Gilead Launches Access Program to Provide Anti-HIV Therapy Viread in 68 Developing Countries at No Profit

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FOSTER CITY, Calif.--(BUSINESS WIRE)--April 4, 2003--Gilead Sciences (Nasdaq:GILD) today announced details of the Gilead Access Program, which will provide access to Viread(R) (tenofovir disoproxil fumarate), the company's once-a-day antiretroviral medication for HIV, at no profit in every country in Africa and in 15 additional countries in other parts of the world classified as "least developed" by the United Nations (UN).

The Gilead Access Program is now open to receive requests for the drug from the 68 eligible nations. The program has been designed to expeditiously review requests for Viread and to ship drug directly to treatment programs in the eligible countries.

"The Gilead Access Program was created in consultation with experts and advocates, with the objective of making Viread available where the need is greatest and in a way that best addresses the treatment landscape in the developing world," said John C. Martin, PhD, President and CEO, Gilead Sciences. "Based on its efficacy, positive resistance and side effect profile, and once-daily dosing, we believe that Viread will be a particularly important treatment option for physicians and patients in these regions."

Gilead will make Viread available to any private or public program treating people with HIV/AIDS in the 68 nations for US$39 for a 30-day supply, or $1.30 per day. The price for supplying Viread represents Gilead's cost of manufacturing the drug and administering the program.

"Price is just one component of the access equation, but it is an important piece, and we have worked diligently to reduce the cost of providing Viread in the countries where it is needed most," said Dr. Martin. "In creating this program, we also have included other elements designed to meet the needs of treaters in resource-challenged settings, such as a streamlined and rapid review of requests, and shipment of drug direct to treatment programs, without expensive or time-consuming intermediaries."

Key Features of the Program

The Gilead Access Program is comprised of four main elements designed to improve access to Viread on a sustainable basis:

Sale of the drug at no profit in the 53 nations of Africa and in 15 other UN-designated "least-developed" countries.

Simplified purchasing in which Gilead will provide Viread directly to treatment programs, avoiding the cost and delay frequently caused by third-party suppliers.

Information and guidance to programs seeking access to Viread, including technical assistance in the preparation of requests for reduced-price access to the drug.

Research to optimize HIV treatment strategies through clinical trials that help to define the best method for delivering anti-HIV therapy in resource-challenged settings. Gilead is participating in the "Development of Antiretroviral Therapies" (DART) study, a 3,000-patient clinical trial sponsored by the United Kingdom's Medical Research Council that began earlier this year in Uganda and Zimbabwe. The DART study is designed to evaluate antiretroviral management strategies adapted for use in parts of the world where resources are limited. Gilead also is participating with Family Health International, with the support of the Bill and Melinda Gates Foundation, in a multinational study to evaluate the potential use of Viread as a method of preventing transmission of HIV.

Program Details

Request forms can be submitted via the Internet or by email, mail or fax. The company will be prepared to ship Viread to qualifying programs as soon as requests forms are reviewed and approved.

Requests will be reviewed by independent experts, and programs requesting drug will be evaluated based on their ability to provide quality and sustainable patient care. Gilead will take appropriate steps to ensure that Viread shipments reach their intended destination and, to the extent possible, will monitor the recipient programs to ensure that quality care is being provided.

Complete program information and requests forms are available at www.gileadaccess.org. Programs without Internet access can call the Gilead Access Program in the United States at 1-800-GILEAD-5 (1-800-445-3235) or 1-650-574-3000 or in Uganda at +256-41-340-806.

Gilead also announced that the company is completing plans for reduced price access to Viread in middle-income developing countries in Eastern Europe, Asia and Latin America.

About Viread

Viread is the first nucleotide analogue reverse transcriptase inhibitor (NtRTI) approved for the treatment of HIV in the United States and Europe. Since approval, more than 100,000 patients have been prescribed Viread as part of combination therapy. The U.S. Food and Drug Administration approved Viread for marketing in October 2001 and the European Commission granted approval in February 2002.

In clinical trials and expanded access programs, approximately 10,000 patients have been treated with Viread in combination with other antiretroviral products for periods up to four years. The drug works by blocking reverse transcriptase, an enzyme involved in the replication of HIV. The approved dose of Viread for the treatment of HIV infection is 300 mg once daily taken orally with a meal, in combination with other anti-HIV medications.

In the United States, Viread is indicated for use 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-naive patients are ongoing; consequently, the risk-benefit ratio for this population has yet to be determined.

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. Adverse event rates in the Viread group were similar to those in the placebo-treated patients.

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.

In clinical practice, a number of adverse events, including renal impairment, nausea, rash and asthenia (weakness) have been reported. Renal impairment occurred most often in patients with underlying systemic or renal disease, or in patients taking concomitant nephrotoxic agents. 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.

About Gilead

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 six marketed products and focuses its research and clinical programs on anti-infectives. Headquartered in Foster City, CA, Gilead has operations in the United States, Europe and Australia.

Note to Editors: Viread is a registered trademark of Gilead Sciences, Inc.

For full U.S. prescribing information on Viread, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.viread.com.

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