Gilead Initiates Phase III Clinical Trial of Elvitegravir, an Investigational Integrase Inhibitor for HIV

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-- Trial Will Assess Non-Inferiority of Once-Daily Elvitegravir Compared to Twice-Daily Raltegravir --

FOSTER CITY, Calif.--(BUSINESS WIRE)--July 22, 2008--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has begun enrolling patients in a Phase III clinical trial of its investigational antiretroviral agent elvitegravir (GS 9137), a novel oral integrase inhibitor that is being evaluated for the treatment of HIV-1 infection. The study is designed to assess the non-inferiority of ritonavir-boosted elvitegravir, dosed once daily, compared to raltegravir (Isentress(R)), another integrase inhibitor that is dosed twice daily. The study will enroll 700 HIV-infected, treatment-experienced patients at approximately 125 sites in the United States and Puerto Rico. A second Phase III study with a similar design involving 700 HIV-infected, treatment-experienced patients will be initiated later this year in Europe, Canada and Australia.

"Advancing novel compounds for the treatment of HIV/AIDS remains a key area of focus for Gilead, and we are very pleased that our integrase inhibitor, elvitegravir, continues to make progress with the initiation of this Phase III clinical trial," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "As HIV patients remain on therapy for longer periods of time, the development of resistance to existing classes of drug is a significant concern. Based on the results observed in our Phase II study of elvitegravir, we believe the compound may have the potential to play an important role for patients in need of new treatment options."

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.

About the Elvitegravir Phase III Study

The elvitegravir Phase III study is a randomized, double-blind, 48-week clinical trial that will assess the non-inferiority of ritonavir-boosted elvitegravir (n=350) versus raltegravir (n=350), 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 will 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. Patients who have previously taken an integrase inhibitor will be excluded.

Trial participants will receive either once-daily elvitegravir 150 mg or twice-daily raltegravir 400 mg. Patients' background regimens will be based on the results of resistance testing and will include a fully-active ritonavir-boosted protease inhibitor (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 will receive an 85 mg dose of elvitegravir.

The primary efficacy endpoint will be the proportion of subjects in both arms of the study who achieve and maintain confirmed viral load of less than 50 copies/mL through 48 weeks. Secondary endpoints will include various additional measures of the efficacy, safety and tolerability of the two treatment regimens.

About Elvitegravir

Elvitegravir, also known as GS 9137 or JTK 303, 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.

Elvitegravir is an investigational therapy and has not yet been determined safe or efficacious in humans.

About GS 9350

Because elvitegravir requires a boosting agent to allow for once-daily dosing, Gilead is currently developing a proprietary pharmacokinetic-enhancing compound, GS 9350, that may potentially be used in conjunction with elvitegravir. Gilead's goal is to develop and bring to market a pharmacokinetic enhancer that does not have HIV activity, can be dosed once daily, is in solid form and is stable at room temperature, such that it can be co-formulated with elvitegravir and Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) into a single tablet. A recently completed pilot formulation study has demonstrated that this can be achieved with GS 9350.

GS 9350 is currently being evaluated in a Phase I single and multiple dose-ranging clinical study. The study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of escalating single and multiple doses of GS 9350 in healthy volunteers.

GS 9350 is an investigational therapy and has 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 Australia.

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 clinical studies for elvitegravir and GS 9350 may not yield positive results, which may in turn impede the development of these compounds. 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, 2007 and its Quarterly Report on Form 10-Q for the first quarter of 2008, 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.gilead.com.

Truvada is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

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