Gilead's Investigational Antiretroviral Quad Regimen Meets 48-Week Primary Objective in Pivotal Phase 3 Clinical Study 102

August 15, 2011 8:31 AM ET

FOSTER CITY, Calif., Aug 15, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that a Phase 3 clinical trial (Study 102) of its investigational fixed-dose, single-tablet "Quad" regimen of elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate, being evaluated for HIV-1 infection in treatment-naïve patients, met its primary objective, which was non-inferiority at week 48 as compared to Atripla(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg). The primary endpoint analysis indicated that 88 percent of patients in the Quad arm compared to 84 percent in the Atripla (95% CI for the difference: -1.6% to 8.8%) achieved HIV RNA (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 -12 percent.

The mean 48-week increase in CD4 cell count from baseline was 239 cells/mm^3 in the Quad arm compared to 206 cells/mm^3 in the Atripla arm (p=0.009). The frequency of Grade 3-4 adverse events and laboratory abnormalities was similar between the Quad-treated and the Atripla-treated arms. 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 early next year.

The Quad contains four Gilead compounds in a complete once-daily, single-tablet regimen: elvitegravir, an investigational integrase inhibitor; cobicistat, an investigational pharmacoenhancing or "boosting" agent that increases blood levels of certain HIV medicines; and Truvada(R) (emtricitabine/tenofovir disoproxil fumarate). The Phase 3 clinical program for the Quad includes two studies (Studies 102 and 103) which are evaluating the Quad regimen versus a standard of care among HIV-1 infected antiretroviral treatment-naïve adults. The second pivotal Quad study (Study 103), a randomized, double-blind clinical trial comparing the efficacy, safety and tolerability of the Quad versus ritonavir-boosted atazanavir and Truvada, is ongoing, and results are expected later this quarter.

"Achieving non-inferiority to the current standard of care in HIV therapy is a major developmental milestone for our Quad regimen," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "We are very pleased with these results, which are in line with our expectations and allow us to begin preparations for a U.S. regulatory filing in the first quarter of 2012."

Cobicistat is also being evaluated as a stand-alone boosting agent for other antiretrovirals, in particular, the protease inhibitor atazanavir. Results from the Phase 3 clinical trial of cobicistat are expected in the fourth quarter of this year. Forty-eight week results from the Phase 3 trial of elvitegravir as a stand-alone agent were presented last month at the 6th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2011) in Rome, Italy.

About Study 102

Study 102 is a randomized, double-blind clinical trial comparing the efficacy, safety and tolerability of the Quad versus Atriplaover a 96-week period at 130 study sites in the United States and Puerto Rico. Eligible participants were HIV-infected treatment-naïve adults with HIV RNA levels greater than or equal to 5,000 copies/mL. Trial participants were randomized (1:1) to receive a once-daily tablet containing elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (n=348) or Atripla (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) (n=352).

The primary endpoint of the study is the proportion of patients achieving HIV RNA levels of less than 50 copies/mL at 48 weeks of treatment. Secondary objectives will evaluate the efficacy, safety and tolerability of the treatment regimens through 96 weeks of treatment.

The study is ongoing in a blinded fashion. After week 96, subjects will continue to take their blinded study drug until treatment assignments have been unblinded, at which point all subjects will be given the option to participate in an open-label rollover extension and receive the Quad single-tablet regimen.

Additional information about the study can be found at http://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 Cobicistat

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. In addition to studying the agent as part of an integrase-based fixed-dose regimen, Gilead is also examining cobicistat's potential stand-alone role in boosting commercially available HIV protease inhibitors, which are used in many HIV treatment regimens.

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 Gilead's anticipated timelines for submitting data from Study 102 for presentation at a scientific conference, obtaining results from Study 103, preparing for a U.S. regulatory filing for the Quad and obtaining results from the Phase 3 clinical trial of cobicistat. In addition, Gilead may obtain unfavorable results from its elvitegravir, cobicistat and Quad studies, may need to modify or delay its studies or to perform additional trials and may fail to obtain approvals from the U.S. Food and Drug Administration and other 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, 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 year ended June 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.

Truvada is a registered trademark of Gilead Sciences, Inc.
Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

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.

Gilead Sciences, Inc.
Susan Hubbard, 650-522-5715 (Investors)
Erin Rau, 650-522-5635 (Media)