Alkermes Announces Initiation of Phase 2a Clinical Study of ALKS 27 for the Treatment of COPD

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 18, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 2a clinical study of ALKS 27 in patients with chronic obstructive pulmonary disease (COPD). The study will assess the efficacy, safety, tolerability and pharmacokinetics of ALKS 27 in approximately 24 patients with COPD. ALKS 27 is an inhaled formulation of trospium based on Alkermes' proprietary AIR® pulmonary technology.

This phase 2a study follows completion of a previous clinical study in patients with COPD, which showed that single doses of ALKS 27 demonstrated a rapid onset of action and produced a significant improvement in lung function ($p<0.0001$) over 24 hours compared to placebo.

The fourth leading cause of death in the U.S., COPD is a serious, chronic disease characterized by a gradual loss of lung function. It is estimated that over 12 million adults have been diagnosed with COPD and approximately 24 million adults have evidence of impaired lung function, indicating COPD is significantly underdiagnosed. As an inhaled formulation of trospium, a muscarinic receptor antagonist that relaxes smooth muscle tissue, ALKS 27 could potentially improve airflow and provide a new treatment option for patients with COPD.

"We are excited to move forward with the ALKS 27 program, one of several proprietary product candidates in our advancing pipeline," stated Elliot Ehrich, chief medical officer of Alkermes. "By applying our AIR technology to trospium, a molecule with established efficacy and a known safety profile, ALKS 27 offers the opportunity to create a new, patient-friendly approach for the treatment of COPD."

The phase 2a study is designed to assess the efficacy, safety, tolerability and pharmacokinetics of ALKS 27 in approximately 24 patients with COPD. In this randomized, double-blind, cross-over, placebo-controlled study, patients will receive single administrations of three doses of ALKS 27 and placebo, each separated by a wash out period. The efficacy of ALKS 27 will be evaluated based on improvements in pulmonary function in patients with COPD, as measured by FEV_1, a commonly used measure of lung function.

In addition, the phase 2a study will explore the safety, tolerability and effects of ALKS 27 in combination with formoterol fumarate inhalation powder, a long-acting beta agonist (LABA) already approved for the treatment of COPD. All patients will receive the combination dose following the randomized, double-blind, placebo-controlled portion of the study. Research indicates that LABAs and muscarinic receptor antagonists, such as ALKS 27, may have a synergistic effect on improving symptoms in patients with COPD by acting on complementary pathways.[1] Alkermes expects to report top-line results from the full study in the second half of 2009.

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 dependence and manufactures RISPERDAL® CONSTA® for schizophrenia. Alkermes' robust 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. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in 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 development activities for ALKS 27 and the therapeutic potential of ALKS 27 in COPD. 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: whether the clinical trial discussed in this release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trial; whether ALKS 27 will be further developed; and whether ALKS 27 for the treatment of COPD will be approved by regulatory authorities and subsequently commercialized. 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] Van Noord Ja, Aumann JL, Janssens E, Smeets JJ, Verhaert J, Disse B, Mueller A, Cornelissen PJ. 2005. Comparison of tiotropium once daily, formoterol twice daily and both combined once daily in patients with COPD. *Eur Repir J* 26: 214-222.

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