Alkermes and Cephalon Issue Statement in Response to COMBINE Study Publication; Companies Partner to Make VIVITROL(TM), a New Treatment for Alcohol Dependence, Available in the U.S.

May 2, 2006

CAMBRIDGE, Mass. and FRAZER, Penn., May 02, 2006 (BUSINESS WIRE) -- The "Combining Medications and Behavioral Interventions for Alcoholism" (COMBINE) Study, published in the May 3, 2006 edition of the Journal of the American Medical Association(1), further supports the use of medication, medical management and psychosocial support to treat alcohol dependence. The study confirms the effectiveness of medication in conjunction with psychosocial support and the important role of healthcare professionals in the treatment of alcohol dependence.

Current statistics show approximately 50 percent of treated patients relapse back to drinking within the first few months of treatment(2) and 75 percent relapse within the first year(3). Data from the COMBINE Study underscore the need to develop new treatment options for the serious and chronic disease of alcohol dependence.

VIVITROL(TM) (naltrexone for extended-release injectable suspension), was approved by the U.S. Food and Drug Administration (FDA) for the treatment of alcohol dependence on April 13, 2006. 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.

The extended-release technology behind VIVITROL allows the medicine to be gradually released into the body at a controlled rate over a one-month time period; therefore, patients do not need to take an oral medication every day. Because VIVITROL is a once-monthly injection, patients will have the opportunity to meet with their healthcare provider regularly.

The efficacy of VIVITROL was studied in a six-month Phase III double-blind, placebo-controlled, randomized clinical trial of alcohol dependent patients, with results published in the Journal of the American Medical Association (April 5, 2005)(4).

VIVITROL is expected to be available to physicians and patients in the U.S. by the end of June 2006. Alkermes, Inc. and Cephalon, Inc. are committed to improving the lives of those affected by alcohol dependence and supporting the healthcare professionals who treat them. For full prescribing information, please visit www.vivitrol.com or call 1-800-896-5855.

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.

(1) Anton RF, et al. Combined Pharmacotherapies and Behavioral Interventions for Alcohol Dependence. The COMBINE Study: A Randomized Controlled Trial. Journal of the American Medical Association. 2006;295:2003-20017.

(2) Grant BF, et al. 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.

(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) Garbutt JC, et al. Efficacy and Tolerability of Long-Acting Injectable Naltrexone for Alcohol Dependence: A Randomized Controlled Trial. Journal of the American Medical Association. 2005;293:1617-1625.

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