Gilead Sciences Broadens Entry Criteria for Tenofovir DF Expanded Access Program in the United States

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Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company has broadened the entry criteria for its U.S. expanded access program to provide its investigational agent tenofovir disoproxil fumarate (tenofovir DF) to patients with HIV infection who have failed prior antiretroviral therapy, regardless of their CD4 cell count or viral load. The expanded access program, initiated in January 2001, previously was limited to patients who met minimum viral load and maximum CD4 cell count criteria.

Tenofovir DF is an investigational reverse transcriptase inhibitor, dosed as a single tablet once daily, and is currently being evaluated in combination with other agents in multinational Phase III clinical studies as a potential treatment for HIV infection. Early access programs are ongoing in the United States, France and the United Kingdom, and Gilead expects to initiate additional programs in Germany, Italy, Spain, Canada and other countries as regulatory approvals are obtained. Tenofovir DF is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

Expanded access programs are part of an effort by regulatory agencies and the pharmaceutical industry to make investigational drugs available for the treatment of serious or life-threatening diseases during the later stages of clinical development.

"We are committed to providing tenofovir DF to those patients in need of new treatment options, and we are pleased to be able to expand the entry criteria for this important program," said James Rooney, MD, Vice President of Clinical Research and leader of the worldwide Tenofovir DF Early Access Program at Gilead.

Program Design
The U.S. program makes tenofovir DF available to patients 18 years of age and older with HIV infection who have failed treatment with at least two protease inhibitors (PIs) or one PI and one non-nucleoside analog reverse transcriptase inhibitor. Patients will receive tenofovir DF 300 mg dosed as a single tablet once daily. Gilead will advise physicians to include in a treatment regimen, in addition to tenofovir DF, at least one new antiretroviral agent that has not previously been administered to their patients. Patients may enroll in other programs providing investigational anti-HIV agents through compassionate use or expanded access programs provided they meet the eligibility criteria for those programs.

Physician Registration
For more information regarding the tenofovir DF early access program or to request registration materials, physicians in the United States may call 1-800-GILEAD-5 (1-800-445-3235) and those within Europe may call 33-1-44-90-34-46.

Tenofovir DF Phase III Program
To evaluate the safety and efficacy of tenofovir DF 300 mg in combination with other antiretroviral agents for the treatment of HIV infection, Gilead initiated Study 907, a 552-patient Phase III clinical trial, in November 1999 and completed enrollment in June 2000. Conducted in the United States, Europe and Australia, Study 907 is an ongoing intensification of therapy study of tenofovir DF in antiretroviral treatment-experienced patients.

Gilead initiated a second Phase III trial, Study 903, to evaluate tenofovir DF as a potential therapy for treatment-naive patients with HIV infection. This 48-week trial is designed to compare a treatment regimen of tenofovir DF, lamivudine (3TC) and efavirenz to a treatment regimen of stavudine (d4T), lamivudine 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.

Fast Track Designation
In November 2000, the U.S. FDA granted Fast Track designation to tenofovir DF, recognizing the product's potential to address an unmet medical need for a serious or life-threatening condition. Fast Track designation allows sponsors to initiate a rolling submission of a New Drug Application (NDA).

Gilead Sciences
Gilead Sciences, Inc., headquartered in Foster City, CA, 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 or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK and Dublin, Ireland and sales and marketing organizations 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. Such risks and uncertainties include risks related to regulatory approval of tenofovir DF, including unexpected results of ongoing clinical trials and unexpected requests from the FDA for additional data regarding tenofovir DF. 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.

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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 (1-800-445-3235).