Gilead Initiates Early Access Program for Adefovir Dipivoxil, Investigational Treatment for Chronic Hepatitis B Infection

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FOSTER CITY, Calif., Mar 12, 2002 (BUSINESS WIRE) --

Program Open for Patients Without Treatment Options Due to Lamivudine Resistance

Gilead Sciences, Inc. (Nasdaq:GILD) today announced the initiation of an Early Access Program (EAP) to provide its investigational agent adefovir dipivoxil 10 mg to people with chronic hepatitis B virus (HBV) infection resistant to the currently available antiviral treatment lamivudine. The program will open initially in the United States, followed by Canada, Australia and countries in Europe as local regulatory approvals for the program are obtained. Based on positive data from two pivotal Phase III studies, Gilead anticipates submitting applications for marketing approval of adefovir dipivoxil 10 mg in the United States and Europe in the first half of 2002.

"Less than half of patients with chronic HBV are candidates for interferon alpha, and resistance to lamivudine is a key factor in treatment failures. This leaves a large patient population without a viable treatment, many of whom are at serious risk for disease progression," said Robert Perrillo, MD, Ochsner Clinic, New Orleans, LA. "The Adefovir Dipivoxil Chronic Hepatitis B Early Access Program will provide access to a drug that may represent the best hope for these patients."

Early access programs are part of an effort by the U.S. Food and Drug Administration (FDA), European regulatory agencies 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.

Program Design

The Early Access Program will make adefovir dipivoxil 10 mg available to patients in the United States 16 years or older with chronic HBV resistant to lamivudine and who are at risk for disease progression. Lamivudine resistance is defined as a positive serum HBV DNA greater than or equal to 10(6) copies/mL (PCR assay) and ALT greater than or equal to 1.2 times the upper limit of normal within four weeks of screening despite ongoing treatment with lamivudine. Patients must have received at least 24 cumulative weeks prior treatment with lamivudine and have adequate hematologic and renal function at screening. Those patients co-infected with HIV, HCV or other viral infections will be eligible provided they meet all other entry criteria.

Physicians will be required to evaluate patients at baseline and after one month on therapy, then every two months until drug discontinuation or study termination following the protocol-specified guidelines. Patients enrolled in the U.S. Early Access Program will receive adefovir dipivoxil via their physician until the drug has been licensed for marketing by the U.S. Food and Drug Administration and is commercially available, or until the program is terminated by Gilead Sciences. A similar program was initiated in France in July 2001 and has enrolled 278 patients to date.

"Providing advanced care to patients through improved therapeutics is at the core of the Gilead mission," said John C. Martin, PhD, President and CEO, Gilead Sciences. "Initiating this program is a significant step toward providing early access to adefovir dipivoxil to patients who have become resistant to lamivudine."

Physician Registration

For more information regarding the Adefovir Dipivoxil Chronic Hepatitis B Early Access Program or to request registration materials, physicians may call 1-800-GILEAD-5 or 1-650-574-3000. Parexel is the contract research organization that will manage the program on Gilead's behalf for sites in the United States, Canada, Australia and Europe.

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 HBV in the body. The investigational drug is dosed as one 10 mg tablet taken once daily.

Data from two pivotal Phase III studies were released in 2001. All primary and secondary efficacy endpoints were achieved, and the safety profile of adefovir dipivoxil 10 mg over 48 weeks of dosing was similar to placebo. Study 437 is a Phase III clinical trial evaluating the safety and efficacy of adefovir dipivoxil once daily as monotherapy compared to placebo in 515 hepatitis B "e" antigen-positive patients with chronic HBV infection and compensated liver function. Results from this study were presented at the 52nd annual meeting of the American Association for the Study of Liver Diseases (AASLD) in November 2001.

Study 438 is an ongoing Phase III clinical trial that enrolled 185 patients with precore mutant HBV, or hepatitis B "e" antigen-negative virus, and compensated liver function. This two-year study is being conducted in Australia, Canada, France, Greece, Israel, Italy and Southeast Asia. Preliminary results were released in September 2001 and will be presented at the 37th annual meeting of the European Association for the Study of the Liver (EASL) in Madrid in April 2002. Data from these studies will comprise the core of the regulatory filing packages in both the United States and Europe. To further evaluate the long-term safety and resistance profiles of adefovir dipivoxil, some patients are continuing on Studies 437 and 438 for an additional three years of treatment.

Data from additional studies of adefovir dipivoxil in a variety of patient populations, including those with lamivudine-resistant HBV, patients with compensated and decompensated liver disease, post-liver transplant patients and patients co-infected with HBV and HIV, also were presented at AASLD in November 2001, and further data will be presented at EASL in April 2002. To date, Gilead has provided access to adefovir dipivoxil through Study 435 to approximately 400 patients with lamivudine-resistant chronic HBV infection who are wait listed for or have received a liver transplant. Adefovir dipivoxil is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

Chronic Hepatitis B Virus Infection

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

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 the safety, efficacy and resistance profile of adefovir dipivoxil observed to date may not be observed following longer periods of treatment, risks related to Gilead's ability to complete regulatory filings as anticipated, the risk that the FDA and other regulatory agencies could require longer-term safety and efficacy data prior to approval, and other risks related to regulatory approval of adefovir dipivoxil. 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, 2000 and in Gilead's Quarterly Reports on Form 10-Q, all of which are 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 1-650-574-3000.

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