Gilead Sciences Begins Human Testing of Oral PMPA for Treatment of HIV

May 7, 1997 5:17 PM ET

Data From Phase I/II Study of Intravenous PMPA Showed Significant Reduction of HIV

Foster City, CA -- May 7, 1997

Gilead Sciences, Inc. (NASDAQ:GILD) announced today that it has begun enrolling patients in a Phase I/II study to evaluate the oral prodrug of PMPA (oral PMPA) for the potential treatment of human immunodeficiency virus (HIV) infection. This Phase I/II study is being conducted to assess the safety, pharmacokinetics and anti-HIV activity of oral PMPA.

The Phase I/II study is a double-blind, placebo-controlled dose-escalating trial that will evaluate the safety, tolerability, pharmacokinetics and antiviral activity of oral PMPA. The study is designed to enroll HIV-infected patients with CD4 counts ò 200 cells/mm3 and HIV RNA ò 10,000 copies/ml, who will be randomly assigned to placebo or active PMPA tablet at one of several different dose levels. At each dose level, ten patients will receive a single dose of oral PMPA or placebo, followed by a six day observation period. After determination of safety and tolerability, these patients will be eligible to receive oral PMPA or placebo treatment once daily for an additional four weeks. Escalation to the next higher dose level may take place after data from the lower dose levels are evaluated. The study will be conducted at three clinical research centers in the United States.

Intravenous PMPA Phase I/II Study Results

The design of the oral PMPA study is based on data from a Phase I/II study of intravenous PMPA that demonstrated that as a single agent, eight doses of PMPA resulted in a median viral load decreases of 0.6 log in patients receiving 1 mg/kg/dose and 1.1 log in patients receiving 3 mg/kg/dose. During treatment, viral load decreased continuously until completion of dosing. The 1.1 log viral load decrease in the high dose group was sustained for up to one week after treatment ended. These data were presented in April at both the International Conference on Antiviral Research in Atlanta and the American Chemical Society Conference in San Francisco.

Preclinical Data

PMPA is a nucleotide analogue, a class of drugs being developed by Gilead Sciences that inhibit viral replication for prolonged periods and have been associated with infrequent development of resistance. PMPA has shown unprecedented antiviral activity in the prophylaxis and treatment of simian immunodeficiency virus (SIV) infection, a primate model for AIDS. In preclinical studies, primates treated once daily with injections or intravaginal topical applications of PMPA either before or after exposure to SIV were completely protected against infection. Additional studies have demonstrated that PMPA reduced SIV RNA levels by 99% or greater (2 to 3 log decrease) or to below the limit of detection after four weeks of treatment.

GS 840 - Another Anti-HIV Treatment in Development

In addition to oral PMPA, Gilead is developing an anti-HIV nucleotide analogue known as GS 840 (adefovir dipivoxil). GS 840 has demonstrated antiviral activity against a broad spectrum of viruses, including HIV, cytomegalovirus (CMV) and hepatitis B virus. GS 840 is in Phase III clinical evaluation and is being studied in combination with approved anti-HIV agents, including protease inhibitors, for the treatment of HIV.

One ongoing Phase II/III study, which recently met the accrual target of 400 patients, will determine the safety and efficacy of GS 840 when administered in combination with approved antiretroviral therapies for the treatment of patients infected with HIV. In addition, The Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA), a National Institutes of Health sponsored organization, is conducting a Phase III study designed to enroll up to 2,000 patients to determine the ability of GS 840, when administered with approved antiretrovirals, to treat HIV, prolong survival and prevent CMV end-organ disease in patients with advanced AIDS.

Information on Enrolling in Gilead's Clinical Trials

Patients and physicians who would like more information and enrollment criteria for oral PMPA Phase I/II trial or the ongoing GS

840 clinical trials may call the AIDS Clinical Trials Information System (ACTIS) at 1-800-TRIALS-A or Gilead Sciences Medical Information at 1-800-GILEAD-5 (1-800-445-3235, press 3).

Gilead Sciences

Gilead Sciences is a biopharmaceutical company dedicated to the discovery, development and commercialization of treatments for human diseases. The company's business and scientific endeavors are focused on making new therapies available to patients, physicians and the healthcare system. Gilead's expertise has resulted in proprietary therapeutics for important viral diseases, including a currently available therapy for cytomegalovirus retinitis, and products in development to treat diseases caused by human immunodeficiency virus, hepatitis B virus, herpes simplex virus, human papillomavirus and influenza virus. Gilead's research programs seek treatments for these and other viral infections, vascular diseases and cancer. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.