Gilead Announces Expanded Access Program for Aztreonam Lysine for Inhalation for Patients with Cystic Fibrosis

July 9, 2007 4:32 PM ET

FOSTER CITY, Calif.--(BUSINESS WIRE)--July 9, 2007--Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company will initiate an expanded access program beginning August 1, 2007 to provide its investigational therapy, aztreonam lysine for inhalation, to patients with cystic fibrosis (CF) and Pseudomonas aeruginosa (P. aeruginosa) infection who have limited treatment options and are at risk for disease progression. The expanded access program for aztreonam lysine for inhalation will be open to participating treatment centers in the United States. Based on results from two pivotal Phase III clinical studies, Gilead anticipates submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for aztreonam lysine by the end of 2007.

"We are encouraged by the study results we have seen for aztreonam lysine for inhalation in people with CF who have P. aeruginosa infection," said A. Bruce Montgomery, MD, Senior Vice President, Head of Respiratory Therapeutics, Gilead Sciences. "We are working rapidly to prepare and submit the NDA. In the interim, we hope this program will ensure that more patients with advanced disease and limited treatment options will have access to treatment with aztreonam lysine."

Gilead recently completed two pivotal Phase III clinical studies, AIR-CF1 and AIR-CF2. Data from AIR-CF1 demonstrated improvement in respiratory symptoms for patients with CF as measured by the respiratory domain 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 CF. AIR-CF2 data demonstrated that aztreonam lysine for inhalation significantly improved 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 these 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 groups. Aztreonam lysine is an investigational compound and has not yet been determined safe or efficacious in humans.

Expanded access programs are part of an effort by the FDA and the pharmaceutical industry to make investigational drugs available during the later stages of clinical development for the treatment of serious or life-threatening diseases.

The Cystic Fibrosis Foundation, through its affiliate pharmacy, Cystic Fibrosis Services, Inc. will assist in drug distribution to the treatment centers.

Program Design

The expanded access program will make aztreonam lysine for inhalation available to patients in the United States six years or older with CF who have P. aeruginosa present in expectorated sputum or throat swab culture within two months prior to consent. Patients with severe lung function impairment who are waitlisted or eligible for lung transplantation or who have completed participation in the open-label trial AIR-CF3 (CP-AI-006) will be eligible to participate. Patients who have a level of lung function impairment consistent with lung transplantation criteria, but who are ineligible for transplantation for other reasons, can enroll in this program.

Gilead intends to expand the program to additional patient populations in defined stages. 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.

Physicians will be required to evaluate patients 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(R) 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.

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 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 in the United States and Europe.

About the Cystic Fibrosis Services, Inc.

Cystic Fibrosis Services, Inc. (CF Services Pharmacy) is a wholly owned subsidiary of the Cystic Fibrosis Foundation. The CF Services Pharmacy was established in 1988 as a specialty pharmacy to provide availability and access to CF medications, as well as assistance with the complex insurance issues faced in obtaining these medications. The CF Services Pharmacy shares in the CF Foundation's mission to serve the CF population and help patients and families manage their prescription medication needs. Today, the CF Services Pharmacy continues this mission. More than just a pharmacy, the CF Services Pharmacy provides personalized service, patient advocacy, patient education and reimbursement support to the CF community. Furthermore, because the CF Foundation funds the groundbreaking research that brings new drugs and therapies to the market, the CF Services Pharmacy is immediately able to offer new medications when they become available. Together, the CF Services Pharmacy and the CF Foundation work toward improving the quality of life for individuals with CF.

About PARI 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 continually 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 expanded access program will

not provide patients with CF and P. aeruginosa greater access to aztreonam lysine for inhalation and risks related to Gilead's ability to submit an NDA for aztreonam lysine for inhalation for the treatment of CF to the U.S. FDA as currently planned. Safety and efficacy data from additional clinical studies may not warrant further development of this product candidate and initiating and completing clinical trials may take longer or cost more than expected. In addition, future discussions with the FDA may impact the amount of data needed and timelines for review, which may differ materially from Gilead's current projections. Further, the FDA may not approve aztreonam lysine for inhalation for the treatment of CF in the United States, and any 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 Report on Form 10-Q for the first quarter of 2007, 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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