Alkermes Provides Update on Advancing Product Portfolio and Outlines Business Goals for 2011

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-- Company to Expand ALKS 33 Clinical Program into Treatment-Resistant Depression --

-- Alkermes Presents Positive Data from Phase 4 Study of VIVITROL® in Healthcare Professionals with Opioid Dependence --

WALTHAM, Mass., Jan 07, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) will provide an overview of upcoming milestones for its commercial products, late-stage product candidates and emerging clinical candidates from the company's proprietary pipeline on Monday, January 10, 2011, at the 29th Annual JPMorgan Healthcare Conference in San Francisco. Highlights include the expansion of the ALKS 33 clinical program into treatment-resistant depression (TRD) and the presentation of interim data from the VIVITROL® (naltrexone for extended-release injectable suspension) phase 4 study in healthcare professionals with opioid dependence.

"We are very much looking forward to 2011 as we expect major developments in virtually all of our late-stage clinical and commercial programs," commented Richard Pops, Chief Executive Officer of Alkermes. "We will discuss the details of these major milestones in our webcast presentation at the conference."

Alkermes 2011 Milestones

During the year, Alkermes expects:

- the submission of the reply to the complete response letter for BYDUREON(TM) (exenatide extended-release for injectable suspension) to the U.S. Food and Drug Administration (FDA) by its partner, Amylin Pharmaceuticals, Inc.;
- regulatory action on the BYDUREON Marketing Authorization Application (MAA) in the EU;
- to report topline data from the DURATION-6 head-to-head study of BYDUREON versus VICTOZA® (liraglutide);
- to announce results from the phase 2 clinical trial of exenatide once-monthly in type 2 diabetes;
- to report data from the phase 2 clinical study of ALKS 33 in binge eating disorder;
- to initiate a phase 2 study of the ALKS 33/buprenorphine combination therapy in cocaine dependence;
- to initiate a phase 1/2 study of ALKS 33 in combination with buprenorphine for the treatment of TRD;
- to report data from the phase 2 clinical trial of ALKS 37 in opioid-induced bowel dysfunction (OBD);
- to announce data from the phase 1/2 study of ALKS 9070 in schizophrenia;
- to launch VIVITROL with the expanded indication for the prevention of relapse to opioid dependence, following opioid detoxification, and increase sales; and
- to present data updates on the phase 4 study of VIVITROL for the treatment of healthcare professionals with opioid dependence.

Program Highlights to be Presented at JPMorgan Conference

- **Expansion of the ALKS 33 clinical program into TRD:** Alkermes will announce that ALKS 33, in combination with buprenorphine, is being studied for TRD. TRD, which is also known as refractory depression, refers to depressive episodes that are not adequately controlled by standard antidepressant therapy. Depression is a serious and chronic disease that affects more than 20 million American adults each year[1] and finding the right treatment can be difficult for many patients. Approximately half of depressed patients have an inadequate response to monotherapy[2] and as many as 20% have chronic depression despite multiple interventions.[3] ALKS 33 and buprenorphine have established activity at the Mu receptor, although buprenorphine is a partial agonist while ALKS 33 is an antagonist. The net effect of this combination may attenuate buprenorphine's Mu agonist effects. Blockade activity from the combination of ALKS 33 and buprenorphine at Kappa opioid receptors may affect neurochemical changes associated with depression. Preclinical research has demonstrated that Kappa blockade has antidepressant effects in behavioral models of depression. The company plans to file an Investigational New Drug application (IND) in mid-calendar year 2011 and initiate a phase 1/2 trial by the end of calendar year 2011.

The expansion of the ALKS 33 clinical program into TRD follows the recent announcement of phase 2 data for ALKS 33 for the treatment of alcohol dependence. This phase 2 study was designed to assess the safety, tolerability, pharmacokinetics and efficacy of daily oral administration of three different dose levels of ALKS 33 compared to placebo in approximately 400 alcohol dependent patients. The phase 2 study showed that ALKS 33 was generally well tolerated and characterized by its potential for daily dosing, non-hepatic metabolism, extended pharmacologic benefit in the event of missed doses and pharmacologic activity in reducing heavy drinking behavior. ALKS 33 is also in clinical development for the treatment of binge eating disorder and as a combination therapy with buprenorphine for the treatment of cocaine addiction.

- **Positive phase 4 data for VIVITROL in the treatment of healthcare professionals with opioid dependence:** Alkermes will present interim data from an ongoing, multicenter, open-label, two-year, phase 4 study of VIVITROL. This study is designed to evaluate the safety and efficacy of VIVITROL in the treatment of 38 healthcare professionals with a history of opioid dependence who are enrolled in an extended outpatient treatment program that includes psychosocial support, such as counseling. At the time of the interim analysis, of the 38 patients who initiated VIVITROL treatment, approximately 70% of subjects persisted with VIVITROL treatment for at least six months, all of whom had opioid-free screens for the full six-month period.

  According to the 2009 U.S. National Survey on Drug Use and Health, an estimated 1.6 million people aged 18 or older were dependent on pain relievers or heroin.[4] Physicians display higher rates of prescription drug abuse and dependence than the general population, including misuse of prescription opioids.[5] Physician impairment is a major public health issue, as it affects not only these individuals but also their patients, colleagues and families.

Webcast

A live webcast of the JPMorgan presentation will begin on Monday, January 10, 2011, at 11:00 a.m. ET (8:00 a.m. PT). The webcast will be available on the investor relations section of the company's website at www.alkermes.com. To ensure a timely connection to the webcast, it is recommended that users register 15 minutes prior to the scheduled webcast. This webcast will be archived for 14 days.

About VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) 380 mg/vial is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and opioid dependence. The proprietary Medisorb® 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. The VIVITROL clinical development program was funded in part with a Small Business Innovation Research Program grant from the National Institute of Drug Abuse (NIDA). For a copy of the VIVITROL full prescribing information, please visit www.vivitrol.com or call 1-800-VIVITROL (1-800-848-4876). Please see below for important safety information, including boxed warning.

VIVITROL IMPORTANT SAFETY INFORMATION

VIVITROL is contraindicated in patients with acute hepatitis or liver failure, patients receiving opioid analgesics, patients with current physiologic opioid dependence, patients in acute opioid withdrawal, any individual who has failed the naloxone challenge test or has a positive urine screen for opioids, and in patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose or any other components of the diluent.

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 administered as an intramuscular (IM) gluteal injection. Inadvertent subcutaneous injection of VIVITROL may increase the likelihood of severe injection site reactions. VIVITROL must be injected using one of the customized needles provided in the carton. Because needle length may not be adequate due to body habitus, each patient should be assessed prior to each injection to assure that needle length is adequate for IM administration. VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including in some cases surgical intervention.

Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia. Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis. Opioid-dependent patients including those being treated for alcohol dependence, must be opioid-free for a minimum of 7-10 days before VIVITROL treatment. Attempts to overcome opioid blockade due to VIVITROL may result in a fatal overdose. After opioid detoxification, patients are likely to have reduced tolerance to opioids. Use of lower doses of opioids after VIVITROL is discontinued, at the end of a dosing interval or after missing a dose could result in life threatening opioid intoxication. Alcohol- and opioid-dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thoughts. As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder. In an emergency situation in patients receiving VIVITROL,

suggestions for pain management include regional analgesia or use of non-opioid analgesics. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by appropriately trained personnel in a setting equipped for cardiopulmonary resuscitation. Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol and opioid dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

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 concerning the sales growth of VIVITROL, the timing and success of development activities for the company's programs, including BYDUREON, VIVITROL, ALKS 33, ALKS 37 and ALKS 9070 and the potential therapeutic value of Alkermes' products. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees. The company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: whether the development activities discussed in this press release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trials; whether the company's product candidates will demonstrate sufficient efficacy and safety; whether advancement of the company's partnered product candidates will be delayed due to actions or decisions by its partners with regard to development and regulatory strategy, timing and funding which are out of its control; the outcome of clinical and preclinical work the company and its partners are pursuing; decisions by the FDA and foreign regulatory authorities regarding the company's products, including the timeline for review of, and the outcome of regulatory action relating to, BYDUREON; and the company's ability to manufacture its products on a commercial scale, economically or in sufficient quantities; the company's ability to commercialize VIVITROL successfully in the U.S.; and whether the company's products may be precluded from commercialization by proprietary rights of third parties. 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 forward-looking statements made in this release are made only as of the date hereof, and the company disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

[1] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun; 62 (6): 617-27.

[2] Bauer M, Whybrow PC, Angst J, et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and continuation treatment of major depressive disorder. *World J Biol Psychiatry,* 2002; 3:5-43.

[3] Paykel ES. Epidemiology of refractory depression. In: Nolen WA, Zohar J, Roose SP, et al, editors. Refractory depression: current strategies and future directions. New York: Wiley; 1994:3-18.

[4] SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2009.

[5] Hughes PH, Brandenburg N, Baldwin DC, et al. Prevalence of substance use among US physicians. *JAMA,* 1992;267:2333-9.

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