Gilead Announces Presentation of Phase I/II Study Results of Oral PMPA for HIV at Upcoming Medical Conference

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Once-Daily Oral PMPA Reduced HIV Viral Load By 1.22 Log

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Gilead Sciences, Inc. (NASDAQ:GILD) announced today that data from a Phase I/II study of the oral formulation of PMPA, which is being developed for the treatment of HIV, will be presented at the 5th Conference on Retroviruses and Opportunistic Infections in Chicago, Illinois on Thursday, February 5, 1998. These data will be presented at a late-breaker session of the conference by clinical investigator Steven G. Deeks, M.D., Assistant Clinical Professor of Medicine at the University of California, San Francisco (San Francisco General Hospital). An abstract summarizing these data has been made available to conference participants in pre-registration materials.

Data from this Phase I/II placebo-controlled multicenter study demonstrate that oral administration of PMPA as monotherapy substantially decreased HIV RNA levels at each of the three dose levels studied and was well tolerated.

"Based on these encouraging data, Gilead is designing a program of Phase II longer-term dosing studies that will further define PMPA's therapeutic profile, including its safety and efficacy in combination with other anti-HIV agents," said John C. Martin, Ph.D., President and CEO of Gilead Sciences. "As part of Gilead's continued efforts to accelerate the development of new treatment options for patients in need, we will work diligently over the next few months to initiate this next phase of the PMPA clinical development program."

Once-Daily Oral PMPA Significantly Reduced HIV Levels

A total of 36 HIV-infected patients enrolled in the study received either placebo or treatment with PMPA once per day at one of three dose levels (75 mg, 150 mg or 300 mg). Data from this study demonstrate that PMPA monotherapy reduced plasma HIV RNA levels from baseline after 28 days of dosing by a median of 0.32 log10 in the 75 mg group ($p = 0.06$), 0.44 log10 in the 150 mg group ($p = 0.008$) and 1.22 log10 in the 300 mg group ($p = 0.003$), compared to a median decrease of 0.06 log10 in the placebo group.

All patients received a single dose of oral PMPA or placebo, then no treatment for one week, followed by oral PMPA or placebo once per day for an additional four weeks. More than half the patients enrolled in the trial previously had received antiretroviral therapy for the treatment of HIV. The study was conducted at the Johns Hopkins University School of Medicine in Baltimore, Maryland; the University of California, San Francisco (San Francisco General Hospital); and the University of Washington in Seattle, Washington.

In the study, treatment with oral PMPA was well tolerated. Reported adverse events in both the treatment and placebo groups included reversible elevations in creatine kinase (CK at 18% in the treatment groups vs. 13% in the placebo group), a laboratory marker of muscle metabolism that can be related to exercise. In addition, exacerbation of pre-existing neuropathy was reported in two patients (one in a treatment group and one in the placebo group).

Data Support Results From Earlier Human and Primate Studies

Previous studies of an intravenous formulation of PMPA in HIV-infected patients demonstrated that PMPA, as a single agent, reduced HIV RNA levels by a median of 1.1 log10 after eight doses of PMPA (3 mg/kg). In preclinical studies, primates treated once daily with injections of PMPA either before or after exposure to simian immunodeficiency virus (SIV), a primate model for HIV, were completely protected against infection. A topical gel form of PMPA has provided complete protection against SIV when applied intravaginally in primates.

Gilead Sciences is a biopharmaceutical company dedicated to the discovery, accelerated 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 and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.