Alkermes Announces Positive Data from Exploratory Study of Extended-Release Naltrexone for Blockade of Opioid Effect

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Study Results Illustrate the Potential of Extended-Release Naltrexone for the Treatment of Opioid Dependence

CAMBRIDGE, Mass., Dec 04, 2006 (BUSINESS WIRE) -- Alkermes (Nasdaq: ALKS) today announced positive results from a Phase 2 exploratory study of injectable extended-release naltrexone (XR-NTX) in opioid-using adults not physically dependent on opioids, which showed that the two highest doses tested demonstrated opioid blockade for 28 days. The clinical data from this study will be used to support the further development of XR-NTX for the treatment of opioid dependence, a serious chronic brain disease. This pilot study was conducted at the Johns Hopkins University School of Medicine and the National Institute on Drug Abuse (NIDA), two leading institutions in the treatment of addiction.

"The data from this Phase 2 study demonstrate that extended-release naltrexone may offer a new approach for the treatment of opioid dependence by successfully blocking the effect of opioids over one month," stated George Bigelow, Ph.D., Professor, Department of Psychiatry and Behavioral Sciences and Director, Behavioral Pharmacology Research Unit (BPRU), Johns Hopkins University School of Medicine. "Opioid dependence is a major public health problem, and new therapeutic options are needed that can help the millions of people suffering from opioid addiction."

In addition to the use of heroin, an illegal opioid, opioid abuse and addiction includes the non-medical use of approved opioid analgesics, including prescription pain relievers, and represents a growing public health problem in the U.S. According to the 2005 National Survey on Drug Use and Health, an estimated 4.4 million people aged 12 or older used pain relievers non-medically in the month prior to being surveyed.(1)

Study Design

The Phase 2 double-blind, exploratory study was designed to assess the efficacy and tolerability of XR-NTX in 27 opioid-using adults who had used opioids non-medically for at least one year and were not physically dependent on opioids. Subjects were randomized to receive a single intramuscular administration of extended-release naltrexone at one of three doses (75 mg, 150 mg, or 300 mg). At repeated intervals throughout the eight-week study, the level of opioid blockade by XR-NTX was assessed by administering increasing doses of the opioid hydromorphone at one hour intervals, with a maximum cumulative dose of 13.5 mg. Measures of efficacy included a subjective response to a self-rated visual analog scale (VAS) question "Do you feel any drug effect?" and pupil size measurement following a dose of hydromorphone 3 mg. Investigators also assessed subjects for drug intoxication following increasing doses of hydromorphone.

Study Results

In the study, subjective responses based on the VAS question indicated that blockade of hydromorphone 3 mg was achieved for at least 28 days with XR-NTX 150 mg and XR-NTX 300 mg, and for at least 21 days with XR-NTX 75 mg. Subjective responses of the blockade of opioid effects reported by patients are considered the most relevant measure in this study from a therapeutic perspective. Pupil size measurements confirmed the substantial and extended-duration blockade of hydromorphone 3 mg by XR-NTX. Based on investigator assessment of drug intoxication, at day 28 83% of subjects who received XR-NTX 300 mg were able to receive the maximum cumulative dose of 13.5 mg hydromorphone without excessive intoxication; dose dependent blockade was also evident for XR-NTX 150 mg and 75 mg.

XR-NTX was generally well tolerated. No serious or severe adverse events occurred during the study. The most commonly reported adverse events were headache and fatigue, and the incidence of adverse events was similar for all three dose groups.

XR-NTX is an investigational drug currently under development and is not approved for the treatment of opioid dependence.

About Alkermes, Inc.

Alkermes, Inc. is a biotechnology company that develops innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. Alkermes currently 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, and marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson; and VIVITROL(R) (naltrexone for extended-release injectable suspension) the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the U.S. primarily by Cephalon, Inc. Alkermes' pipeline includes extended-release injectable, pulmonary, and oral products for the treatment of prevalent, chronic diseases such as central nervous system disorders, addiction and diabetes. Alkermes' 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 the continued development of XR-NTX for the treatment of opioid dependence and the potential therapeutic value of XR-NTX to patients. 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 and 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: the outcome of clinical work the Company is pursuing, both on its own and with partners; decisions by the FDA or foreign regulatory authorities regarding the Company's product candidates; potential changes in cost, scope and duration of clinical trials. 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.

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(1) U.S. Department of Health and Human Services and National Institutes of Health. National Institute on Drug Abuse Research Report Series; Prescription Drugs, Abuse and Addiction. 2005; NIH Publication Number 05-4881.

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Rebecca Peterson
Corporate Communications
Alkermes, Inc.
(617) 583-6378