with the Securities and Exchange Commission ("SEC"), including the company's Registration Statement on Form S-1 (commission file number 333-179550), which was declared effective by the SEC on March 2, 2012, and in other filings made by the company with the SEC and 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^(R) and Medisorb^(R) are registered trademarks of Alkermes, Inc.

SOURCE: Alkermes plc

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