92-Week Data From Clinical Study of Gilead's Adefovir Dipivoxil in Patients Co-Infected With HIV and Lamivudine-Resistant HBV Presented At International Medical Meeting

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MADRID, Spain, Apr 18, 2002 (BW HealthWire) --

Data Discussed at 37th Meeting of European Association for the Study of the Liver

Gilead Sciences (Nasdaq:GILD) today announced results from a single-center, open-label clinical trial (Study 460i) of its novel, once-daily, oral antiviral agent adefovir dipivoxil 10 mg that is being developed for the treatment of chronic hepatitis B. These data show that adefovir dipivoxil was associated with significant, sustained reductions in levels of hepatitis B virus (HBV) DNA through 92 weeks in chronic hepatitis B patients with lamivudine-resistant HBV and co-infected with HIV.

The data are scheduled for presentation (#643) at the 37th Annual Meeting of the European Association for the Study of the Liver (EASL) in Madrid, Spain by Yves Benhamou, MD, Service d'Hepato-Gastroenterologie, Groupe Hospitalier Pitie-Salpetriere, Paris, France. This presentation is one of more than 20 abstracts characterizing data from studies of adefovir dipivoxil slated for presentation at EASL.

"These data show that adefovir dipivoxil is active against the most common HBV resistance mutation -- YMDD -- that develops within four years in nearly 90 percent of chronic hepatitis B patients co-infected with HIV who have been treated with lamivudine," said Dr. Benhamou. "Treatment with adefovir dipivoxil results in a continued and progressive reduction of serum HBV DNA through nearly two years of treatment. This is especially important because patients co-infected with both HIV and lamivudine-resistant HBV are often more difficult to treat than patients infected with either virus by itself."

About Study 460i

Study 460i is a single-center, open-label study of adefovir dipivoxil 10 mg in chronic hepatitis B patients with lamivudine-resistant HBV and co-infected with HIV. The study enrolled 35 patients with controlled HIV infection (mean baseline HIV RNA serum level of 2.88 log10 copies/mL) who were receiving lamivudine 150 mg twice daily as part of their combination anti-HIV treatment regimen for a median of 42.3 months prior to enrollment. Lamivudine-resistant HBV (confirmed YMDD mutations) was detected in patients a median of 21.3 months prior to initiating treatment with adefovir dipivoxil. The mean baseline serum HBV DNA level in these patients was 8.64 log10 copies/mL.

After 92 weeks of treatment, adefovir dipivoxil was associated with a significant decrease in mean serum HBV DNA levels of 5.13 log10 copies/mL (n=31; p less than 0.001). Levels of serum HBV DNA steadily declined over the course of treatment, from 2.90 log10 copies/mL at week 12, 3.40 log10 copies/mL at week 24, 4.01 log10 copies/mL at week 48, 4.74 log10 copies/mL at week 72 to 5.13 log10 copies/mL at week 92. These levels were undetectable (less than 1000 copies/mL by Roche PCR) in 29 percent of patients.

Over the course of the study, no resistance mutations developed that were associated with decreased susceptibility to adefovir dipivoxil or rebound in serum HBV DNA levels. In addition, nine percent of chronic hepatitis B patients who were hepatitis B "e" antigen (used to denote hepatitis B viral replication) positive at baseline achieved seroconversion by week 92. Overall, adefovir dipivoxil 10 mg was well tolerated in this study. During the course of the trial, four patients discontinued for reasons thought to be unrelated to adefovir dipivoxil, as judged by the investigator.

Study 460i Virology Analyses

Results of a 48-week virology analysis from Study 460i also will be presented at the conference (#516) by Vincent Thibault, MD, Virology and Gastroenterology Department, Groupe Hospitalier Pitie-Salpetriere, Paris, France. In this genotypic analysis, patients were monitored for the emergence of new resistance mutations at 24 and 48 weeks. At both time points, participants' serum HBV DNA levels had significantly decreased, and no adefovir resistance mutations were detected as a result of long-term therapy with adefovir dipivoxil.

About Adefovir Dipivoxil

Adefovir dipivoxil belongs to a class of drugs called nucleotide analogues which are designed to work by blocking HBV DNA polymerase, an enzyme involved in the replication of the virus in the body. Gilead recently filed a New Drug Application (NDA) for adefovir dipivoxil with the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) with the European Medicines Evaluation Agency (EMEA). Gilead has requested a priority, or six month, review in the United States, and anticipates review of its MAA in Europe in 2003.

Chronic Hepatitis B

Worldwide, there are approximately 350 million chronic carriers of hepatitis B, of which approximately one million die each year from complications of the disease, making chronic hepatitis B one of the 10 most common causes of death. Complications of chronic hepatitis B include cirrhosis (scarring of the liver), liver failure and primary liver cancer (hepatocellular carcinoma). Between one quarter and one third of people with chronic hepatitis B are expected to develop progressive liver disease. Patients infected with the precore mutant strain of hepatitis B may be predisposed to more severe and progressive liver injury. Precore mutant hepatitis B infects up to approximately 50 percent of the 350 million chronic hepatitis B carriers worldwide and is most prevalent in countries of the Mediterranean and Southeast Asia, where between 30-80 percent of chronic hepatitis B patients are estimated to be infected with this strain.

Early Access Program Initiated

In March 2002, Gilead announced the initiation of an early access program in the United States to provide adefovir dipivoxil to chronic hepatitis B patients with lamivudine-resistant HBV. A similar program opened in France in July 2001 and has enrolled 300 patients to date, and additional programs in Canada, Australia and in other countries in Europe will open in the coming months as appropriate regulatory approvals are obtained.

For more information regarding the adefovir dipivoxil early access program, or to request program registration materials, physicians may call 1-800-GILEAD-5 or 650/574-3000.

Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The company has five marketed products and focuses its research and clinical programs on anti-infectives, including antivirals, antifungals and antibacterials. Headquartered in Foster City, CA, Gilead has operations in the United States, 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 that could cause actual results to differ materially from those referred to in the forward-looking statements. Such risks and uncertainties include the risk that further data from ongoing and future clinical trials may not be as favorable as current data and other risks related to regulatory review and approval of adefovir dipivoxil in the United States and Europe. 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, 2001 on file 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 Sciences, please visit the company's web site at www.gilead.com or call the Gilead Corporate Communications Department at 1-800-GILEAD-5 or 650/574-3000.

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