VIVITROL, the First, Once-Monthly Injectable Medication for Alcohol Dependence Now Available in the United States

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- Cephalon and Alkermes Introduce VIP3 Program to Facilitate Access for Physicians and Patients -

FRAZER, Pa., and CAMBRIDGE, Mass., June 13 /PRNewswire-FirstCall/ -- Cephalon, Inc. (Nasdaq: CEPH) and Alkermes, Inc. (Nasdaq: ALKS) today announced that VIVITROL(TM) (naltrexone for extended-release injectable suspension), the first and only once-monthly injectable medication for alcohol dependence, is now commercially available in the United States. VIVITROL is indicated for patients who are able to abstain from drinking in an outpatient setting and are not actively drinking when initiating treatment. VIVITROL should be used as part of a comprehensive treatment management program, which includes psychosocial support, such as counseling or group therapy.

(Photo: http://www.newscom.com/cgi-bin/prnh/20060613/PHTU011)

The U.S. Food and Drug Administration (FDA) approved VIVITROL in April 2006. In clinical studies, those treated with VIVITROL demonstrated a greater reduction in the number of heavy drinking days than those treated with placebo. 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 heavy drinking, as well as a greater reduction in heavy drinking days, compared to the placebo-treated group over the six- month treatment period.

VIVITROL is administered by a healthcare provider. Frequent interactions with healthcare providers could strengthen the therapeutic alliance - the collaborative relationship a healthcare professional is able to form with a patient - a crucial factor in the success of therapy. VIVITROL also provides patients with the convenience of monthly dosing, which alleviates the need for patients to remember to take a daily oral medication.

VIP3: Unique Program to Support the Treatment of Alcohol Dependence with VIVITROL

To ensure that physicians and patients can obtain product and treatment with ease, the companies have developed a comprehensive support program called VIP3 (VIVITROL Information for Patients, Physicians and Providers). VIP3 will integrate support services to address each step in distribution, reimbursement and administration of VIVITROL. By calling the VIP3 support line, 1-800-VIVITROL (1-800-848-4876), patients and physicians will receive necessary support from trained coordinators to help them obtain VIVITROL in a timely, convenient manner. VIP3 is designed to protect the privacy of patients and to comply with federal privacy regulations, including the Code of Federal Regulation (42 CFR) and Health Insurance Portability and Accountability Act (HIPAA).

VIVITROL is available through a limited network of specialty pharmacy providers, including Coram, Inc., Caremark, PharmaCare Specialty Pharmacy, Aetna Specialty Pharmacy and CuraScript. These pharmacies have specialized capabilities to meet the storage and handling needs of VIVITROL and will be working through the VIP3 program to coordinate product distribution.

"With more than 400 physicians currently enrolled in VIP3, our professional education plans, and a combined field presence of Cephalon and Alkermes personnel, we are confident VIVITROL will be a success and that many patients will benefit from this important new therapy," stated Robert P. Roche, Jr., Executive Vice President, Worldwide Pharmaceutical Operations at Cephalon.

VIVITROL combined with psychosocial support and the VIP3 support program may help patients with alcohol dependence stay on the road to recovery.

"With VIVITROL and my counseling sessions, I was able to stay sober and focus on other important things in my life," said Laurie O'Connor, a person in recovery from alcohol dependence and VIVITROL clinical trial participant. "I am just the average woman. If I can have a problem with alcoholism, I know other people can too. I would just like to reach out to those people and their families to tell them that more help is available."

About VIVITROL

VIVITROL is available as a once-monthly, single dose 380 mg intramuscular injectable medication indicated for patients who are able to abstain from drinking alcohol in an outpatient setting and who are not actively drinking 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. For more information about VIVITROL, please call 1-800-VIVITROL (1-800-848-4876) or visit http://www.vivitrol.com.

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. 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.

Important Safety Information

In clinical trials, VIVITROL was generally well tolerated and adverse events in a majority of patients were mild to moderate in intensity. The most common adverse events associated with VIVITROL in 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 http://www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876).

About Alcohol Dependence

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. Psychosocial support, such as counseling or group therapy, 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.(1,2)

Of the more than 18 million Americans who abuse or are dependent on alcohol,(3) approximately 2.2 million seek treatment for their alcohol problems.(4) More than 75% of these patients relapse back to drinking within the first year of beginning treatment using currently available treatment approaches.(5) Alcohol abuse and dependency are an economic burden to society that costs approximately $185 billion annually in the U.S.(6)

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.

The company currently markets five proprietary products in the United States: PROVIGIL(R) (modafinil), GABITRIL(R) (tiagabine hydrochloride) ACTIQ(R) (oral transmucosal fentanyl citrate), TRISENOX(R) (arsenic trioxide) injection, VIVITROL 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.

About Alkermes, Inc.

Alkermes, Inc. is a biotechnology 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 and is marketed in the United States primarily by Cephalon, Inc. The Company has a pipeline of extended-release injectable products and pulmonary 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.

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, including operation of the VIP3 program and the therapeutic value of VIVITROL to patients. 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 continue to manufacture VIVITROL at a level sufficient to meet demand; whether VIVITROL will be launched successfully by Alkermes and Cephalon; whether VIP3 will ensure that physicians and patients can obtain product and treatment with ease; whether third-party payors will cover or reimburse VIVITROL; whether all experiences with VIVITROL will be the same 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.

Inc.; Medisorb(R) is a registered trademark of Alkermes, Inc.; RISPERDAL(R) CONSTA(R) is a registered trademark of Johnson & Johnson Corporation.

(1) Saitz R. Unhealthy Alcohol Use. New England Journal of Medicine; 2005; 352:596-607.

(2) U.S. Department of Health and Human Services, National Institutes of Health, Helping Patients Who Drink too Much: A Clinician's Guide, 2005.

(3) 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.

(4) SAMHSA, Office of Applied Studies. Substance Dependence, Abuse and Treatment Tables; 2003.

(5) 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.

(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.

SOURCE Cephalon, Inc.; Alkermes, Inc. -0- 06/13/2006 /CONTACT: Investor Contacts: Chip Merritt, Sr. Director, Investor Relations, Cephalon, Inc., +1-610-738-6376, cmerritt@cephalon.com, or Rebecca Peterson, VP, Corporate Communications, Alkermes, Inc., +1-617-583-6378, rebecca.peterson@alkermes.com; Media Contact: Karen Boyce, Sr. Manager, Public Relations, Cephalon, Inc., +1-610-883-5771, kboyce@cephalon.com/ /Photo: NewsCom: http://www.newscom.com/cgi-bin/prnh/20060613/PHTU011 AP Archive: http://photoarchive.ap.org AP PhotoExpress Network: PRN3 PRN Photo Desk, photodesk@prnewswire.com/ /Company News On-Call: http://www.prnewswire.com /comp/134563.html/ /Web site: http://www.vivitrol.com http://www.cephalon.com / (CEPH ALKS)