Second Phase III Study Evaluating Gilead's Viread(R) for the Treatment of Chronic Hepatitis B Virus Meets Primary Endpoint

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FOSTER CITY, Calif.--(BUSINESS WIRE)--June 25, 2007--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that Study 103, a Phase III clinical trial evaluating the company's once-daily anti-HIV drug Viread(R) (tenofovir disoproxil fumarate or tenofovir DF) 300 mg as a potential treatment for chronic hepatitis B virus (HBV) infection, met its primary efficacy endpoint. The data show that Viread is non-inferior to the company's once-daily antiviral drug Hepsera(R) (adefovir dipivoxil) among patients with "e" antigen (HBeAg)-positive chronic hepatitis B. The primary efficacy endpoint, the proportion of patients with a complete response at week 48, was defined by serum HBV DNA levels below 400 copies/mL and histologic improvement characterized by at least a two point reduction in the Knodell necroinflammatory score (a measure of necro-inflammation - an inflammatory process in the liver including or leading to death of liver cells) with no concurrent worsening of fibrosis (scarring of liver tissue).

At 48 weeks, 66.5 percent of patients in the Viread arm (n=176) had a complete response compared to 12.2 percent in the Hepsera arm (n=90; p less than 0.001). The most commonly observed treatment-emergent adverse events of moderate intensity or higher were abdominal pain, back pain, headache, respiratory infections and transaminase elevations. The incidence of these events was comparable between the Viread and Hepsera arms of the study. In addition, the most frequently observed grade 3 or 4 laboratory abnormalities were elevations in transaminase and serum amylase and were comparable between the two arms. Full study results will be submitted for presentation at an upcoming scientific meeting.

Study 103 is the second of two Phase III pivotal studies evaluating the efficacy, safety and tolerability of Viread for the treatment of chronic hepatitis B to have met its primary efficacy endpoint. Earlier this month, the company announced that the first study (Study 102) met its primary 48-week efficacy endpoint showing that Viread is non-inferior to Hepsera among patients with HBeAg-negative/anti-HBe positive (presumed pre-core mutant) chronic hepatitis B.

"The preliminary data observed in both Phase III trials evaluating Viread as a potential treatment option for chronic hepatitis B are very encouraging," said Franck Rousseau, MD, Vice President, Clinical Research, Gilead Sciences. "We look forward to reviewing these data with regulatory authorities and are working quickly to file a New Drug Application in the United States and Marketing Authorisation Application in Europe in the fourth quarter of this year."

The active ingredient in Viread, tenofovir DF, is currently the most prescribed molecule in the United States for combination HIV therapy. Viread received approval as an anti-HIV medication from the U.S. Food and Drug Administration (FDA) in October 2001 and from the European Commission in February 2002. Viread is not approved as a treatment for chronic hepatitis B, and data from this analysis have not been reviewed by the FDA.

Study Design

Study 103 is a multi-center, randomized, double-blind Phase III clinical trial that compares the efficacy, safety and tolerability of Viread and Hepsera over 48 weeks among patients with HBeAg-positive chronic hepatitis B. Two hundred and sixty-six patients were randomized in a 2:1 ratio to receive either Viread (300 mg once daily; n=176) or Hepsera (10 mg once daily; n=90).

About Viread (tenofovir disoproxil fumarate)

In the United States, Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Viread should not be used in combination with the fixed-dose combination products Truvada(R) or Atripla(TM) because they already contain Viread.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination with other antiretrovirals. Viread is not approved for the treatment of chronic

hepatitis B and the safety and efficacy of Viread have not been established in patients coinfected with HBV and HIV. Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued Viread. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are co-infected with HIV and HBV and discontinue Viread. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported in association with the use of Viread. It is recommended that creatinine clearance be calculated in all patients prior to initiating therapy with Viread and as clinically appropriate during therapy. Coadministration of Viread and didanosine should be undertaken with caution. Patients should be monitored closely for didanosine-associated adverse events, and didanosine should be discontinued if these occur. Patients on atazanavir and lopinavir/ritonavir plus Viread should be monitored for Viread-associated adverse events, and Viread should be discontinued if these occur. When co-administered with Viread, it is recommended that atazanavir 300 mg be given with ritonavir 100 mg. Atazanavir without ritonavir should not be co-administered with Viread.

Decreases in bone mineral density (BMD) at the lumbar spine and hip have been seen with the use of Viread. The effects of Viread-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Changes in body fat have been observed in patients taking anti-HIV medicines. The cause and long-term health effect of these changes are unknown. Immune Reconstitution Syndrome has been reported in patients treated with combination therapy, including Viread.

The most common adverse events among patients receiving Viread with other antiretroviral agents in a pivotal clinical study (Study 903) were mild to moderate gastrointestinal events and dizziness. Moderate to severe adverse events occurring in more than 5 percent of patients receiving Viread included rash (rash, pruritis, maculopapular rash, urticaria, vesiculobullous rash and pustular rash), headache, pain, diarrhea, depression, back pain, fever, nausea, abdominal pain, asthenia (weakness) and anxiety. In another pivotal study (Study 907), less than 1 percent of patients discontinued participation because of gastrointestinal events.

It is important for patients to be aware that anti-HIV medicines including Viread do not cure HIV infection or AIDS and do not reduce the risk of transmitting HIV to others. Full prescribing information is available at www.GileadHIV.com.

The parent compound of Viread was discovered through a collaborative research effort between Dr. Antonin Holy, Institute for Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic (IOCB) in Prague and Dr. Erik DeClercq, Rega Institute for Medical Research, Katholic University in Leuven, Belgium.

About Hepsera

Hepsera, a nucleotide analogue for the treatment of chronic hepatitis B, works by inhibiting HBV DNA polymerase, an enzyme involved in the replication of the virus in the body.

In the United States, Hepsera is indicated for the treatment of chronic hepatitis B in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

The adverse reactions considered at least possibly related to treatment reported in 3 percent or greater of patients in the first 48 weeks in Hepsera pivotal clinical studies were asthenia, headache, abdominal pain, nausea, flatulence, diarrhea and dyspepsia. With extended treatment, mild to moderate increases in serum creatinine were observed uncommonly in patients with chronic hepatitis B and compensated liver disease treated with Hepsera for a median of 49 weeks up to a maximum of 240 weeks. Changes in serum creatinine were observed very commonly in patients pre- and post-transplantation with lamivudine-resistant liver disease and multiple risk factors for changes in renal function who were treated with Hepsera for up to 129 weeks, with a median time on treatment of 19 and 56 weeks, respectively. Clinical and laboratory evidence of exacerbations of hepatitis have occurred after discontinuation of treatment with

antiviral therapies for hepatitis B, including Hepsera. Special warnings and precautions for use are included in the package insert regarding monitoring of renal function, post-treatment exacerbations of hepatitis, and the occurrence of lactic acidosis and severe hepatomegaly with steatosis. Dosing instructions for patients with underlying renal impairment and for patients co-infected with HIV are also provided in the package insert, which is available for download online at www.hepsera.com.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, 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, including risks related to Gilead's ability to successfully commercialize tenofovir DF for chronic hepatitis B. For example, safety and efficacy data from additional clinical studies may not warrant further development of this compound for the treatment of chronic hepatitis B and completing our clinical studies may take longer or cost more than expected. In addition, feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. Further, the FDA and other regulatory authorities may not approve tenofovir DF for the treatment of chronic hepatitis B, and marketing approval, if granted, may have significant limitations on its use and physicians and may not see advantages of tenofovir DF over other treatment options and may therefore be reluctant to prescribe tenofovir DF for chronic hepatitis B. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2006 and its Quarterly Report on Form 10-Q for the first quarter of 2007, filed 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, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

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