

Gilead Sciences Receives Approval to Initiate Clinical Trials in China for Adefovir Dipivoxil, an Investigational Compound for the Treatment of Chronic Hepatitis B Infection

December 11, 2000 6:12 PM ET

Company to Initiate Phase I Studies in 2001

Foster City, CA -- December 11, 2000

Gilead Sciences, Inc. (Nasdaq: GILD) announced today that it has received approval from the People's Republic of China State Drug Administration of its clinical trial application for adefovir dipivoxil, the company's investigational compound for the treatment of patients with chronic hepatitis B virus (HBV) infection. Gilead was granted Class 1 designation for adefovir dipivoxil in December 1999. Gilead is currently evaluating adefovir dipivoxil in Phase III clinical studies in North America, Europe, Asia and Australia, and plans to initiate Phase I studies in China in 2001.

"The designation of adefovir dipivoxil as a Class 1 compound and approval to initiate clinical studies in China are important steps in the development of this product," said John C. Martin, Ph.D., President and Chief Executive Officer, Gilead Sciences. "As part of our strategy to reach a broad market with this product candidate, we plan to augment our international program of Phase III trials by initiating Phase I studies of adefovir dipivoxil in China, the cornerstone of the Asian marketplace."

In order to meet requirements for Class 1 designation, an investigational product must not yet be approved for marketing by any regulatory agency. To maintain Class 1 status, clinical studies in China must be initiated within one year of receiving approval of a clinical trial application. Class 1 designation also ensures 12 years of market exclusivity following marketing authorization. As such, generic versions of the compound cannot be developed during that time period.

"More than 350 million people suffer from chronic hepatitis B infection, and over 100 million of those live in China. The disease is the ninth leading cause of death worldwide," said Carol Brosgart, M.D., Senior Director, Clinical Research, Gilead Sciences. "In early clinical studies, adefovir dipivoxil was associated with an approximate 4 log₁₀ reduction in HBV DNA. We believe that this compound may offer an important treatment option to many Chinese patients infected with chronic HBV, and we are working closely with our colleagues in China to bring this compound to market."

Adefovir Dipivoxil Pivotal Phase III Studies

Two pivotal Phase III trials are currently underway to evaluate adefovir dipivoxil monotherapy as a potential treatment for chronic HBV infection. Study 437, initiated in March 1999 and being conducted in Australia, Europe, North America and Southeast Asia, is a randomized, double-blind, placebo-controlled trial of adefovir dipivoxil 10 and 30 mg. Enrollment in this trial was completed in March 2000 with 515 patients.

Study 438, initiated in January 2000, is evaluating adefovir dipivoxil 10 mg for the treatment of patients with precore mutant HBV infection, a strain of the virus that has evolved without the hallmark "e" antigen. This trial is being conducted in Australia, Canada, France, Greece, Israel, Italy and Southeast Asia. Enrollment was completed in June 2000 with 184 patients. Gilead anticipates the presentation of data from the one year endpoint of these studies at scientific conferences during the second half of 2001 and potential U.S. and European regulatory filings during the first half of 2002.

Studies in Lamivudine-Resistant Patients

Gilead also is evaluating the use of adefovir dipivoxil as a treatment for patients with lamivudine-resistant HBV. Study 435, an open-label clinical trial, is designed to evaluate the use of adefovir dipivoxil for the treatment of lamivudine-resistant HBV in liver transplant recipients or pre-transplant patients. This study is being conducted in North America, Asia, Australia and Europe.

The company recently initiated Study 461, a randomized, double-blind, placebo-controlled study designed to evaluate the safety and antiviral efficacy of adefovir dipivoxil 10 mg alone and in combination with lamivudine in patients with lamivudine-resistant HBV infection. This 48-week study will enroll 51 patients at approximately 14 centers in North America, Europe and Australia. Patients will be randomized 1:1:1 to receive one of three treatment regimens (adefovir dipivoxil + lamivudine, adefovir + placebo or lamivudine + placebo).

Additionally, Glaxo Wellcome, in collaboration with Gilead, initiated a controlled clinical trial in March 2000 designed to evaluate

the once-daily use of adefovir dipivoxil 10 mg as combination therapy with lamivudine 100 mg (Epivir-HBV®) in chronic HBV patients who have experienced diminished therapeutic response to lamivudine monotherapy.

Patients and physicians who would like more information about adefovir dipivoxil may contact Gilead Sciences Medical Information at 1-800-GILEAD-5 (1-800-445-3235) or 1-650-574-3000 from outside the United States.

Gilead Sciences

Gilead Sciences, Inc., 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. Gilead 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; Cambridge, UK and Dublin, Ireland and sales and marketing organizations 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 data observed in Gilead's earlier clinical trials and preclinical testing may not be observed in Gilead's more reliable Phase III clinical trials and 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, 1999 and in Gilead's Quarterly Reports on Form 10-Q, all of which are on file with the U.S. Securities and Exchange Commission.

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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 (1-800-445-3235).