Phase III Clinical Trial of Gilead's Investigational Elvitegravir Meets 48-Week Primary Objective

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FOSTER CITY, Calif., Mar 23, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the Phase III clinical trial of its investigational antiretroviral agent elvitegravir, a novel oral integrase inhibitor being evaluated for the treatment of HIV-1 infection in treatment-experienced patients, met its primary objective. The primary endpoint of this study was non-inferiority at week 48 of elvitegravir, dosed once daily, compared to raltegravir, dosed twice daily, each administered with a background regimen that includes a ritonavir-boosted protease inhibitor (PI) and a second antiretroviral agent. Responses at 48 weeks of elvitegravir met the statistical criteria of non-inferiority as compared to raltegravir based on the proportion of subjects who achieved and maintained HIV RNA levels (viral load) of less than 50 copies/mL. Discontinuation rates due to adverse events were comparable in both arms of the study. Gilead plans to submit these data for presentation at a scientific conference later this year.

On January 10, 2011, Gilead announced an amendment to the design of this clinical trial, extending the blinded, randomized period of the study to up to 96 weeks to obtain longer term safety and efficacy data than originally planned. Based on the achievement of the non-inferiority endpoint, patients will continue to receive the regimen to which they were randomized in a blinded fashion.

Elvitegravir is also being studied as part of Gilead's investigational fixed-dose, single-tablet "Quad" regimen. The Quad contains four Gilead compounds in a fixed-dose, single-tablet: elvitegravir; cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels of certain HIV medicines; and Truvada$^{(R)}$ (emtricitabine/tenofovir disoproxil fumarate). The Quad is currently in Phase III testing. In addition, cobicistat is being evaluated as a stand-alone boosting agent for other antiretrovirals, in particular, protease inhibitors.

"We are very pleased to have achieved the primary endpoint in this clinical trial, as data from this study will support regulatory filings for elvitegravir as well as Gilead's investigational Quad pill," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "By analyzing these data now we will be in a better position to advance filings as quickly as possible once data from subsequent Phase III clinical trials in our Quad development program become available later this year."

About the Elvitegravir Phase III Study

Study 145 is a randomized, double-blind, 48-week clinical trial evaluating the non-inferiority of elvitegravir (n=351) versus raltegravir (n=351), each administered with a background regimen in HIV-infected treatment-experienced adults with HIV RNA (viral load) of greater than or equal to 1,000 copies/mL. Patients have documented viral resistance, as defined by International AIDS Society-USA guidelines, or at least six months of treatment experience with two or more different classes of antiretroviral agents prior to screening.

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

The primary endpoint analysis indicated that 59.0 percent of patients in the elvitegravir arm compared to 57.8 percent in the raltegravir arm (95% CI for the difference: -6.0% to +8.2%) achieved and maintained a viral load of less than 50 copies/mL through week 48. The predefined criterion for non-inferiority was a lower bound of a two sided 95% CI of -10 percent. The nature and frequency of Grade 3/4 adverse events and laboratory abnormalities were similar between the two arms.

The study is ongoing in a blinded fashion. 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 www.clinicaltrials.gov.

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

About Elvitegravir

Elvitegravir is an HIV integrase inhibitor. Unlike other classes of antiretroviral agents, 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 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.

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 related to completing the Phase III clinical studies of elvitegravir, cobicistat and the Quad in the currently anticipated timelines. In addition, we may obtain unfavorable results from these studies, may need to modify or delay our studies or to perform additional trials and we may fail to obtain approvals from the regulatory authorities. As a result, elvitegravir, cobicistat or the Quad may never be successfully commercialized. Further, Gilead may make a strategic decision to discontinue development of elvitegravir, cobicistat or the Quad 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 Annual Report on Form 10-K for the year ended December 31, 2010, 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.

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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