



## Pharmacoeconomic Value of Addiction Treatments, Including VIVITROL®, Published in Leading Healthcare Policy Journal

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### **- New Studies in The American Journal of Managed Care Reinforce the Economic Value of Treating Substance Abuse with Modern Pharmacologic Treatments -**

WALTHAM, Mass., Jun 27, 2011 (BUSINESS WIRE) -- [Alkermes, Inc.](http://www.alkermes.com) (NASDAQ: ALKS) today announced the publication of two new studies in the June issue of *The American Journal of Managed Care*<sup>1,2</sup> evaluating pharmacoeconomic data on addiction treatments, including [VIVITROL®](http://www.vivitrol.com) (naltrexone for extended-release injectable suspension), with the endpoint of total healthcare costs. The first paper<sup>1</sup> showed that patients receiving an FDA-approved medication for their alcohol dependence had reduced total healthcare costs, including inpatient, outpatient and pharmacy costs, compared to patients treated without medication. Patients treated with VIVITROL had significantly lower hospital costs, fewer days in detoxification and fewer admissions to the hospital than patients treated with any of three other medications: oral naltrexone, disulfiram or acamprosate. The second paper<sup>2</sup> evaluated patients treated for opioid dependence and again showed that treatment with an FDA-approved medication reduced total healthcare costs, with VIVITROL-treated patients experiencing fewer hospitalizations than patients treated with the oral medications buprenorphine, oral naltrexone and methadone. In addition, despite higher pharmacy costs for VIVITROL, the total healthcare costs for VIVITROL were no greater than buprenorphine or oral naltrexone, and were 49% lower than methadone.

Both studies demonstrated the cost effectiveness of treating addiction with pharmacotherapy. In the study of alcohol-dependent patients, total healthcare costs were 30% lower for patients who received an FDA-approved medication for their alcohol dependence versus those who did not. In the study of opioid-dependent patients, total healthcare costs were 29% lower for patients who received an FDA-approved medication for their opioid dependence versus those who did not.

"In spite of the fact that much of the population with opioid dependence and alcohol dependence remains untreated, these studies show that the use of medications to treat these addictions makes strong economic sense by reducing total healthcare costs," said Mady Chalk, Ph.D., an author of the studies and Director of the Center for Policy Research and Analysis at the Treatment Research Institute. "Specifically, patients treated with VIVITROL had total healthcare costs on par with, or lower than, the FDA-approved oral treatments for these addictions, primarily driven by reduced hospitalizations. VIVITROL offers patients suffering from addiction a once-monthly, non-addictive medication that alleviates the issue of non-adherence to daily medications."

*The American Journal of Managed Care* supplement and these two studies were funded by Alkermes. These studies were retrospective claims database analyses of all medical and pharmacy claims from patients identified from a large U.S. health plan and the IMS PharMetrics Integrated Database. The studies matched the patients based on demographic, clinical and healthcare utilization variables. The study of alcohol-dependent patients included healthcare utilization variables for 20,752 patients, half of whom used an FDA-approved medication for alcohol dependence - VIVITROL, oral naltrexone, oral disulfiram or oral acamprosate - and half of whom had not used one of these medications. The study with opioid-dependent patients included 13,316 patients, half of whom had used an FDA-approved medication for opioid dependence - VIVITROL, buprenorphine, oral naltrexone or methadone - and half of whom had not used one of these medications. Two additional studies included in the supplement were independently funded and conducted by Horizon Blue Cross Blue Shield of New Jersey and Aetna Behavioral Healthcare, both of which showed comparable findings.

The pharmacoeconomic study of opioid-dependent patients is the first retrospective comparison among patients taking any opioid dependence medication versus no medication and the first study examining costs among the four currently FDA-approved opioid dependence treatments. The pharmacoeconomic study of alcohol-dependent patients is the largest cost study to date of alcohol pharmacotherapy.

#### **About VIVITROL**

[VIVITROL](http://www.vivitrol.com) (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.

#### **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®](http://www.alkermes.com) 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. 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 treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification and whether VIVITROL reduces total healthcare costs and hospitalization rates. 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 pharmacoeconomic results demonstrated in studies of VIVITROL for alcohol and opioid dependence will be predictive of future cost saving results; whether VIVITROL will be commercialized successfully; and whether third party payors will cover or reimburse VIVITROL for the treatment of alcohol dependence or 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.

VIVITROL® and Medisorb® are trademarks of Alkermes, Inc. RISPERDAL® CONSTA® is a trademark of Janssen-Cilag group of companies.

<sup>1</sup> Baser O, Chalk M, Rawson R, Gastfriend DR. Alcohol dependence treatments: comprehensive healthcare costs, utilization outcomes, and pharmacotherapy persistence. Am J Manag Care. 2011;17(8):S222-S234.

<sup>2</sup> Baser O, Chalk M, Fiellin DA, Gastfriend DR. Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care. 2011;17(8):S235-S248.

SOURCE: Alkermes, Inc.

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