Preliminary Phase II Clinical Results For Once-Daily Anti-HIV Agent, Tenofovir DF, Presented At ICAAC

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Gilead Sciences, Inc. (Nasdaq: GILD) today announced preliminary results from a Phase II clinical trial (Study 902) evaluating the safety and efficacy of once-daily tenofovir disoproxil fumarate (tenofovir DF), formerly known as oral PMPA, when added to a stable background antiretroviral regimen in treatment-experienced HIV patients. In this study, treatment with tenofovir DF was well tolerated and associated with dose-related antiviral activity.

These data will be presented for the first time on Monday, September 27, 1999, at 12:48 p.m. in a late breaker session at the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) convening in San Francisco, California.

The 48-week double-blind, dose-ranging study enrolled 189 treatment-experienced patients at 22 U.S. sites who were on a stable antiretroviral regimen for at least 8 weeks prior to entering the study. Patients were randomized to receive one of three tenofovir DF doses (300 mg, 150 mg or 75 mg) or placebo (2:2:2:1) in addition to their existing treatment regimen. At week 24, all placebo patients were switched to the tenofovir DF 300 mg treatment arm.

The primary efficacy analysis was conducted on data compiled through the 24 week placebo-controlled period; safety results for up to 48 weeks of treatment also will be presented. Anti-HIV activity was observed in all three active treatment arms, with the greatest mean DAVG24 (time-weighted difference from baseline over 24 weeks) associated with the 300 mg dose of tenofovir DF. Patients receiving the 300 mg dose had a mean DAVG24 of -0.62 log10 copies/mL compared with +0.04 log10 copies/mL for those receiving placebo ($p < 0.001$). The mean DAVG24 for patients in the 150 mg and 75 mg dose groups was -0.36 and -0.27 log10 copies/mL ($p = 0.001$ and $p = 0.014$), respectively. The mean absolute difference in HIV RNA from baseline for patients receiving the 300 mg dose was -0.75 log10 copies/mL after 24 weeks of treatment, as compared to a mean reduction of -0.05 log10 copies/mL for those receiving placebo ($p = 0.02$). Patients in the 150 mg and 75 mg tenofovir DF arms had mean reductions in viral load of -0.40 and -0.45 log10, respectively.

“The highest dose of tenofovir DF in this study reduced circulating virus in the bloodstream by more than 80 percent,” said Robert Schooley, MD, Professor and Division Head, Department of Infectious Diseases, University of Colorado and principal investigator of the study. “This represents an impressive and durable effect given that tenofovir DF was added as a single new agent to a failing background regimen in extensively pre-treated patients.”

At baseline, patients had a mean HIV RNA of 3.7 log10 copies/mL and a mean CD4 cell count of 376 cells/mm3. Patients had received antiretroviral therapy for a mean of 55 months at the time of study enrollment. Baseline genotypic analyses of patient HIV isolates demonstrated that more than 90 percent of patients had evidence of nucleoside reverse transcriptase inhibitor-associated resistance mutations; 67 percent and 75 percent had evidence of 3TC or AZT resistance, respectively.

Study 902 Safety Results

In this study, treatment with tenofovir DF was well tolerated at all three dose levels for up to 48 weeks. The incidence of serious adverse events was similar among all study arms and was reported in 4 patients (7%) in the 300 mg dose group compared with 3 patients (11%) in the placebo group. Additionally, no patients receiving 300 mg daily for up to 48 weeks developed elevations in serum creatinine greater than 0.5 mg/dL above baseline; drug-related nephrotoxicity has not been observed.

“Based on this preliminary data, the efficacy and safety profile of tenofovir DF in this treatment-experienced population is very encouraging,” said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead Sciences. “As part of Gilead’s continued efforts to accelerate the development of new treatment options for challenging diseases, we plan to launch the Phase III multinational clinical program for tenofovir DF later this year.”

Gilead Sciences, headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA, Boulder, CO, San Dimas, CA, and

Cambridge, UK, and sales and marketing organizations in the United States, Europe and Australia. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD. For more information about Gilead, please visit the company Web site at www.gilead.com.

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 that could cause actual results to differ materially from those referred to in the forward-looking statements. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective as human therapeutics. Actual results could differ materially from those projected in this release. 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, 1998 on file with the U.S. Securities and Exchange Commission.