U.S. Food and Drug Administration Approves Gilead's Truvada® for Reducing the Risk of Acquiring HIV

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– First Agent Indicated for Uninfected Adults at High Risk of Acquiring HIV Through Sex –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 16, 2012-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved once-daily oral Truvada® (emtricitabine and tenofovir disoproxil fumarate), in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. Truvada is the first agent to be approved for HIV prevention in uninfected adults, a strategy called pre-exposure prophylaxis (PrEP). As part of the approval, Gilead worked with the FDA to develop a Risk Evaluation and Mitigation Strategy (REMS) to help ensure safe use of Truvada for PrEP as part of a comprehensive prevention strategy. Truvada was originally approved in 2004 in combination with other antiretroviral agents as a treatment of HIV-1 infection in adults and is currently the most-prescribed antiretroviral product in the United States.

"Today's decision is the culmination of almost 20 years of research involving investigators, academic and medical institutions, funding agencies and nearly 20,000 trial participants around the world, and Gilead is proud to have been a partner in this effort," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "This advancement in the field of HIV prevention was made possible due to the leadership and commitment of the FDA and the Department of Health and Human Services to reduce the number of new HIV infections in the United States and worldwide."

It is estimated that 1.2 million Americans are currently living with HIV, and, despite the availability of existing prevention tools such as condoms, the incidence rate has remained steady over the past two decades with approximately 50,000 new infections occurring each year. Nearly one-quarter (23 percent) of new HIV cases occur among women, and more than half (61 percent) occur among men who have sex with men (MSM). In particular, young African American MSM bear a heavy burden of the epidemic, with new HIV cases among this group increasing by nearly 50 percent between 2006 and 2009.

Data supporting the approval of Truvada for PrEP came primarily from two large placebo-controlled trials known as the Pre-Exposure Prophylaxis Initiative (iPrEx), sponsored by the U.S. National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation, and Partners PrEP, sponsored by the University of Washington and funded by the Bill and Melinda Gates Foundation. The iPrEx and Partners PrEP trials found that Truvada reduced the risk of acquiring HIV infection by 42 percent and 75 percent, respectively. Several other clinical studies also support the use of Truvada for HIV risk reduction.

"This approval is a major milestone in our 30-year fight against AIDS," said Robert M. Grant, MD, MPH, Betty Jean and Hiro Ogawa Endowed Investigator, Gladstone Institute of Virology and Immunology, University of California, San Francisco and lead investigator of the iPrEx trial. "The use of PrEP alongside routine HIV testing gives us a tremendous opportunity to reduce the rate of new HIV infections in this country and around the world."

Based on the iPrEx results, in January 2011 the Centers for Disease Control and Prevention (CDC) issued interim guidance on Truvada as PrEP among high-risk adult MSM. CDC is currently developing formal U.S. Public Health Service guidelines for the use of PrEP among both men and women, which will address procedures for HIV testing and health screening prior to PrEP initiation, as well as ongoing monitoring for cases of HIV infection that may occur despite PrEP use, possible drug resistance among those who become infected, side effects and clinical toxicities.

"The data clearly demonstrate that Truvada as pre-exposure prophylaxis is effective at reducing the risk of HIV infection acquired through sexual exposure," said Connie Celum, MD, MPH, Professor of Global Health and Medicine at the University of Washington and lead investigator of the Partners PrEP trial. "It is exciting to consider the potential impact of this new HIV prevention tool, which could contribute to significantly reducing new HIV infections as part of a combination HIV prevention strategy. Although the implementation of PrEP will bring challenges, they can be anticipated and systems developed to address these challenges. In particular, systems to provide comprehensive education and support to health care providers and people who use PrEP will be required to ensure appropriate and effective use of this potentially groundbreaking new HIV prevention intervention."

As part of the REMS developed by Gilead and FDA to ensure safe use of Truvada for PrEP, Gilead has developed FDA-

approved materials to educate and inform healthcare providers and uninfected individuals about Truvada for PrEP. These materials highlight the importance of strict adherence to the dosing regimen, emphasize that Truvada must be considered as only one part of a comprehensive prevention strategy to reduce the risk of HIV-1 infection and convey that Truvada for PrEP should only be used in individuals who are confirmed HIV negative and HIV-1 screening should be repeated at least every three months while taking Truvada for PrEP. Truvada for PrEP should not be initiated when clinical signs or symptoms consistent with acute HIV-1 infection are present.

As a separate measure to support the safe use of Truvada for PrEP, Gilead also will provide vouchers for free HIV testing and condoms, an opt-in service for regular reminders about HIV testing and subsidized HIV resistance testing for any individual who becomes HIV-positive while taking Truvada for PrEP.

In all studies of Truvada for PrEP, the most commonly reported side effects included headache, stomach discomfort and weight loss. The incidence and types of side effects were consistent with Truvada's safety and tolerability profile when used as an HIV treatment, which is supported by more than four million years of patient use. Overall, there have been nearly nine million patient years of experience with tenofovir-containing regimens.

Important Safety Information about Truvada:

WARNINGS: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including Viread®, a component of Truvada, in combination with other antiretrovirals.

Truvada is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Truvada have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued Truvada. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue Truvada. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Truvada used for a PrEP indication must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and periodically during use. Drug-resistant HIV-1 variants have been identified with use for Truvada for a PrEP indication following undetected acute HIV-1 infection. Do not initiate Truvada for a PrEP indication if signs and symptoms of acute HIV infection are present unless a negative infection status is confirmed.

Do not use Truvada for pre-exposure prophylaxis in individuals with unknown or positive HIV status. Truvada should be used in HIV-infected patients only in combination with other antiretroviral agents.

New onset or worsening of renal impairment may occur, including acute renal failure and Fanconi Syndrome. Creatinine clearance should be calculated prior to administering Truvada. Truvada for HIV-1 infection should not be used in patients with severe renal disease (CrCl < 30 mL/min), and routine monitoring of CrCl and serum phosphorous all patients at risk for renal impairment is recommended. Avoid administering concurrently with or with recent use of nephrotoxic drugs.

- **Do not use Truvada for** pre-exposure prophylaxis in individuals with a creatinine clearance (CrCl) below 60 mL/min. Re-assess risk and benefits of using Truvada for PrEP if a decrease in CrCL is observed during use for PrEP.

Decreases in Bone Mineral Density (BMD) may occur. Consider assessing BMD in individuals with a history of pathologic fracture or other risk factors for osteoporosis or bone loss. **Fat Redistribution** has also been observed in patients receiving antiretroviral therapy. **Immune Reconstitution Syndrome** may occur in HIV-1-infected patients. Autoimmune disorder may occur in the setting of Immune Reconstitution.

Truvada for a PrEP indication:

Comprehensive Management to Reduce the Risk of Acquiring HIV: Truvada for PrEP should only be used as part of a comprehensive prevention strategy that includes other prevention measures such as safer sex practices. A comprehensive prevention strategy includes consistent and correct use of condoms, the individual knowing both their and their partner's HIV status, getting regular testing for HIV and other sexually transmitted infections, and informing individuals about and supporting their efforts to reduce sexual risk behavior.

Use Truvada for PrEP to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV negative because HIV-1 resistance substitutions may emerge. HIV-1 negative status must be confirmed immediately prior to prescribing and regularly thereafter (at least every three months). Defer initiating Truvada for PrEP if clinical signs and symptoms of acute HIV-1 infection are present or if recent exposure (< 1 month) is suspected, or confirm HIV-1 negative status using a test approved by the FDA to aid diagnosis of acute or primary HIV-1 infection. While individuals are on TRUVADA for PrEP, discontinue if symptoms of acute infection develop after a potential HIV-1 exposure event until negative HIV-1 status can be confirmed using a test approved by the FDA to aid in the diagnosis of acute or primary HIV-1 infection.

Truvada for use with other antiretroviral agents to treat HIV-1 infection*:* Truvada should not be co-administered with any other antiretroviral agents for HIV that contain emtricitabine or tenofovir disoproxil fumarate, nor should it be co-administered with products containing lamivudine. Do not administer with Hepsera.

Common side effects reported during clinical studies with Truvada (in combination with efavirenz) include diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams and rash.

In clinical trials for Truvada for PrEP, the most common side effects associated with Truvada were headache, stomach discomfort and weight loss. Caution should be exercised when co-administering Truvada with didanosine, atazanavir and lopinavir/ritonavir due to the potential for toxicity.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

Forward-Looking Statement

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 risks that physicians and patients may be reluctant to use Truvada for HIV risk reduction. As a result, there may not be significant use of Truvada as a risk reduction tool. These risks, uncertainties and other factors 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 Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed 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.

U.S. full prescribing information for Truvada is available at www.Truvada.com.

Truvada is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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