FDA Issues Approvable Letter for VIVITROL(TM) (Formerly VIVITREX(R)), for the Treatment of Alcohol Dependence; Alkermes and Cephalon Continue to Anticipate Product Launch in Second Quarter 2006

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CAMBRIDGE, Mass.& FRAZER, Pa., Dec 28, 2005 (BUSINESS WIRE) -- Alkermes, Inc. (Nasdaq: ALKS) and Cephalon, Inc. (Nasdaq: CEPH) today announced that the U.S. Food and Drug Administration (FDA) issued an approvable letter for VIVITROL(TM) (naltrexone for extended-release injectable suspension), which is under review for the treatment of alcohol dependence in combination with a treatment program that includes psychosocial support. The New Drug Application (NDA) for VIVITROL, formerly known as VIVITREX(R), was submitted on March 31, 2005. Alkermes and Cephalon continue to prepare for the launch of VIVITROL during the second quarter of 2006.

FDA approval of VIVITROL is contingent upon finalizing the product label and satisfying a request by the FDA for preclinical pharmacokinetic data to support reference to existing oral naltrexone preclinical data. VIVITROL was filed as a 505(b)(2) NDA application, permitting Alkermes to reference results of studies that were previously submitted to the FDA in support of the original oral naltrexone NDA.

"This approvable letter is a positive step toward the approval of VIVITROL," stated Richard Pops, CEO of Alkermes. "We look forward to working diligently with the FDA to gain final approval and bring forward VIVITROL as an important new medication for the treatment of alcohol dependence."

"Our plans for the launch of VIVITROL in the second quarter of 2006 are on track," said Frank Baldino, Jr., Ph.D., Chairman and CEO of Cephalon. "We are hiring sales representatives and designing education and training programs to ensure that physicians and counselors can identify patients who could benefit the most from the inclusion of this medication in their treatment plan."

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's lead commercial product, RISPERDAL(R) CONSTA(R) ((risperidone) long-acting injection), is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson. The Company's lead proprietary product candidate, VIVITROL(TM) (naltrexone for extended-release injectable suspension), is being developed as a once-monthly injection 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 to treat sleep and neurological disorders, cancer and pain. Cephalon currently employs approximately 2,600 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.

The company currently markets four proprietary products in the United States: PROVIGIL(R) (modafinil) (C-IV), GABITRIL(R) (tiagabine hydrochloride), ACTIQ(R) (oral transmucosal fentanyl citrate) (C-II) and TRISENOX(R) (arsenic trioxide) injection, and more than 20 products internationally. Full prescribing information for all U.S. products is available at 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 related to attaining final regulatory approval of VIVITROL, which will include labeling discussions with FDA and satisfying a request for preclinical data, the status of launch plans, the timing of the VIVITROL launch, and the ultimate commercial success of VIVITROL. Although both Cephalon and Alkermes believe that such statements are based on reasonable assumptions within the bounds of their respective knowledge, 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 Cephalon's or Alkermes' actual results will not differ materially from their respective expectations. Such expectations are subject to risks, including, among others whether Alkermes can successfully scale up and manufacture VIVITROL at a commercial scale; whether VIVITROL will ultimately receive marketing approval from FDA in a timely fashion or at all, and, if approved, whether it will be launched and commercialized successfully by Alkermes and Cephalon; the outcome of clinical and preclinical work Alkermes and its partners are pursuing, including the results of preclinical pharmacokinetic data; decisions by the FDA regarding VIVITROL, which may be based on interpretations of data that differ from Alkermes' interpretations; 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 actual results to differ from expectations, reference is made to the reports on Forms 8-K, 10-Q and 10-K that Cephalon and Alkermes 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 Cephalon and Alkermes disclaim any intention or responsibility for updating such statements, except as may be required by law.

SOURCE: Alkermes, Inc.

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