Gilead's Boosting Agent, Cobicistat, Meets 48-Week Primary Objective in Pivotal Phase 3 Study

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– Cobicistat is a Component of Company's Quad Single-Tablet Regimen, Currently Being Reviewed by U.S. FDA –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 5, 2011-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that a Phase 3 clinical trial (Study 114) of its pharmacoenhancing or "boosting" agent cobicistat, which increases blood levels of certain HIV medicines to allow for one pill once-daily dosing, met its 48-week primary objective of non-inferiority to ritonavir.

The Study 114 primary endpoint analysis indicated that after 48 weeks of treatment, 85 percent of patients taking a regimen of cobicistat-boosted atazanavir (a protease inhibitor) plus Truvada® (emtricitabine and tenofovir disoproxil fumarate) achieved HIV RNA (viral load) of less than 50 copies/mL, compared to 87 percent of patients taking ritonavir-boosted atazanavir plus Truvada (95 percent CI for the difference: -7.4 percent to 3.0 percent). The predefined criterion for non-inferiority was a lower bound of a two-sided 95 percent CI of -12 percent. Discontinuation rates due to adverse events were 7.3 percent and 7.2 percent in the cobicistat and ritonavir arms of the study, respectively. Gilead plans to submit these data for presentation to a scientific conference in 2012.

"The majority of today's protease-based HIV treatment regimens depend on a boosting agent for optimal efficacy," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "These results demonstrate that cobicistat may provide patients taking protease-based regimens with a much-needed alternative boosting agent. We are now working toward a second quarter 2012 U.S. regulatory filing for cobicistat."

Small increases in serum creatinine (a value used to estimate kidney function) with resulting decreases in estimated creatinine clearance (by Cockroft-Gault) were observed in this study. At 48 weeks, the mean increase from baseline in serum creatinine was 0.14 mg/dL among cobicistat patients and 0.09 mg/dL among ritonavir patients. The increase in serum creatinine with cobicistat occurs within days of drug initiation and is reversible with values returning to baseline within days after cessation of cobicistat. Results from a separate Phase 1 renal study in healthy volunteers indicate that cobicistat does not affect actual glomerular filtration rates (GFR) as assessed by iohexol clearance (a true measure of kidney function).

About the Cobicistat Phase 3 Study

Study 114 is a randomized, double-blind, Phase 3 clinical trial comparing the efficacy and safety of cobicistat-boosted atazanavir versus ritonavir-boosted atazanavir, each administered with Truvada, over a 96-week period at more than 200 study sites in North America, South America, Europe and Asia Pacific. 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 regimen of cobicistat 150 mg, atazanavir 300 mg and Truvada (n=344) or ritonavir 100 mg, atazanavir 300 mg and Truvada (n=348).

The primary endpoint of the study was the proportion of patients achieving HIV RNA levels of less than 50 copies/mL at 48 weeks of treatment, as determined by the FDA-defined snapshot analysis. Secondary objectives will evaluate the efficacy, safety and tolerability of the treatment regimens through 96 weeks of treatment. Additional information about the study can be found at www.clinicaltrials.gov.

About Cobicistat

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. Cobicistat is an investigational product and its 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 Gilead's plans to present the data at a scientific conference and file for regulatory approval of cobicistat in the timelines currently anticipated and the possibility of unfavorable results from further clinical studies of cobicistat. Further, Gilead may fail to obtain approvals from regulatory authorities and any marketing approval, if granted, may have significant limitations on its use. As a result, cobicistat may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of cobicistat 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 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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