U.S. FDA Approves Gilead Sciences' Anti-HIV Drug Viread™

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Gilead Sciences (Nasdaq: GILD) today announced that it has received U.S. Food and Drug Administration (FDA) approval for its antiretroviral agent Viread™ (tenofovir disoproxil fumarate) for the treatment of human immunodeficiency virus (HIV) infection when taken in combination with other antiretroviral agents. The approval comes six months after Gilead submitted the Viread New Drug Application (NDA) to the FDA. Viread is dosed as one 300 mg tablet once daily with a meal and will be available in pharmacies within days.

"Viread addresses many of the needs of people living with HIV today. The drug has demonstrated a significant antiviral response, even in patients who may no longer respond well to available therapies due to the development of viral resistance," said Calvin Cohen, M.D., Research Director, Community Research Initiative of New England and Harvard Vanguard Medical Associates. "There has been a great deal of progress in the fight against HIV, but we still urgently need new treatments. Viread is an important new option because it is powerful and convenient -- it has a strong track record of safety in clinical studies, is well tolerated and is dosed as one tablet once a day. These all are important attributes for patients taking these types of drugs."

Viread is the first nucleotide analogue reverse transcriptase inhibitor approved for the treatment of HIV. The drug works by blocking reverse transcriptase, an enzyme involved in the replication of HIV. As a nucleotide, Viread remains in cells for longer periods of time than many other antiretroviral drugs, allowing for once-daily dosing.

"The availability of Viread marks an important advance for people living with HIV disease in the United States. We extend our gratitude to the patients and investigators who participated in clinical trials of Viread and to the Gilead employees who have worked diligently to bring this important new therapy to market," said John C. Martin, Ph.D., President and CEO of Gilead Sciences.

More than 900,000 Americans are infected with HIV, the virus that causes acquired immunodeficiency syndrome (AIDS). Each year, approximately 350,000 patients receive anti-HIV treatment regimens and an estimated 15,000 new patients begin treatment in the United States. Treatment with antiretroviral agents is crucial to control viral load and delay the emergence of AIDS-defining events. Over years of treatment with existing agents, however, multiple factors can lead to the development of viral mutations that render patients' HIV resistant to currently available medications.

Antiviral Response, Even in Difficult-to-Treat Patients In controlled clinical studies, Viread has been shown to reduce the level of HIV in the blood for up to 48 weeks when added to patients' existing antiretroviral regimens. Viread reduced viral load even in patients whose HIV has developed resistance to currently available antiretroviral drugs, as demonstrated in a multicenter, placebo-controlled Phase III study involving 552 treatment-experienced patients. This study showed that Viread reduced the level of circulating HIV by 75 percent in patients who received the drug for 24 weeks in addition to their existing antiretroviral regimen (a reduction in mean DAVG24 of 0.61 log10 copies/mL; n=368).

Resistance Profile
Resistance to Viread is rare and slow to develop. Tenofovir selects for the K65R mutation in vitro, and viruses expressing this mutation show a 3- to 4-fold reduced susceptibility to the drug. Zalcitabine, didanosine and abacavir can also select for this mutation. In clinical trials, three percent of patients developed the K65R mutation. The clinical significance of the K65R mutation for patients treated with Viread or other antiretroviral agents is not fully known at this time.

Safety Profile Comparable to Placebo
More than 1,000 patients have been treated with Viread alone or in combination with other antiretroviral products for a period of 28 days to 143 weeks in Phase I, II and III clinical trials and in a compassionate access study (908). Assessment of adverse reactions is based on two studies (902 and 907) in which 653 treatment-experienced patients received treatment with Viread 300 mg (n=443) or placebo (n=210) for 24 weeks followed by extended treatment with the drug.

The most common adverse events in patients receiving Viread were mild to moderate gastrointestinal events, such as nausea, diarrhea, vomiting and flatulence. Laboratory abnormalities observed in clinical studies occurred with similar frequency in the

Viread and placebo-treated groups. 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 Indication
Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. This indication is based on analyses of plasma HIV-1 RNA levels and CD4 cell counts in a controlled study of Viread of 24 weeks duration and in a controlled, dose ranging study of Viread of 48 weeks duration. Both studies were conducted in treatment-experienced adults with evidence of HIV-1 viral replication despite ongoing antiretroviral therapy. Studies in antiretroviral-naïve patients are ongoing; consequently, the risk-benefit ratio for this population has yet to be determined.

Ongoing Clinical Studies
Gilead is conducting Study 903 to further evaluate Viread in treatment-naive patients with HIV infection. This 96-week trial is designed to compare a treatment regimen of Viread, lamivudine (3TC) and efavirenz to a treatment regimen of stavudine (d4T), lamivudine (3TC) and efavirenz in a blinded fashion in patients in the United States, Europe and South America who have not previously received antiretroviral treatment. Enrollment in Study 903 was completed in January 2001 with 601 patients, and 48-week efficacy and safety data will be available in the first half of 2002. In addition, Gilead has initiated a program to evaluate Viread in treatment-experienced pediatric patients.

In May 2001, Gilead submitted a Marketing Authorisation Application to the European Agency for the Evaluation of Medicinal Products (EMEA). On October 18, the European Union's Committee for Proprietary Medicinal Products (CPMP) recommended marketing approval of Viread in the 15 member states of the European Community. The EMEA will consider the CPMP opinion in evaluating Gilead's application for marketing authorization of Viread. The company anticipates a final EMEA decision in early 2002. In August, Gilead submitted an application seeking regulatory approval of Viread in Australia.

Expanded Access Program
More than 5,500 patients have enrolled in Viread expanded access programs in the United States, Australia, Canada, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain and the United Kingdom.

For more information regarding the Viread expanded access program, physicians in the United States and Canada may call 1-800-GILEAD-5, those in Australia may call 800-806-112 and those in Europe may call 33-1-44-90-34-46.

Gilead Sciences
Gilead Sciences, Inc., headquartered in Foster City, CA, USA, 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, manufacturing or sales and marketing facilities 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. 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.