Gilead Submits New Drug Application to U.S. FDA for Aztreonam Lysine for Inhalation for Cystic Fibrosis

November 16, 2007 1:39 PM ET

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 16, 2007--Gilead Sciences, Inc. (Nasdaq:GILD) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of aztreonam lysine for inhalation (75 mg three times daily), an investigational therapy in development for people with cystic fibrosis (CF) who have pulmonary Pseudomonas aeruginosa (P. aeruginosa) infection. The NDA is supported by data from two Phase III clinical studies (AIR-CF1 and AIR-CF2) and interim data from an ongoing open-label extension study (AIR-CF3) of patients who participated in AIR-CF1 or AIR-CF2. Aztreonam lysine for inhalation is delivered by the eFlow(R) Electronic Nebulizer (PARI GmbH).

"Chronic pseudomonal airway infection represents the single greatest cause of morbidity and mortality for people with cystic fibrosis, and with a limited number of inhaled antibiotics, there remains a significant unmet medical need," said A. Bruce Montgomery, MD, Senior Vice President, Head of Respiratory Therapeutics, Gilead Sciences. "The completion of this new drug application is reflective of Gilead's commitment to developing novel therapies for people with this life-threatening disease."

Data from AIR-CF1 demonstrated improvement in respiratory symptoms for people with cystic fibrosis as measured by the Respiratory Symptoms scale of the Cystic Fibrosis Questionnaire-Revised (CFQ-R), a patient-reported outcome (PRO) tool used to measure health-related quality of life for people with cystic fibrosis. AIR-CF2 data demonstrated that aztreonam lysine for inhalation significantly delayed the time to need for inhaled or intravenous (IV) antibiotics following a course of inhaled tobramycin. Both studies also demonstrated improvements from baseline in respiratory function, as measured by relative improvement of forced expiratory volume in one second (FEV1) compared to placebo.

The most common treatment-emergent adverse events in the AIR-CF studies were cough, productive cough, nasal congestion, wheezing and sore throat. The incidences of these events were not significantly different between the placebo and the aztreonam lysine for inhalation groups.

In August 2007, Gilead initiated an expanded access program (EAP) to provide aztreonam lysine for inhalation to people with cystic fibrosis and P. aeruginosa who have limited treatment options and are at risk for disease progression.

Aztreonam lysine for inhalation is an investigational therapy and has not yet been determined safe or efficacious in humans.

About the Expanded Access Program

The EAP is open to treatment centers in the United States for people with cystic fibrosis who are six years or older and have P. aeruginosa present in expectorated sputum or throat swab culture within two months prior to consent. The Cystic Fibrosis Foundation, through its affiliate pharmacy, Cystic Fibrosis Services, Inc. is assisting in drug distribution to treatment centers.

People with cystic fibrosis in the U.S. with severe lung function impairment as defined as having an FEV1 of less than 50 percent predicted or who have completed participation in the open-label AIR-CF3 trial are eligible to participate.

Participating patients are evaluated at screening, at baseline, at Day 28 and at Day 56 visits, and then every two months thereafter. In this program, patients will receive aztreonam lysine for inhalation, administered via the PARI eFlow Electronic Nebulizer, 75 mg three times daily, in 56-day cycles of therapy (28 days on drug followed by 28 days off) as provided by their physician until patients or physicians withdraw from participation in the study or the program is terminated by Gilead.

For more information regarding the expanded access program or to request registration materials, physicians may call

1-800-490-2697 or log on to www.EAPforCF.com.

About the AIR-CF Phase III Program

The Phase III AIR-CF clinical program was designed to determine the safety and efficacy of aztreonam lysine for inhalation for use in people with cystic fibrosis who have pulmonary P. aeruginosa. In each of these studies, aztreonam lysine for inhalation was administered by the PARI eFlow Electronic Nebulizer.

AIR-CF1 was 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 cystic fibrosis who have pulmonary P. aeruginosa. The primary endpoint was the change at day 28 from baseline in respiratory symptoms as assessed by the CFQ-R. This study enrolled 164 patients who were randomized to receive 28 days of treatment with aztreonam lysine for inhalation or volume-matched placebo administered three times daily.

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 for inhalation following a 28-day treatment course of tobramycin inhalation solution in people with cystic fibrosis who have pulmonary P. aeruginosa. Patients were randomized to receive 28 days of treatment with 75 mg of aztreonam lysine for inhalation or volume-matched placebo each administered two times or three times daily. Patients were followed for an overall study period of 126 days, with 56 days of observation after receiving aztreonam lysine for inhalation therapy or placebo.

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 cystic fibrosis. Patients will receive treatment with aztreonam lysine for inhalation with the same dosing regimen they received in AIR-CF1 or AIR-CF2. This trial is ongoing.

About Aztreonam Lysine for Inhalation

Aztreonam lysine for inhalation is an antibiotic candidate currently being studied in an ongoing Phase III open label trial for people with cystic fibrosis who have pulmonary P. aeruginosa. Aztreonam has potent activity against Gram-negative bacteria such as P. aeruginosa. Aztreonam formulated with arginine is a FDA-approved agent for intravenous administration. Aztreonam lysine for inhalation is a proprietary formulation of aztreonam developed specifically for inhalation and has been designated with orphan drug status in the United States and Europe.

About PARI Pharma and the eFlow Electronic Nebulizer

Aztreonam lysine for inhalation is delivered by a novel inhalation device, the eFlow Electronic Nebulizer, developed by PARI Pharma GmbH. eFlow is a quiet, portable nebulizer that enables efficient aerosolization of liquid medications via a vibrating, perforated membrane. PARI Pharma also contributed to the development and optimization of the drug formulation (aztreonam lysine for inhalation) for delivery via eFlow. Based on PARI's 100-year history working with aerosols, PARI Pharma is dedicated to advancing inhalation therapies by developing innovative delivery platforms and new pharmaceutical formulations that work together to improve patient care.

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 that traps bacteria and predisposes patients to lung infections, which damage their lungs. Pulmonary infection with Gram-negative bacteria, particularly pulmonary P. 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.

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 the risk that the FDA may not approve aztreonam lysine for inhalation for treatment of people with cystic fibrosis (CF) who have pulmonary P. aeruginosa infection. In addition, marketing approval, if granted, may have significant limitations on its use. 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 Gilead's Annual Report on Form 10-K for the year ended December 31, 2006 and Quarterly Reports on Form 10-Q for the first, second and third quarters of 2007, as 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.

For more information on Gilead, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

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