U.S. FDA Grants Priority Review for Truvada® for Reducing the Risk of Acquiring HIV Infection

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 13, 2012-- Gilead Sciences, Inc. (Nasdaq:GILD) announced today that the U.S. Food and Drug Administration (FDA) has accepted the supplemental New Drug Application (sNDA) and granted a six-month Priority Review for once-daily Truvada® (emtricitabine/tenofovir disoproxil fumarate) for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection among uninfected adults. 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.

The FDA grants priority review status to drug candidates that provide major advances in treatment or provide a treatment where no adequate therapy exists. Gilead submitted the Truvada for PrEP sNDA on December 15, 2011. The FDA has set a target review date for Truvada for PrEP under the Prescription Drug User Fee Act (PDUFA) of June 15, 2012. The agency has also indicated that Truvada for PrEP will be discussed at the FDA Antiviral Drugs Advisory Committee meeting scheduled in May.

If the sNDA is approved, Truvada would be the first agent indicated for uninfected individuals to reduce the risk of acquiring HIV. The sNDA is based on the results of two large placebo-controlled trials of Truvada as PrEP sponsored by the U.S. National Institutes of Health and the University of Washington. Several other clinical studies support the use of Truvada for HIV risk reduction.

Truvada is not currently indicated to reduce the risk of HIV infection.

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 September 30, 2011, 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.

Source: Gilead Sciences, Inc.

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