Gilead Sciences' New HIV Drug Viread Approved for Marketing in European Union

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FOSTER CITY, Calif.--(BW HealthWire)--Feb. 7, 2002--Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Medicines Evaluation Agency (EMEA) has granted the Marketing Authorisation for Viread(R) (tenofovir disoproxil fumarate) in all 15 member states of the European Union. Viread is approved in Europe for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in patients who are experiencing early virological failure. This approval comes after the European Union's Committee for Proprietary Medicinal Products (CPMP) adopted a positive opinion on Viread in October 2001. Gilead submitted its Marketing Authorisation Application (MAA) for Viread for review by the EMEA in May 2001.

Viread is the first nucleotide reverse transcriptase inhibitor (NtRTI) approved for the treatment of HIV. The drug works by blocking reverse transcriptase, an enzyme crucial to the replication of HIV. As a nucleotide, Viread remains in cells for longer periods of time than many other antiretroviral agents, allowing for once-daily dosing. A key benefit of Viread is its ability to reduce the viral load in HIV-1 infected adult patients who have become resistant to other available HIV drugs.

"There are increasing needs across Europe for treatments to combat HIV infection, particularly for individuals who have failed other therapy," commented Brian Gazzard, M.D., Clinical Research Director, Chelsea and Westminster Hospital, Imperial College, London. "Clinical studies have highlighted Viread's safety and tolerability, favorable resistance profile and potent antiviral activity. Additionally, the drug's convenient once-daily dosing makes it an important new option for physicians and their patients with HIV infection."

At the end of 2001, an estimated 560,000 people in Western Europe were living with HIV, with 30,000 people newly infected each year. As the HIV patient population grows and patients live longer, the need for optimal long-term antiretroviral therapy has intensified.

Viread, which is dosed as one tablet once daily with a meal, will be available shortly in Europe following completion of local reimbursement approvals. Viread was approved for marketing in the United States by the Food and Drug Administration (FDA) on October 26, 2001. Regulatory filings for the drug also have been completed in Australia and Canada and additional regulatory filings are planned in other countries in the coming months.

Expanded Access Program

Approximately 7,700 patients with advanced HIV infection have enrolled in Viread expanded access programs in Australia, Canada, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, the United Kingdom and the United States. More than 4,000 patients have enrolled in Europe. For more information regarding the Viread expanded access program, physicians in Europe may call 33-1-44-90-34-46, those in Australia may call 800/806-112 and those in Canada may call 1-800/GILEAD-5. These programs will continue until the product is commercially available.

Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The company has five marketed products and focuses its research and clinical programs on anti-infectives, including antivirals, antifungals and antibacterials. Headquartered in Foster City, CA, Gilead has operations 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.

Viread is a trademark of Gilead Sciences, Inc.

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 or 1-650/574-3000.

Notes to the Editor

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 multi-center, 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).

Safety Profile Comparable to Placebo

More than 1,000 patients have been treated with Viread alone or in combination with other antiretrovirals for a period of 28 days to 143 weeks in Phase I, II and III clinical trials and in a compassionate access study. 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. In general, laboratory abnormalities observed in clinical studies occurred with similar frequency in the Viread and placebo-treated groups.

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.

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