Gilead Announces Preliminary Results From Phase III Study of Aztreonam Lysine for Inhalation in Patients With Cystic Fibrosis

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Study of CF Patients With Pulmonary Pseudomonas Aeruginosa Meets Primary Efficacy Endpoint

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 19, 2006--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that its Phase III AIR-CF2 (CP-AI-005) study of aztreonam lysine for inhalation for the treatment of people with cystic fibrosis (CF) who have pulmonary Pseudomonas aeruginosa (P. Aeruginosa) met its primary efficacy endpoint, the time to need for inhaled or intravenous (IV) antibiotics, which was assessed by the onset of common symptoms predictive of a pulmonary exacerbation. Data from the 247-patient study demonstrated a significant improvement in time to need for inhaled or IV antibiotics after a 28-day treatment course of aztreonam lysine for inhalation compared to placebo, both following a 28-day treatment course of tobramycin inhalation solution (pooled p-value=0.007 by log rank test). The primary efficacy endpoint analyzed the pooled data from both aztreonam treatment arms, as pre-specified under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). Full study results will be submitted for presentation at an upcoming scientific meeting.

The most common treatment-emergent adverse events were cough, productive cough, nasal congestion, respiratory tract congestion and wheezing. The incidence of these events did not differ significantly between the placebo and the aztreonam lysine groups.

"The completion of this study and achievement of its primary endpoint is an important step toward our goal of developing aztreonam lysine for inhalation as a new therapeutic option for people with CF who have pulmonary Pseudomonas aeruginosa," said A. Bruce Montgomery, MD, senior vice president, head of Respiratory Therapeutics, Gilead Sciences. "Gilead appreciates the continued support and leadership of the Cystic Fibrosis Foundation, and we thank the patients and investigators who participated in this study."

AIR-CF2 Study Design

AIR-CF2 was a randomized, double-blind, placebo-controlled study designed to assess the safety and efficacy of a 28-day treatment course with aztreonam lysine, as well as its ability to maintain or improve clinical status following a 28-day treatment course of tobramycin inhalation solution therapy in people with CF who have pulmonary P. Aeruginosa. Patients were randomized to receive 28 days of treatment with 75 mg of aztreonam lysine or volume-matched placebo administered twice or three times daily by the eFlow(R) Electronic Nebulizer. Following an overall study period of 126 days, patients were eligible to enter AIR-CF3 (CP-AI-006), an open-label follow-up study for patients in AIR-CF2 and AIR-CF1 (CP-AI-007).

"We look forward to further defining the role of both the twice daily and three times daily dosing in our ongoing open-label study, where we continue to gather longer-term data on more than 190 patients," commented Dr. Montgomery.

Data from this analysis have not been reviewed by the FDA. Aztreonam lysine is an investigational compound and has not yet been determined safe or efficacious in humans.

About AIR-CF Phase III Clinical Program

AIR-CF2 is one of three Phase III studies in the AIR-CF clinical program. The program, which also includes AIR-CF1 and AIR-CF-3, is designed to determine the safety and efficacy of aztreonam lysine for inhalation for treatment of people living with CF who have pulmonary P. Aeruginosa.

AIR-CF1 is a double-blind, randomized, placebo-controlled study designed to assess the safety and efficacy of a 28-day treatment course of aztreonam lysine for inhalation in people with CF who have pulmonary P. Aeruginosa. The primary endpoint is the change at Day 28 from baseline in respiratory symptoms as assessed by the CFQ-R questionnaire (a patient-reported tool used to measure health-related quality of life for people with cystic fibrosis). This study will enroll 140 patients, who will be randomized to receive 28 days of treatment with 75 mg aztreonam lysine for inhalation or volume-matched placebo administered three times daily by the eFlow(R) Electronic Nebulizer. This study is currently enrolling patients.

AIR-CF3 is an open-label, multi-center study of patients who participated in the AIR-CF1 or AIR-CF2 studies. The primary objective of the study is to evaluate the safety of repeated exposure to aztreonam lysine for inhalation in people with CF. Each patient's participation in the study will last up to 18 months. Patients will receive treatment with 75 mg of aztreonam lysine for inhalation with the same regimen they received in AIR-CF1 or AIR-CF2 (twice or three times daily). Patients will receive up to nine 28-day courses of aztreonam lysine for inhalation, each of which will be followed by a 28-day off-treatment period.

About Aztreonam Lysine for Inhalation

Aztreonam lysine for inhalation is an antibiotic candidate currently being studied in Phase III clinical trials as a treatment for people with CF who have pulmonary P. Aeruginosa. Aztreonam has potent activity against Gram-negative bacteria such as P. Aeruginosa. Aztreonam formulated with arginine is a U.S. FDA-approved agent for intravenous administration. Aztreonam lysine for inhalation is a proprietary inhaled formulation of aztreonam and has been designated with orphan drug status by the U.S. FDA. It is delivered through a novel inhalation device, eFlow(R), developed by PARI GmbH.

About Cystic Fibrosis

Today more than 30,000 people in the United States have CF. CF is a chronic, debilitating genetic disease. A major characteristic of CF is production of abnormally thick, sticky mucus in the lungs, trapping bacteria and predisposing patients to lung infections, which continually damage their lungs. Pulmonary infection with Gram-negative bacteria, particularly pulmonary Pseudomonas aeruginosa, represents the single greatest cause of morbidity and mortality among CF patients. Currently there is no known cure for CF, and the goal of CF therapy is to control symptoms and prevent further lung damage.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Australia. For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including risks related to Gilead's ability to develop and commercialize this product. For example, the safety and efficacy data from additional clinical studies may not warrant further development of this compound and initiating and completing clinical trials may take longer or cost more than expected. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2005, filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead and Gilead assumes no obligation to update any such forward-looking statements.

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