Data Demonstrating Significant Efficacy of Viread(R) in Treating Chronic Hepatitis B Published in New England Journal of Medicine

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-- Important Findings for Treatment of One of World's Most Common Life-Threatening Liver Diseases --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 3, 2008--Gilead Sciences, Inc. (Nasdaq: GILD) today announced the publication of detailed 48-week data from two Phase III pivotal clinical trials evaluating the safety and efficacy of its once-daily Viread(R) (tenofovir disoproxil fumarate) for the treatment of chronic hepatitis B virus (HBV) infection in adults. The results of both studies (Studies 102 and 103), published in the December 4, 2008 issue of The New England Journal of Medicine (N Engl J Med 2008; #80-2878), show that Viread is significantly more effective in treating the virus that causes chronic hepatitis B than one of the most widely prescribed oral medications for HBV in the United States, Hepsera(R) (adefovir dipivoxil), also developed and marketed by Gilead.

Studies 102 and 103 compare Viread to Hepsera among patients with compensated liver disease and HBeAg-negative (presumed pre-core mutant) chronic hepatitis B and HBeAg-positive hepatitis B, respectively. Results demonstrate that at week 48, patients with chronic hepatitis B who received Viread experienced superior efficacy results compared to those who received Hepsera, as shown by the significantly higher percentage of Viread patients in each trial achieving the primary efficacy endpoint. Data also indicate that at week 48, Viread was superior to Hepsera in reducing HBV DNA levels to below 400 copies/mL and was comparable to Hepsera in achieving histological response.

"Chronic hepatitis B is a long-term, life-threatening disease that may result in tremendous complications if left untreated," said Patrick Marcellin, MD of Hopital Beaujon in Clichy, France, the principal investigator of Study 102 and one of the lead authors of The New England Journal of Medicine paper. "Hepsera represented an important advance in the treatment of chronic HBV, but these findings demonstrate that Viread can result in an even greater antiviral response."

"Chronic hepatitis B infection is a tremendous global public health problem that is vastly under-diagnosed and under-treated," said Jenny Heathcote, MD of the University of Toronto, Canada, the principal investigator for Study 103 and one of the lead authors of the paper. "But hepatitis B is both preventable and treatable, and as the results of these two studies demonstrate, Viread is a significant therapeutic treatment option in our fight against this disease."

The U.S. Food and Drug Administration (FDA) approved Viread for chronic HBV in adults in August 2008 based on these pivotal trial results. Two-year data from these studies were announced in October 2008 and presented at the annual meeting of the American Association for the Study of Liver Diseases (The Liver Meeting 2008). After the completion of 48 weeks of randomized blinded therapy, all eligible patients were rolled over to open-label Viread monotherapy. After 72 weeks, patients with confirmed viremia (HBV DNA levels at or above 400 copies/mL on two consecutive visits) had the option of adding emtricitabine treatment in the form of Truvada(R), an investigational product for the treatment of chronic hepatitis B. Notably, no mutations associated with resistance to Viread were reported among patients randomized to the Viread arm for up to 96 weeks or in Hepsera-treated patients who rolled over to Viread.

Chronic HBV affects an estimated 400 million people worldwide. Many are unaware that they are infected because the disease may not produce obvious symptoms in its early stages. One in four people with chronic hepatitis B die from complications such as cirrhosis and liver cancer.

Viread was approved for the treatment of chronic hepatitis B in the European Union, Turkey, Australia, New Zealand and Canada earlier this year. In addition to its indication for HBV, Viread is also indicated in combination with other antiretroviral agents for the treatment of HIV infection in adults, and is currently the most-prescribed molecule in antiretroviral therapy in the United States.

About Studies 102 and 103

Studies 102 and 103 were multi-center, randomized, double-blind Phase III clinical trials evaluating the efficacy, safety, and tolerability of Viread (300 mg once daily) compared to Hepsera (10 mg once daily). In Study 102, 375 patients with compensated liver disease and HBeAg-negative (presumed pre-core mutant) chronic hepatitis B who were predominantly new to HBV therapy were randomized to receive either Viread (n=250) or Hepsera (n=125) for 48 weeks. In Study 103, 266 patients with HBeAg-positive chronic hepatitis B were randomized to receive either Viread (n=176) or Hepsera (n=90) for 48 weeks.

The primary efficacy endpoint in both studies was defined as 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) with no concurrent worsening of fibrosis (scarring). Baseline characteristics were similar within each study among patients in the randomized treatment arms.

At week 48, significantly more patients receiving Viread achieved the primary endpoint compared to Hepsera-treated patients (71 percent versus 49 percent of patients in Study 102 [p<0.001]; and="" 67="" percent="" versus="" 12="" percent="" in="" study="" 103=""><0.001]). in="" addition,="" significantly="" more="" patients="" who="" received="" viread="" achieved="" a="" reduction="" in="" hbv="" dna="" levels="" to="" below="" 400="" copies/ml="" compared="" to="" hepsera-treated="" patients="" (93="" percent="" versus="" 63="" percent="" of="" patients="" in="" study="" 102=""><0.001]; and="" 76="" percent="" versus="" 13="" percent="" in="" study="" 103=""><0.001]). of="" those="" patients="" remaining="" on="" viread="" treatment="" at="" week="" 48,="" 97="" percent="" in="" study="" 102="" and="" 83="" percent="" of="" patients="" in="" study="" 103="" had="" hbv="" dna="" levels="" below="" 400="" copies/ml=""><0.001). seventy-two="" percent="" of="" patients="" who="" received="" viread="" versus="" 69="" percent="" of="" patients="" who="" received="" hepsera="" in="" study="" 102="" and="" 74="" percent="" of="" patients="" who="" received="" viread="" versus="" 68="" percent="" of="" patients="" who="" received="" hepsera="" in="" study="" 103="" (p="">0.05) achieved a histological response.

At baseline, 94 percent of patients in Study 102 and 97 percent of those in Study 103 had elevated levels of alanine aminotransferases (ALT, enzymes that serve as a measure of liver damage). Normalized ALT levels were observed in a similar proportion of Viread and Hepsera patients in Study 102 at week 48 (76 percent and 77 percent, respectively), and in 68 percent of Viread patients versus 54 percent of Hepsera patients in Study 103 (p=0.03).

In Study 103, among patients for whom seroconversion data were available at 48 weeks, a similar proportion of patients in the Viread and Hepsera groups experienced HBeAg seroconversion (21 percent versus 18 percent, respectively; p=0.36). Seroconversion is defined as both the disappearance of the hepatitis B "e" antigen, a marker of HBV replication (rendering the patient "HBe-antigen negative"), and the appearance of antibodies specific for this antigen (making the patient "HBe-antibody positive").

Notably, significantly more patients in the Viread group in Study 103 experienced "s" antigen (HBsAg) loss: 3 percent versus 0 percent (p=0.018). Loss of the "s" antigen contributes to the resolution of chronic hepatitis B infection. One percent of patients in the Viread group versus 0 percent in the Hepsera group experienced HBsAg seroconversion.

Viread and Hepsera were generally well tolerated by patients in both studies and safety outcomes were consistent with the known safety profiles of these drugs in patients with HIV and HBV, respectively. In pooled safety results from both studies, the incidence of observed Grade 2-4 adverse events was similar for each medication (30 percent for Viread and 32 percent for Hepsera). Treatment-related adverse events observed in greater than 5 percent of patients included: headache, nasopharyngitis, fatigue, upper abdominal pain, back pain, diarrhea and dizziness, which all occurred with similar frequency in the Viread and Hepsera arms. Nausea occurred in more Viread-treated patients (9 percent) than Hepsera-treated patients (3 percent); except for one case of moderate (grade 2) nausea, all other cases of nausea considered related to Viread were mild in severity.

At week 48, the only clinical serious adverse event reported in more than one patient was hepatocellular carcinoma (3 patients in Study 102), which is a known complication of chronic HBV. No deaths were reported during either study. The

following five adverse events led to discontinuation of Viread in Study 102 and occurred in one patient each: anorexia, bladder neoplasm, fatigue, cervical carcinoma and feeling hot. No Viread-treated patients in Study 103 discontinued treatment due to adverse events.

The frequency of on-treatment ALT flares was similar across both studies (3 percent for Viread and 2 percent for Hepsera). Nearly all ALT flares occurred within the first 8 weeks of initiating Viread; the flares were limited to increases in aminotransferases with continued and profound decreases in HBV DNA, and resolved within 4 to 8 weeks without treatment interruption or discontinuation.

There was no evidence of compromised renal function or renal tubular dysfunction in any patient treated with Viread. No patient developed mutations of HBV DNA polymerase associated with resistance to Viread or other HBV drugs.

Important Information About Viread for Chronic Hepatitis B and HIV

Viread (tenofovir disoproxil fumarate) is indicated for the treatment of chronic hepatitis B in adults. This indication is based on data from one year of treatment in primarily nucleoside-treatment-naive adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease. The numbers of patients in clinical trials who were nucleoside-experienced or who had lamivudine-associated mutations at baseline was too small to reach conclusions of efficacy. Viread has not been evaluated in patients with decompensated liver disease.

Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. The following points should be considered when initiating therapy with Viread for the treatment of HIV-1: Viread should not be used in combination with Truvada (emtricitabine/tenofovir disoproxil fumarate) or Atripla(R) (efavirenz/emtricitabine/tenofovir disoproxil fumarate).

The recommended dose for the treatment of chronic hepatitis B and HIV is 300 mg once daily taken orally without regard to food. The dosing interval of Viread should be adjusted in patients with renal impairment.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including Viread, in combination with other antiretrovirals.

Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including Viread. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including Viread. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

New onset or worsening of renal impairment including cases of acute renal failure and Fanconi syndrome has been reported with the use of Viread. It is recommended to assess creatinine clearance (CrCl) before initiating treatment with Viread and monitor CrCl and serum phosphorus in patients at risk. Administering Viread with concurrent or recent use of nephrotoxic drugs should be avoided. Viread should not be administered in combination with Hepsera.

HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with Viread. Viread should only be used as part of an appropriate antiretroviral combination regimen in HIV-infected patients with or without HBV coinfection.

Decreases in bone mineral density (BMD) have been observed in HIV-infected patients. It is recommended that BMD monitoring be considered for patients with a history of pathologic fracture or who are at risk for osteopenia. The bone effects of Viread have not been studied in patients with chronic HBV infection.

Redistribution/accumulation of body fat has been observed in HIV-infected patients receiving antiretroviral combination therapy.

Immune reconstitution syndrome has been observed in HIV-infected patients receiving antiretroviral combination therapy,

including Viread, which may necessitate further evaluation and treatment.

Early virologic failure has been reported in HIV-infected patients on triple nucleoside-only regimens. Patients on a therapy utilizing a triple nucleoside-only regimen should be carefully monitored and considered for treatment modification.

In controlled clinical trials in patients with chronic hepatitis B, the most common adverse reaction (all grades) is nausea. In HIV-infected patients, the most common adverse reactions (incidence ≥10 percent, grades 2-4) are rash, diarrhea, headache, pain, depression, asthenia, and nausea.

About Hepsera (adefovir dipivoxil)

Hepsera is indicated for the treatment of chronic hepatitis B in patients 12 years of age and older with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. This indication is based on histological, virological, biochemical, and serological responses in adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver function, and with clinical evidence of lamivudine-resistant HBV with either compensated or decompensated liver function.

For patients 12 to <18 years="" of="" age,="" the="" indication="" is="" based="" on="" virological="" and="" biochemical="" responses="" in="" patients="" with="" hbeag-positive="" chronic="" hbv="" infection="" with="" compensated="" liver="" function.="">

The recommended dose for the treatment of chronic hepatitis B is 10 mg once daily taken orally without regard to food. The dosing interval of Hepsera should be adjusted in patients with renal impairment.

Severe acute exacerbations of hepatitis have been reported in patients who have discontinued anti-hepatitis B therapy, including Hepsera. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

In patients at risk of or having underlying renal dysfunction, chronic administration of Hepsera may result in nephrotoxicity. These patients should be monitored closely for renal function and may require dose adjustment. It is important to monitor renal function for all patients during treatment with Hepsera.

HIV resistance may emerge in chronic hepatitis B patients with unrecognized or untreated HIV infection treated with anti-hepatitis B therapies, such as Hepsera, that may have activity against HIV. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with Hepsera.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination with other antiretrovirals.

For patients with lamivudine-resistant HBV, adefovir dipivoxil should be used in combination with lamivudine. For all patients, consider modifying treatment in the event that serum HBV DNA remains above 1,000 copies/mL with continued treatment.

Co-administration with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of adefovir and/or the co-administered drug. Monitor for Hepsera-associated adverse events. The most common adverse reaction (>10 percent) in compensated liver disease patients is asthenia and in pre- and post-transplantation lamivudine-resistant liver disease patients is increased creatinine.

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 the risks that physicians may not prescribe Viread over existing HBV medications and that the safety and efficacy data obtained through 48 weeks of Studies 102 and 103 may not be observed in other studies or in clinical practice. 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, 2007 and its Quarterly Report on Form 10-Q for the first, second and third quarters of 2008, as 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.

U.S. full prescribing information for Viread is available at www.Viread.com

U.S. full prescribing information for Hepsera is available at www.Hepsera.com

U.S. full prescribing information for Truvada is available at www.Truvada.com

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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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