Gilead Submits Marketing Applications in the United States and European Union for Viread(R) (Tenofovir Disoproxil Fumarate) for the Treatment of Chronic Hepatitis B

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 11, 2007--Gilead Sciences, Inc. (Nasdaq: GILD) today announced that it has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) and a Type II variation to the European Medicines Agency (EMEA) for marketing approval of Viread(R) (tenofovir disoproxil fumarate) for the treatment of chronic hepatitis B in adults. Viread is already approved in the United States and European Union for the treatment of HIV as part of combination antiretroviral therapy.

"New treatments are critically important in the fight against chronic hepatitis B, a potentially life-threatening infection that impacts millions of people worldwide," said Eugene Schiff, MD, Chief of the Division of Hepatology and Director of the Center for Liver Diseases at the University of Miami School of Medicine. "We've made great progress in our ability to diagnose and treat the disease, but a significant unmet medical need remains and ongoing efforts in research and development are essential."

The submissions contain data from two Phase III pivotal clinical trials, Studies 102 and 103, in patients chronically infected with the hepatitis B virus (HBV). These studies evaluate the efficacy, safety and tolerability of Viread compared to Gilead's Hepsera(R) (adefovir dipivoxil). Gilead announced the primary results from Study 102 and 103 on June 6 and June 25, 2007, respectively. Detailed data from both studies will be described in late-breaker presentations at the annual meeting of the American Association for the Study of Liver Diseases (The Liver Meeting 2007) in Boston, Massachusetts, November 2-6.

"The active ingredient in Viread -- tenofovir disoproxil fumarate -- is the most widely prescribed molecule for the treatment of HIV in the United States," said Franck Rousseau, MD, Vice President, Clinical Research, Gilead Sciences. "With positive data from two pivotal studies now available, we look forward to extending the use of this important therapy to patients with chronic hepatitis B."

Chronic hepatitis B affects more than 400 million people worldwide. The complications of chronic hepatitis B, which include liver cancer and cirrhosis, kill up to 1.2 million people each year, making it one of the world's top 10 causes of death. In the United States, an estimated 1.3 million people are currently living with chronic hepatitis B, of whom more than half are Asian American. In the European region, one million people are estimated to become infected with HBV each year and approximately 90,000 go on to develop chronic hepatitis B.

While there is no cure for the disease, anti-HBV medications can have beneficial effects on chronic hepatitis B throughout the course of infection, potentially preventing fatal liver damage and liver cancer. In many cases, this requires prolonged treatment over the course of many months or years.

About Viread (tenofovir disoproxil fumarate) for HIV

In the United States, Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.

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 virus (HBV) infection 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 treatment may be warranted.

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.

Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), 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. Routine monitoring of calculated creatinine clearance and serum phosphorous should be performed in patients at risk for renal impairment. Dosing interval adjustment and close monitoring of renal function are recommended in all patients with creatinine clearance less than 50mL/min. Viread should be avoided with concurrent or recent use of a nephrotoxic agent.

The U.S. package insert advises that co-administration 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 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 effect on long-term bone health and future fracture risk is unknown. Cases of osteomalacia (associated with proximal renal tubulopathy) have been reported in association with the use of Viread.

Changes in body fat have been observed in patients taking anti-HIV medicines. The mechanism 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.

For full prescribing information outside of the United States, physicians should consult their local product labeling.

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 (adefovir dipivoxil)

Hepsera, a nucleotide analogue, 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 U.S. package insert advises that 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 U.S. package insert regarding monitoring of renal function, post-treatment exacerbations of hepatitis, and the occurrence of lactic acidosis and severe hepatomegaly with steatosis. For physicians in the United States, dosing instructions for patients with underlying renal impairment and for patients co-infected with HIV are also provided in the U.S. package insert, which is available for download online at www.hepsera.com.

For full prescribing information outside of the United States, physicians should consult their local product labeling.

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.

Forward-Looking Statement

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 Viread for chronic hepatitis B. For example, the FDA and EMEA may not approve Viread for the treatment of chronic hepatitis B, and marketing approval, if granted, may have significant limitations on its use and physicians may not see advantages of Viread over other treatment options and may therefore be reluctant to prescribe Viread 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 and second quarters of 2007, 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

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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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