Gilead Sciences Submits New Drug Application to U.S. FDA for Tenofovir DF for the Treatment of HIV Infection

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Gilead Sciences, Inc. (Nasdaq: GILD) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of tenofovir disoproxil fumarate (tenofovir DF), an investigational reverse transcriptase inhibitor in development for the treatment of human immunodeficiency virus (HIV) infection. Gilead anticipates FDA review and action within six months of this submission. The company also plans to submit its application for regulatory approval in the European Union in the near future.

Tenofovir DF is dosed as a single 300 mg tablet taken once daily and works by blocking reverse transcriptase, an enzyme crucial to the replication of HIV. Tenofovir DF is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

"Gilead has a heritage of developing products to treat challenging human diseases," said John C. Martin, Ph.D., President and Chief Executive Officer, Gilead Sciences. "Based on data from our pivotal studies, we believe that tenofovir DF has the potential to be an important new option for the treatment of HIV, and we are pleased to have reached this significant milestone in the development of the product."

New Treatment Options Needed
There are approximately 36 million people in the world living with HIV. Nine hundred thousand live in the United States alone, and 540,000 live in Western Europe. In the United States, 350,000 patients currently receive anti-HIV treatment regimens and an estimated 15,000 new patients begin treatment each year. As the HIV patient population grows and these patients live longer, the need for long-term disease management - achieved through safe, potent and convenient regimens - has intensified.

Early Access Program Initiated
In January, Gilead announced the initiation of an expanded access program to provide tenofovir DF to people with advanced HIV infection. Regulatory review has been concluded and programs are open for registration in the United States, France, Spain and the United Kingdom. Gilead expects to initiate early access programs in Germany, Italy, Canada and other countries as regulatory approvals are obtained.

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.

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. 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).