Alkermes Announces Agreement for the Commercialization of VIVITROL in Russia/CIS

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CAMBRIDGE, Mass., Jan 07, 2008 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) announced today that it has entered into an exclusive agreement with Cilag GmbH International, a subsidiary of Johnson & Johnson, to commercialize VIVITROL(R) (naltrexone for extended-release injectable suspension) for the treatment of alcohol and opioid dependence in Russia and other countries in the Commonwealth of Independent States (CIS). As part of the agreement, Cilag GmbH International will pay upfront and milestone payments up to $39 million as well as ongoing royalties on commercial sales of VIVITROL in this territory. The product will be commercialized by Janssen-Cilag, an affiliate company of Cilag GmbH International. 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.

Under the terms of the agreement, Cilag GmbH International will have primary responsibility for filing the new drug application for VIVITROL in Russia and other countries in the CIS. Alkermes will be responsible for manufacturing VIVITROL and will receive from Cilag GmbH International manufacturing revenues and a royalty based on product sales. Cilag GmbH International will make an initial payment of $5 million cash to Alkermes and up to an additional $34 million cash payments upon regulatory approvals for the product, certain agreed-upon events and levels of VIVITROL sales. Additional terms of the agreement were not disclosed.

"This agreement highlights the value of VIVITROL and provides us with the opportunity to expand the commercialization of this product," stated David Broecker, president and chief executive officer of Alkermes. "We believe Janssen-Cilag brings the commercial capabilities and infrastructure required for a successful product launch in Russia and look forward to a productive partnership."

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. FDA 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 and Opioid 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) Russia is becoming the largest heroin market in Europe and it is estimated that over 2 million people in Russia regularly use opiates.(5,6)

Important Safety Information

In clinical trials, VIVITROL was generally well tolerated and the majority of adverse events were mild to moderate in intensity. The most common adverse events associated with VIVITROL clinical trials were nausea, vomiting, headache, dizziness, fatigue and injection site reactions.

WARNING

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 opioid analgesics, with current physiologic dependence on opioids, in acute opioid withdrawal or who have previously exhibited hypersensitivity to naltrexone, PLG or any other components of the diluent.

VIVITROL is a potent opioid antagonist. Patients must be opioid free for a minimum of seven to 10 days before starting VIVITROL treatment. Any attempt to overcome the opioid blockade produced by VIVITROL using exogenous opioids may result in fatal overdose. In patients with a previous history of opioid abuse, administration of exogenous opioids may result in potentially life-threatening opioid intoxication. When reversal of VIVITROL blockade is required for pain management, patients should be monitored in a setting equipped and staffed for cardiopulmonary resuscitation.

Should a patient receiving VIVITROL develop progressive dyspnea and hypoxemia, the diagnosis of eosinophilic pneumonia should be considered. Patients should be advised to seek medical attention for injection site reactions such as pain, tenderness, induration or pruritus that do not improve within one month following the injection. Alcohol dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thinking.

For full prescribing information, please visit www.vivitrol.com or call 1-800-896-5855.

About Alkermes, Inc.

Alkermes, Inc. is a biotechnology company that uses proprietary technologies and know-how to create innovative medicines designed to yield better therapeutic outcomes for patients with serious disease. Alkermes manufactures RISPERDAL(R) CONSTA(R), marketed by Janssen-Cilag (Janssen, L.P.), a subsidiary of Johnson & Johnson, and developed and manufactures VIVITROL(R), marketed in the U.S. primarily by Cephalon, Inc. The company's 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. Alkermes is headquartered in Cambridge, Massachusetts, with 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 registration, launch and commercialization of VIVITROL in Russia and other countries in the CIS; the successful manufacture of VIVITROL for sale in Russia and other countries in the CIS; the achievement of certain regulatory approvals, other agreed-upon events, and future sales, if any, for VIVITROL; and the expected benefit of the agreement for Alkermes, specifically that Janssen-Cilag possesses the commercial capabilities and infrastructure required for a successful launch of VIVITROL in Russia and other countries in the CIS. 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 delay or denial of regulatory approval of VIVITROL in Russia and other countries in the CIS, including the requirement to perform additional clinical trials; if approved, 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.

(5) Human Rights Watch. "Rehabilitation Required: Russia's Human Rights Obligation to Provide Evidence-based Drug Dependence Treatment." November 2007, http://hrw.org/reports/2007/russia1107/index.htm (accessed December 13, 2007).

(6) United Nations World Drug Report 2007. http://www.unodc.org/unodc/en/data-and-analysis/WDR-2007.html (accessed December 13, 2007).

SOURCE: Alkermes, Inc.

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