Gilead Announces Two-Year Data From Pivotal Phase 3 Study of Elvitegravir, an Integrase Inhibitor for HIV

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– Company to Submit U.S. Regulatory Filing for Elvitegravir in Second Quarter of 2012 –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 9, 2011-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced topline Phase 3 clinical trial results showing that elvitegravir, an integrase inhibitor being evaluated for the treatment of HIV-1 infection, was non-inferior to the integrase inhibitor raltegravir after two years (96 weeks) of therapy in treatment-experienced patients. Gilead plans to file for U.S. regulatory approval of elvitegravir in the second quarter of 2012.

"These positive two-year data indicate that elvitegravir has the potential to be an important new once-daily treatment option for people living with HIV who have developed resistance to other therapies," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences . "In addition, we are very excited about elvitegravir"s role as part of our new Quad single-tablet regimen, which is currently in U.S. regulatory review."

In the pivotal Phase 3 trial (Study 145), elvitegravir (150 mg or 85 mg) dosed once daily was compared to raltegravir (400 mg) dosed twice daily, each administered with a background regimen that included a ritonavir-boosted protease inhibitor (PI) and a second antiretroviral. After 96 weeks of treatment, 48 percent of patients receiving ritonavir-boosted elvitegravir achieved and maintained HIV RNA levels (viral load) less than 50 copies/mL, compared to 45 percent of patients receiving raltegravir, based on the Time to Loss of Virologic Response algorithm (TLOVR) (95 percent CI for the difference: -4.6 percent to 9.9 percent). Discontinuation rates due to adverse events, and safety and resistance profiles were comparable in both arms of the study. Gilead plans to submit these data for presentation to a scientific conference in 2012.

About the Elvitegravir Phase 3 Study

Study 145 was a double-blind, multicenter, randomized (1:1), active-controlled, 96-week clinical trial evaluating the non-inferiority of elvitegravir (n=351) versus raltegravir (n=351), administered with a ritonavir-boosted protease inhibitor and other agents in HIV-infected treatment-experienced adults with HIV RNA (viral load) greater than or equal to 1,000 copies/mL. Patients enrolled in the trial were required to have documented viral resistance and/or at least six months of treatment experience with two or more different classes of antiretrovirals prior to screening.

Trial participants received either once-daily elvitegravir (150 mg or 85 mg) or twice-daily raltegravir 400 mg. Patients' background regimens were based on the results of resistance testing and include a fully-active ritonavir-boosted protease inhibitor, and a second agent that was permitted to be a nucleoside or nucleotide reverse transcriptase inhibitor, etravirine, maraviroc or enfuvirtide. Due to known pharmacokinetic interactions, patients randomized to elvitegravir whose background protease inhibitor was either atazanavir or lopinavir received an 85 mg dose of elvitegravir.

In January 2011, Gilead announced that it would extend the blinded, randomized period of Study 145 from the originally planned 48 weeks to 96 weeks in order to obtain longer-term safety and efficacy data. Based on the achievement of the non-inferiority endpoint at 48 weeks, patients continued to receive the regimen to which they were randomized in a blinded fashion through 96 weeks. Secondary endpoints include various additional measures of the efficacy, safety and tolerability of the two treatment regimens.

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

About Elvitegravir

Integrase inhibitors interfere 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 contains elvitegravir, cobicistat (a pharmacoenhancing or "boosting" agent that enables elvitegravir once-daily dosing), and Truvada® (emtricitabine/tenofovir disoproxil fumarate). In October 2011, Gilead submitted a New Drug Application to the U.S. Food and Drug Administration for the Quad for the treatment of HIV.

Elvitegravir, cobicistat and the Quad are investigational products and have not yet been determined safe or efficacious in humans.

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 Gilead's plans to present the data at a scientific conference and file for regulatory approval of elvitegravir in the timelines currently anticipated and the possibility of unfavorable results from further clinical studies of elvitegravir. Further, Gilead may fail to obtain approvals for elvitegravir or the Quad from regulatory authorities and any marketing approval, if granted, may have significant limitations on its use. As a result, elvitegravir and the Quad may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of elvitegravir or the Quad if, for example, it believes commercialization will be difficult relative to other opportunities in its 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 Truvada is available at www.Truvada.com.

Truvada is a 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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