# Alkermes Announces Approval of VIVITROL(R) for the Treatment of Alcohol Dependence in Russia

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 4, 2008--Alkermes, Inc. (NASDAQ: ALKS) today announced that its partner, Cilag GmbH International, a subsidiary of Johnson & Johnson, received approval from the Russian Regulatory Authorities to market VIVITROL(R) (naltrexone for extended-release injectable suspension) for the treatment of alcohol dependence in Russia. The product will be manufactured by Alkermes and commercialized by Janssen-Cilag, an affiliate company of Cilag GmbH International.

"VIVITROL is the first once-monthly injectable medication for the treatment of alcohol dependence to be approved in Russia. The long-acting, non-addictive formulation ensures that patients get the benefit of medication over the entire month," stated Elliot Ehrich, M.D., chief medical officer of Alkermes. "With VIVITROL, physicians will have a new medication option to help treat patients with alcohol dependence, and patients have new hope to help them in their battle with this devastating disease."

In January 2008, Alkermes and Cilag GmbH International announced an exclusive agreement to commercialize VIVITROL for the treatment of alcohol and opioid dependence in Russia and other countries in the Commonwealth of Independent States (CIS). Alkermes will receive manufacturing revenues and a royalty based on product sales. Alkermes will retain exclusive development and marketing rights to VIVITROL in all markets outside the U.S., Russia and other countries in the CIS. In the U.S., VIVITROL is commercialized primarily by Cephalon, Inc.

About VIVITROL

VIVITROL is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and was approved by the U.S. Food and Drug Administration in April 2006. 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.

About Alcohol Dependence in Russia

There are approximately 10 million people in Russia who are dependent on alcohol.(1) Alcohol is causally related to more than 60 medical conditions, including heart disease, liver disease, infectious disease, and cancer(2,3) and contributes to an estimated 30% of all deaths in Russia each year.(4)

Important Safety Information

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 receiving or dependent on opioids, in acute opioid withdrawal, and in those who have failed the naloxone challenge test or have a positive urine screen for opioids; and in those with previous hypersensitivity to naltrexone, PLG, carboxymethylcelluose, or any other components of the diluent.

Patients must be opioid free for a minimum of 7-10 days before treatment. Attempts to overcome opioid blockade due to VIVITROL may result in fatal overdose. In prior opioid users, use of opioids after discontinuing VIVITROL may result in fatal overdose because patients may be more sensitive to lower doses of opioids. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by appropriately trained personnel in a setting equipped for cardiopulmonary resuscitation.

Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia. Injection site reactions not improving may require prompt medical attention. Alcohol-dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thinking. Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The most common adverse events associated with VIVITROL in clinical trials were nausea, vomiting, headache, dizziness, asthenic conditions and injection site reactions. For full prescribing information, please visit www.vivitrol.com or call 1-800-896-5855.

About Alkermes

Alkermes, Inc., a biotechnology company committed to developing innovative medicines to improve patients' lives, manufactures RISPERDAL(R) CONSTA(R) for schizophrenia and developed and manufactures VIVITROL(R) for alcohol dependence. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research and manufacturing facilities in Massachusetts and Ohio.

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, statements regarding: the successful launch and commercialization of VIVITROL for alcohol dependence in Russia.

Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge, the forward-looking statements are neither promises nor guarantees, and Alkermes' business is subject to significant risk and uncertainties. As such, there can be no assurance that Alkermes' actual results will not differ materially from its expectations. These risks and uncertainties include, among others: the inability to successfully launch, increase sales of or sustain VIVITROL in the market; the inability to successfully and efficiently manufacture 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 company disclaims any intention or responsibility for updating forward-looking statements made in this release.

(1) Janssen-Cilag. Data on file, December 2007.

(2) Room R, Babor T, Rehm J. Alcohol and public health. Lancet, 2005; 365:519-530.

(3) Bagnardi V; Blangiardo M; Vecchia C, et al. Alcohol consumption and the risk of cancer. Alcohol Res Health. 2001; 25(4):263-270.

(4) Nemstov, A. Russia: alcohol yesterday and today. Addiction. 2005; 100(2): 146-9.

CONTACT: Alkermes, Inc.
Rebecca Peterson, 617-583-6378
Vice President,
Corporate Communications

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