FDA Advisory Committee Supports Approval of Gilead's Truvada® for Reducing the Risk of Acquiring HIV

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FOSTER CITY, Calif.--(BUSINESS WIRE)--May. 10, 2012-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the Antiviral Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted to support approval of once-daily oral Truvada® (emtricitabine and tenofovir disoproxil fumarate) to reduce the risk of HIV-1 infection among uninfected adults, an HIV prevention strategy called pre-exposure prophylaxis or PrEP. If the FDA decides to approve Truvada for PrEP, it would be the first agent indicated for uninfected individuals to reduce their risk of acquiring HIV.

In response to questions posed to the committee, members voted 19 to 3 in favor of approval for Truvada for PrEP in men who have sex with men; 19 to 2 (with 1 abstaining) in support of use in HIV-uninfected partners in serodiscordant couples; and 12 to 8 (with 2 abstaining) in other individuals at risk for acquiring HIV through sexual activity.

The recommendations of the Advisory Committee are not binding, but will be considered by the FDA as the agency completes its six-month priority review of Gilead's supplemental New Drug Application (sNDA) of Truvada for PrEP. Gilead submitted the sNDA on December 15, 2011 and the FDA has established a target review date under the Prescription Drug User Fee Act (PDUFA) of June 15, 2012.

The committee's positive recommendation followed presentations today of efficacy and safety data from several clinical studies of Truvada for PrEP, including two large placebo-controlled Phase 3 trials sponsored by the U.S. National Institutes of Health and the University of Washington, respectively. Several other clinical studies support the use of Truvada for HIV risk reduction.

Truvada was approved by the FDA in 2004 for the treatment of HIV-1 infection and is currently the most-prescribed antiretroviral treatment in the United States. Truvada is not indicated for HIV prevention.

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.

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

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. Decreases in bone mineral density, fat redistribution and immune reconstitution syndrome may also occur. 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. Caution should be exercised when co-administering Truvada with didanosine, atazanavir and lopinavir/ritonavir due 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 risk that the FDA may not approve Truvada for HIV-1 risk reduction, and any approval, if granted, may have significant limitations on its use. Additionally, even if approved, physicians may be reluctant to prescribe the product for HIV risk reduction, and payers may be reluctant to approve or provide reimbursement for the product 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 or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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