Gilead Reduces Price of Viread in the Developing World by 37 Percent; Anti-HIV Medication Available to 68 Resource-Limited Countries Through the Gilead Access Program

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FOSTER CITY, Calif.--(BUSINESS WIRE)--July 9, 2004--Gilead Sciences (Nasdaq:GILD) today announced a significant price reduction for Viread(R) (tenofovir disoproxil fumarate) in the developing world. Gilead provides Viread, a once-a-day antiretroviral medication for HIV to be used in combination therapy, through the Gilead Access Program at a no-profit price 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).

As a result of continued improvements in the manufacturing process for Viread and increased economies of scale, Gilead will now be able to make Viread available to any private or public program treating people with HIV/AIDS in the 68 nations for US$24.71 for a 30-day supply, or $0.82 per day. This is nearly a 37 percent reduction in the original no-profit price of Viread. The price for supplying Viread represents Gilead's cost of manufacturing the drug and administering the no-profit program.

"Since the launch of this program Gilead has continued to invest in process improvements that could reduce our manufacturing costs. Now that we have identified improvements, we are able to lower our manufacturing cost and consequently our not-for-profit price," said John C. Martin, PhD, President and CEO, Gilead Sciences. "We created the Gilead Access Program to make Viread available in resource-limited settings, and this price reduction will allow us to make it even more widely available. In addition to this initiative, Gilead is also participating in and providing drug for several studies designed to identify the best treatments and methods for delivering treatment in the developing world, as well as studies that will evaluate Viread as a potential chemoprophylaxis to prevent infection."

Gilead also announced that the company intends to make the fixed-dose combination of Viread and Emtriva(R) (emtricitabine) available through the program as soon as that product receives U.S. regulatory approval. The company submitted its New Drug Application (NDA) for the fixed-dose combination product in March 2004. The application received six month priority review status from the FDA in May and was assigned an action date, under the Prescription Drug User Fee Act (PDUFA), of September 12, 2004. Priority designation is granted to drugs that address unmet medical needs, offering a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease, according to FDA policies and procedures.

"We are looking forward to adding the fixed-dose combination of Viread and Emtriva to the Gilead Access Program," Dr. Martin said. "We believe this combination may be a particularly useful treatment option for resource-limited settings, given its convenient once-daily dosing and side-effect profile."

Program Details

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

Requests are reviewed by independent experts, and programs requesting drug are evaluated based on their ability to provide quality and sustainable patient care. Gilead takes appropriate steps to ensure that Viread shipments reach their intended destination.

Complete program information and request 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.

About Viread

Viread is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults. Assessment of adverse reactions, as described in the U.S. package insert, is based on one study of treatment-experienced patients and one study of treatment-naive patients. In Study 907, a total of 550 treatment-experienced patients received treatment with Viread 300 mg (n=368) or placebo (n=182) for 24 weeks followed by extended treatment with the drug. In Study 903, a total of 600 patients received treatment with Viread (n=299) or stavudine (n=301) in combination with lamivudine and efavirenz for 48 weeks. The most common adverse events in these patients were dizziness and mild to moderate gastrointestinal events, such as nausea, diarrhea, vomiting and flatulence.

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, though some cases have appeared in patients without identified risk factors. 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. In patients co-infected with HIV and the hepatitis B virus, exacerbations of hepatitis B have been reported in patients after discontinuation of Viread. Decreases in bone mineral density (BMD) at the lumbar spine and hip have been seen with the use of Viread. The clinical significance of changes in BMD and biochemical markers is unknown and follow-up is continuing to assess long-term impact.

About Emtriva

Emtriva is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults. Assessment of adverse events, as described in the U.S. package insert, is based on pooled data from two Phase III studies in which 571 treatment-naive and 440 treatment-experienced patients received Emtriva (n=580) or a comparator drug (n=431) for 48 weeks. The most common adverse events that occurred in patients receiving Emtriva were headache, diarrhea, nausea and rash, which were generally of mild to moderate severity. Approximately 1 percent of patients discontinued participation in the clinical studies due to these events. All adverse events were reported with similar frequency in Emtriva and control treatment groups with the exception of skin discoloration, which was reported with higher frequency in the Emtriva treated group. Skin discoloration, manifested by hyperpigmentation (excess pigmentation) on the palms and/or soles, was generally mild and asymptomatic. The mechanism and clinical significance are unknown. 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. Emtriva is not indicated for the treatment of chronic hepatitis B. Exacerbations of hepatitis B have been reported in patients infected with chronic hepatitis B after discontinuation of Emtriva.

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 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 risk that regulatory authorities in the United States may ultimately determine that the application for the fixed-dose co-formulation of Viread and Emtriva does not support approval and the risk that Viread will not show efficacy as a chemoprophylaxis to prevent infection. These risks and uncertainties could cause actual results to differ materially from those referred to in the forward-looking statements. Risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2003 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 and Emtriva are registered trademarks of Gilead Sciences, Inc.

For more information on the Gilead Access Program, please visit www.gileadaccess.com.

For complete prescribing information, please visit www.viread.com or www.emtriva.com.

For more information on Gilead Sciences, please visit the company's web site at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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