



## VIVITROL® to be Featured in Data Presentations at American Society of Addiction Medicine Conference

April 11, 2011

WALTHAM, Mass., Apr 11, 2011 (BUSINESS WIRE) -- [Alkermes, Inc.](#) (NASDAQ: ALKS) today announced that research on the use of [VIVITROL®](#) (naltrexone for extended-release injectable suspension) in the treatment of alcohol and opioid dependence will be presented at the American Society of Addiction Medicine's (ASAM) 42<sup>nd</sup> Annual Medical-Scientific Conference. The ASAM Medical-Scientific Conference takes place April 14 through 17, 2011 in Washington, D.C.

The presentations include:

- Extended-Release Injectable Naltrexone (XR-NTX) for the Treatment of Opioid Dependence: Efficacy in Clinically Relevant Subgroups and Predictors of Response, Friday, April 15, 2011, 11:00 a.m. - 1:00 p.m.
- Healthcare Cost Outcomes for Alcohol Dependence: A Comparison of Four Treatments, Friday, April 15, 2011, 3:00 - 5:00 p.m.

A symposium sponsored by the National Institute on Drug Abuse (NIDA) titled "Naltrexone: New Formulations and Indications" is also being held on Friday, April 15, 2011 from 11:00 a.m. to 1:00 p.m. and continuing from 3:00 p.m. to 5:00 p.m. The symposium will provide an overview of the evidence of the medical safety and efficacy of different indications, doses and formulations of naltrexone, including VIVITROL.

### 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, following opioid detoxification. 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. 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](http://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 RISPEDAL® 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](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 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 and health economic results shown in studies of VIVITROL will be predictive of future therapeutic and health economic results in commercial use; whether VIVITROL will be commercialized successfully; and whether third party payors will cover or reimburse VIVITROL. 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. RISPEDAL® CONSTA® is a trademark of Janssen-Cilag group of companies.

SOURCE: Alkermes, Inc.

Alkermes:

For Investors:

Rebecca Peterson, 781-609-6378

or

For Media:

Jennifer Snyder, 781-609-6166