



## **Alkermes and Cephalon Receive FDA Approval of Vivitrol(TM) for the Treatment of Alcohol Dependence; First, Once-Monthly Injectable Medication Provides New Treatment Option; Companies to Host Conference Call at 4:30 p.m. EDT**

April 13, 2006

CAMBRIDGE, Mass. and FRAZER, Pa.--(BUSINESS WIRE)--April 13, 2006--Alkermes, Inc., (Nasdaq: ALKS) and Cephalon, Inc., (Nasdaq: CEPH) today announced that the U.S. Food and Drug Administration (FDA) has approved VIVITROL(TM) (naltrexone for extended-release injectable suspension) for the treatment of alcohol dependence. VIVITROL, the first and only once-monthly injectable medication for alcohol dependence, is indicated for alcohol dependent patients who are able to abstain from drinking in an outpatient setting and are not actively drinking when initiating treatment. Treatment with VIVITROL should be used in combination with psychosocial support, such as counseling or group therapy.

Alcohol dependence is a serious and chronic disease that affects multiple regions of the brain, providing rationale for the use of medication with psychosocial support as part of an integrated treatment plan. Of the more than 18 million Americans who abuse or are dependent on alcohol,(1) approximately 2.2 million seek treatment for their alcohol problems.(2) More than 75% of these patients relapse back to drinking within the first year of beginning treatment using currently available treatment approaches.(3) A VIVITROL injection provides medication over one month, therefore, patients do not need to make a decision to take their medication every day.

"VIVITROL is the first once-a-month medication for alcohol dependence that ensures patients get the benefit of medication over the entire month," stated Richard Rosenthal, M.D., Chairman, Department of Psychiatry, St. Luke's-Roosevelt Hospital Center, New York, and Professor of Clinical Psychiatry, Columbia University College of Physicians and Surgeons. "With VIVITROL, physicians have a new option to help treat patients with alcohol dependence, and patients have new hope to help them in their battle with this devastating disease."

VIVITROL works by binding to opioid receptors in the brain. Although the mechanism responsible for the reduction in alcohol consumption observed with VIVITROL treatment is not entirely understood, preclinical data suggests that occupation of the opioid receptors results in the blockade of the neurotransmitters in the brain that are believed to be involved with alcohol dependence. This blockade may result in the reduction in alcohol consumption observed in patients treated with VIVITROL.

"The approval of VIVITROL, our first internally developed product, marks a significant milestone for Alkermes and demonstrates the potential of our proprietary extended-release technology to offer patients an entirely new way to get the medication they need," stated Richard Pops, CEO of Alkermes. "Together with Cephalon, we are committed to bringing forward VIVITROL as an exciting new treatment option for millions of people struggling with alcohol dependence."

"VIVITROL will be a major new product in our CNS portfolio and represents an exciting opportunity to assist in the treatment of this complex and chronic disease," said Robert P. Roche, Jr., Executive Vice President, Worldwide Pharmaceutical Operations at Cephalon. "We understand this market and its significant unmet needs and are ready to launch VIVITROL as a new treatment option to meet those needs."

Cephalon and Alkermes expect VIVITROL to be available to physicians and patients in the United States by the end of June 2006. VIVITROL will be available as a single dose 380 mg intramuscular injection.

Based on a joint commercialization agreement signed in June 2005, Cephalon has primary responsibility for the marketing and sales of VIVITROL and Alkermes is responsible for manufacturing VIVITROL. Under the terms of the agreement, Alkermes receives a milestone payment of \$110 million from Cephalon upon the FDA approval.

### **Clinical Data**

The efficacy of VIVITROL was studied in a six-month Phase III double-blind, placebo-controlled, randomized clinical trial of alcohol dependent patients. The primary endpoint of the study was the reduction in the event rate of heavy drinking days, and heavy drinking was defined as five or more drinks per day for men and four or more drinks per day for women. In the overall study population, patients treated with VIVITROL 380 mg and psychosocial support demonstrated a greater reduction in days of heavy drinking than those treated with only psychosocial support and placebo injection over the six-month treatment period. In a subset of patients who abstained from drinking in the week prior to receiving their first dose of medication, those treated with VIVITROL 380 mg were more likely to maintain complete abstinence (without relapse) and showed a greater reduction in drinking days, as well as a greater reduction in heavy drinking days, compared to the placebo-treated group over the six-month treatment period.

### **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](http://www.vivitrol.com) or call 1-800-896-5855.

#### About VIVITROL

VIVITROL is the first and only extended-release medication for the treatment of alcohol dependence. It is a once-monthly, intramuscular injectable medication indicated for patients who are able to abstain from drinking alcohol in an outpatient setting prior to beginning treatment. VIVITROL, which is non-addictive and non-aversive, is administered by a healthcare provider and should be used in combination with psychosocial support. 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

Alcohol dependence is a chronic disease with underlying neurological and genetic factors.(4) The four symptoms most commonly associated with alcohol dependence are cravings, loss of control over drinking, withdrawal symptoms (including sweating, nausea, shakiness and anxiety) and an increased tolerance for alcohol.(5) Approximately 18 million people in the U.S. are dependent on or abuse alcohol; half are considered to be alcohol dependent.(1) Alcohol abuse and dependency is an economic burden to society that costs approximately \$185 billion annually in the U.S.(6) Psychosocial support, such as counseling, is the traditional approach for treating alcohol dependence; however, experts in the field increasingly recommend and support a treatment approach that includes a combination of medication and psychosocial support.(7),(8)

#### Conference Call and Webcast

Alkermes and Cephalon will host a conference call for investors at 4:30 p.m. EDT on Thursday, April 13, 2006. The conference call may be accessed by dialing 1-866-206-6154 for domestic callers and 1-703-639-1107 for international callers. The conference call ID number is 889362. Additionally, the call will be webcast on the investor relations sections of Alkermes' and Cephalon's websites and archived on these sites until Tuesday, April 18, 2006 at 5:00 p.m. EDT.

A replay of the conference call will be available from 6:30 p.m. on Thursday, April 13, 2006 through Tuesday, April 18, 2006 at 5:00 p.m. EDT and may be accessed by dialing 1-888-266-2081 for domestic callers and 1-703-925-2533 for international callers. The replay access code is 889362.

#### About Alkermes, Inc.

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company has two commercial products. RISPERDAL(R) CONSTA(R) ((risperidone) long-acting injection), the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, is marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson. VIVITROL(TM) (naltrexone for extended-release injectable suspension) is the first and only once-monthly injectable medication approved for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies; and it also develops novel, proprietary drug candidates for its own account. The Company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

#### About Cephalon, Inc.

Founded in 1987, Cephalon, Inc. is an international biopharmaceutical company dedicated to the discovery, development and marketing of innovative products in four core therapeutic areas: central nervous system, pain, oncology and addiction. Cephalon currently employs approximately 3,000 people in the United States and Europe. U.S. sites include the company's headquarters in Frazer, Pennsylvania, and offices, laboratories or manufacturing facilities in West Chester, Pennsylvania, Salt Lake City, Utah, and suburban Minneapolis, Minnesota. Cephalon's European headquarters are located in Maisons-Alfort, France.

Cephalon currently markets four proprietary products in the United States: PROVIGIL(R) (modafinil) (C-IV), GABITRIL(R) (tiagabine hydrochloride), ACTIQ(R) (oral transmucosal fentanyl citrate) and TRISENOX(R) (arsenic trioxide) injection, and numerous products internationally. Full prescribing information on its U.S. products is available at <http://www.cephalon.com> or by calling 1-800-896-5855.

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 relating to: the successful launch, manufacture and commercialization of VIVITROL; the timing of the launch of VIVITROL; and receipt by Alkermes of milestone payments from Cephalon related to the approval of VIVITROL. Although both Alkermes and Cephalon believe that such statements are based on reasonable assumptions within the bounds of their respective knowledge of their businesses and operations, the forward-looking statements are neither promises nor guarantees and both the Alkermes and Cephalon businesses are subject to significant risk and uncertainties. As such, there can be no assurance that either or both of Alkermes' and Cephalon's actual results will not differ materially from their respective expectations. These risks and uncertainties include, among others: whether Alkermes can successfully scale up and manufacture VIVITROL at a commercial scale; whether VIVITROL will be launched and commercialized successfully by Alkermes and Cephalon; whether Alkermes and Cephalon will launch VIVITROL by the end of June 2006; whether third party payors will cover or reimburse VIVITROL; and whether VIVITROL in commercial use may have unintended side effects, adverse reactions or incidents of misuse that could cause the FDA or other

health authorities to require post approval studies or require removal of the product from the market. For further information with respect to specific risks, uncertainties and factors that could cause the Companies' actual results to differ materially from expectations, reference is made to the reports that Alkermes and Cephalon each 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 both Alkermes and Cephalon disclaim any intention or responsibility for updating such statements, except as may be required by law.

VIVITROL(TM) is a trademark of Cephalon, Inc; PROVIGIL(R), GABITRIL(R), ACTIQ(R) and TRISENOX(R) are registered trademarks of Cephalon, Inc; Medisorb(R) is a registered trademark of Alkermes, Inc.; RISPERDAL(R) CONSTA(R) is a registered trademark of Johnson & Johnson Corporation.

- (1) Grant BF, Dawson DA, Stinson FS, Chou SP, Dufour MC, Pickering RP. The 12-Month Prevalence and Trends in DSM-IV Alcohol Abuse and Dependence: United States, 1991-1992 and 2001-2002. Drug and Alcohol Dependence; 2004; 74:223-234.
- (2) SAMHSA, Office of Applied Studies. Substance Dependence, Abuse and Treatment Tables; 2003.
- (3) Daley, DC and Marlatt GA. Relapse prevention. In: Lowinson JH, Ruiz P, Millman RB, Langrod JG, eds. Substance Abuse: A Comprehensive Textbook. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2005: 772-785.
- (4) Nestler and Malenka. The addicted brain. Scientific American, 2004: 78-85.
- (5) <http://www.niaaa.nih.gov/FAQs/General-English/FAQ1.htm>. Retrieved April 9, 2006.
- (6) U.S. Department of Health and Human Services. Updating Estimates of the Economic Costs of Alcohol and Abuse in the United States: Estimates, Update Methods, and Data; 2000.
- (7) Saitz R. Unhealthy Alcohol Use. New England Journal of Medicine; 2005; 352:596-607.
- (8) U.S. Department of Health and Human Services, National Institutes of Health, Helping Patients Who Drink too Much: A Clinician's Guide, 2005.

CONTACT: Investor Contacts:

Cephalon, Inc.

Chip Merritt, 610-738-6376

Sr. Director, Investor Relations

cmerritt@cephalon.com

or

Alkermes, Inc.

Rebecca Peterson, 617-583-6378

VP, Corporate Communications

rebecca.peterson@alkermes.com

or

Media Contact:

Biosector 2

Elizabeth Hutter, 212-845-5610

SOURCE: Alkermes, Inc.