Alkermes Announces Initiation of Phase I Clinical Study of AIR(R) Parathyroid Hormone

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--June 7, 2007--Alkermes, Inc. (Nasdaq: ALKS) today announced the initiation of a phase 1 clinical study of AIR® parathyroid hormone (AIR PTH (1-34)) in healthy volunteers. AIR PTH is an inhaled formulation of Eli Lilly and Company's recombinant parathyroid hormone, FORTEO® (teriparatide (rDNA origin) injection), based on Alkermes' proprietary AIR® pulmonary technology. The phase 1 study will assess the safety, tolerability and pharmacokinetics of AIR PTH in healthy postmenopausal women.

In the U.S., osteoporosis is a major public health threat, affecting approximately 10 million people, eighty percent of whom are women. In addition, an estimated 34 million Americans have low bone mass, placing them at increased risk for osteoporosis.(1)

"We are excited to move AIR PTH forward into the clinic," said Elliot Ehrich, chief medical officer of Alkermes. "If proven safe and efficacious, an inhaled formulation may have the potential to increase patient acceptance and ultimately improve clinical outcomes for patients with osteoporosis."

The phase 1, open-label study is designed to assess the safety, tolerability and pharmacokinetics of AIR PTH in approximately 60 healthy, postmenopausal women. Lilly and Alkermes expect to report top-line results from the study by early 2008.

In January 2006, Alkermes and Lilly announced that they signed an agreement to develop and commercialize inhaled formulations of parathyroid hormone utilizing Alkermes' AIR technology. The initiation of the phase 1 clinical study follows extensive feasibility testing and preclinical development.

About Alkermes

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® CONSTA® ((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® (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, statements relating to: development activities for AIR PTH and the therapeutic potential of AIR PTH in osteoporosis. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its respective 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. As such, there can be no assurance that the company's actual results will not differ materially from its expectations. These risks and uncertainties include, among others: whether Lilly and Alkermes can successfully develop an inhaled formulation of AIR PTH for the treatment of osteoporosis; potential changes in cost, scope and duration of the clinical trial; whether AIR PTH will demonstrate sufficient safety and efficacy in this and subsequent trials, if any; whether Alkermes can successfully manufacture AIR PTH for clinical use; and decisions by the FDA regarding the company's product candidates. For further information with respect to specific risks, uncertainties and factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports that the company has 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 such statements, except as may be required by law.

(1) National Osteoporosis Foundation: http://www.nof.org/osteoporosis/diseasefacts.htm. Last accessed June 6, 2007.

CONTACT: Alkermes, Inc.
Rebecca Peterson, 617-583-6378
Vice President
Corporate Communications

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