# Alkermes and Indevus Announce Positive Results from Phase 2a Clinical Study of ALKS 27 for the Treatment of COPD

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- ALKS 27 Showed a Sustained Improvement in Lung Function Over 24 Hours -

CAMBRIDGE & LEXINGTON, Mass.--(BUSINESS WIRE)--Sept. 26, 2007--Alkermes, Inc. (NASDAQ: ALKS) and Indevus Pharmaceuticals, Inc. (NASDAQ: IDEV) today announced positive preliminary results from a randomized, double-blind, placebo controlled phase 2a clinical study of ALKS 27 in patients with chronic obstructive pulmonary disease (COPD). In the study, single doses of ALKS 27 demonstrated a rapid onset of action and produced a significant improvement in lung function (p less than .0001) over 24 hours compared to placebo. ALKS 27 is an inhaled formulation of trospium chloride using Alkermes' proprietary AIR® pulmonary delivery system.

"These preliminary data are encouraging and suggest that ALKS 27 may have several key attributes, including daily administration, rapid onset of action and prolonged duration of bronchodilation that could enhance clinical outcomes for COPD patients," stated Elliot Ehrich, Chief Medical Officer of Alkermes.

"The results of this trial demonstrate that ALKS 27 has the potential to offer patients a new option in the treatment of COPD, a large and underserved disease affecting millions of people each year," stated Glenn L. Cooper, M.D., Chairman and CEO of Indevus. "Based on these positive results, we are moving forward with Alkermes to identify a partner for the future development and commercialization of ALKS 27."

Trial Design and Results

The phase 2a randomized, double-blind, placebo-controlled crossover study was designed to assess the safety, tolerability, pharmacokinetics and efficacy of ALKS 27 in 24 patients with moderate to severe COPD. During the study, patients received a single administration of two different dose levels of ALKS 27 and placebo, with each dose separated by a wash out period. The primary objective of the study was to assess the effect of ALKS 27 as measured by the area under the curve (AUC) of FEV1 over a 24-hour time period. FEV1 is an important clinical measure of lung function defined as the amount (volume) of air expelled during the initial second of forced exhalation.

In the study, patients treated with a single dose of ALKS 27 showed a statistically significant improvement in lung function (p less than 0.0001) compared to placebo. The onset of action of ALKS 27 was rapid and observed as early as 15 minutes post-treatment.

ALKS 27 was well tolerated, and all 24 enrolled patients completed the study. No treatment-related adverse events were reported in this study.

ALKS 27 is an inhaled formulation of trospium chloride, a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. Trospium chloride is the active ingredient in SANCTURA®, Indevus' currently marketed product for overactive bladder. The formulation under development for ALKS 27 is specifically designed for inhalation utilizing Alkermes' proprietary AIR pulmonary delivery system.

About COPD

Chronic obstructive pulmonary disease (COPD), characterized by airflow obstruction and loss of expiratory force, comprises mostly smoking-related diseases such as emphysema and chronic bronchitis. COPD is the fourth largest cause of death in the U.S. and is projected to be the third leading cause of death for both males and females by 2020. 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 under-diagnosed. There is no known cure at the present time. In the U.S., estimated direct healthcare costs for COPD are in excess of $20 billion and surveys indicate a severe quality of life impact to COPD patients. The total U.S. market for COPD product sales is over $3 billion.(1)

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.

About Indevus

Indevus Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company's approved products include SANCTURA® XR and SANCTURA® for overactive bladder, VANTAS® for advanced prostate cancer, SUPPRELIN® LA, for central precocious puberty, and DELATESTRYL® to treat male hypogonadism. The Indevus development pipeline contains multiple compounds within the Company's core therapeutic areas in addition to several partnered or partnerable programs. The most advanced compounds in development include, VALSTAR® for bladder cancer, NEBIDO® for male hypogonadism,

PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and pagoclone for stuttering.

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 ALKS 27 and the therapeutic potential of ALKS 27 in COPD and other indications. Although both Alkermes and Indevus believe that such statements are based on reasonable assumptions within the bounds of their respective knowledge of their businesses and operations, the forward-looking statements are neither promises nor guarantees and both the Alkermes and Indevus businesses are subject to significant risk and uncertainties. As such, there can be no assurance that either or both of Alkermes' and Indevus' actual results will not differ materially from their respective expectations. These risks and uncertainties include, among others: whether Alkermes and Indevus can successfully develop ALKS 27 for the treatment of COPD; potential changes in cost, scope and duration of the clinical trial; whether ALKS 27 will demonstrate sufficient efficacy and safety in subsequent trials; whether Alkermes can successfully manufacture ALKS 27 for clinical use; whether the companies can, either on their own or with a partner, successfully further develop and commercialize ALKS 27; and decisions by the FDA regarding the companies' product candidate. For further information with respect to specific risks, uncertainties and factors that could cause the companies' actual results to differ materially from expectations, reference is made to the reports that Alkermes and Indevus 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 Alkermes and Indevus disclaim any intention or responsibility for updating such statements, except as may be required by law.



(1) U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, Data Fact Sheet; IMS Data.

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