Gilead Initiates Phase 2 Clinical Trial Evaluating GS-7340, A Low-Dose Novel Prodrug of Tenofovir for the Treatment of HIV

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– Phase 2 Study Will Examine GS-7340 as Part of a New Once-Daily, Single-Tablet Regimen –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 24, 2012-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the initiation of a Phase 2 clinical trial evaluating GS-7340 for the treatment of HIV-1 infection in treatment-naïve adults. GS-7340 is a novel prodrug of tenofovir, the active agent in Viread® (tenofovir disoproxil fumarate). In previous studies, GS-7340 has demonstrated the ability to provide greater antiviral efficacy at a dose that is ten times lower than Viread.

"The advancement of GS-7340 into this Phase 2 study is an important milestone in Gilead's efforts to develop the next generation of best-in-class therapies for HIV," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Because it can be used once-daily at one-tenth the dose of Viread, which is a much lower dose compared to other currently available anti-HIV compounds, GS-7340 could enable the development of a new range of single-tablet regimens for HIV that optimize clinical efficacy, safety and tolerability for patients."

The Phase 2 study will evaluate GS-7340 as part of a once-daily, co-formulated single-tablet regimen that will also contain the boosting agent cobicistat, the integrase inhibitor elvitegravir, and Emtriva® (emtricitabine). The GS-7340-containing single-tablet regimen will be compared to Gilead's Quad single-tablet regimen, which contains Viread and Emtriva (as Truvada®), elvitegravir and cobicistat, and is currently under review for marketing approval by U.S. and European regulatory agencies.

Gilead plans to initiate a second Phase 2 trial for GS-7340 later in 2012 that will assess GS-7340 as part of another single-tablet regimen containing cobicistat, Emtriva and Tibotec Pharmaceuticals' protease inhibitor Prezista® (darunavir). Gilead announced an agreement with Tibotec to develop this single-tablet regimen on November 15, 2011.

Viread was approved for HIV treatment in 2001 and has accumulated more than 4.4 million patient years of clinical experience to date.

About the GS-7340 Phase 2 Study

The Phase 2 study is a randomized, double-blind 48-week clinical trial among HIV-1 infected adults with HIV RNA levels (viral load) greater than or equal to 5,000 copies/mL and CD4 cell counts greater than 50 cells/mm^3. A total of 150 patients will be randomized (2:1) to receive a once-daily tablet containing GS-7340 10 mg/cobicistat 150 mg/elvitegravir 150 mg/emtricitabine 200 mg (n=100) or the Quad (tenofovir disoproxil fumarate 300 mg/cobicistat 150 mg/elvitegravir 150 mg/emtricitabine 200 mg) (n=50). The HIV virus of participants must be sensitive to both tenofovir and emtricitabine, prior use of antiretrovirals is not allowed and participants must have adequate renal function (defined as an estimated glomerular filtration rate of greater than or equal to 70 mL/min, according to the Cockcroft-Gault formula).

The primary endpoint will be the proportion of patients with viral load less than 50 copies/mL at 24 weeks of treatment as determined by the FDA-defined snapshot analysis. Secondary endpoints will include the proportion of patients who achieve viral load of less than 50 copies/mL at 48 weeks of therapy, and change from baseline in HIV-1 RNA and in CD4+ cell count to Weeks 24 and 48. After week 48, patients will continue to take their blinded study drug until treatment assignments have been unblinded, at which point all will be given the option to participate in an open-label rollover extension and receive the GS-7340-based single-tablet regimen.

Additional information about the study can be found at www.clinicaltrials.gov.

About GS-7340

GS-7340 is a novel prodrug of tenofovir, the active agent in the company's HIV drug Viread. Like Viread, GS-7340 is a nucleotide reverse transcriptase inhibitor (NtRTI). Phase 2a dose-ranging studies have identified a dose that is ten times lower than Viread and provides greater antiviral efficacy. The smaller milligram size of GS-7340 may enable the development of new

fixed-dose combinations and single-tablet regimens for HIV therapy that are not feasible with Viread.

About Cobicistat

Cobicistat is a potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. Gilead is evaluating cobicistat in three separate pivotal Phase 3 studies, both as a stand-alone boosting agent for protease inhibitors, as well as part of the Quad regimen. Gilead has exclusive rights to develop cobicistat worldwide, except for Japan, where JT is licensed to develop and commercialize the product.

About Elvitegravir

As an integrase inhibitor, elvitegravir interferes with HIV replication by blocking the ability of the virus to integrate into the genetic material of human cells. Elvitegravir was licensed by Gilead from Japan Tobacco Inc. (JT) in March 2005. Under the terms of Gilead's agreement with JT, Gilead has exclusive rights to develop and commercialize elvitegravir in all countries of the world, excluding Japan, where JT retains rights.

About Quad

The Quad is a single-tablet regimen that contains elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate. In October 2011, Gilead submitted a New Drug Application to the U.S. FDA for the Quad for the treatment of HIV among treatment-naïve patients.

GS-7340, cobicistat, elvitegravir and the Quad are investigational products and their safety and efficacy have not yet been established.

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 risks related to our ability to enroll patients in the Phase 2 clinical trial of a single-tablet regimen containing elvitegravir, cobicistat, emtricitabine and GS-7340, our ability to initiate the Phase 2 trial of a single-tablet regiment containing cobicistat, emtricitabine, darunavir and GS-7340, the possibility of unfavorable results of this or other clinical trials involving GS-7340, the need to modify or delay the clinical trials or to perform additional trials and the risk of failing to obtain U.S. Food and Drug Administration and other regulatory body approvals for GS-7340 and single-tablet regimens containing GS-7340, including the Quad. As a result, GS-7340 may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of GS-7340 if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. 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 Viread is available at www.Viread.com.
U.S. full prescribing information for Truvada is available at www.Truvada.com.
U.S. full prescribing information for Emtriva is available at www.GileadHIV.com.
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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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