Gilead Amends Study Design for Ongoing Hepatitis C Clinical Trials That Include GS 9190, Pegylated Interferon and Ribavirin, and Another Direct-Acting Antiviral Agent

September 4, 2011 11:01 AM ET

Change Does Not Affect Ongoing "All Oral" Clinical Trials Evaluating Multiple Direct-Acting Antivirals in Combination

FOSTER CITY, Calif., Sep 04, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that, in consultation with the U.S. Food and Drug Administration (FDA), the company will amend the design of ongoing clinical trials to discontinue dosing of GS 9190 in hepatitis C-infected patients who are receiving that compound in combination with pegylated interferon and ribavirin, and another direct-acting antiviral agent.

This decision follows reports of two serious adverse events in patients enrolled in two separate studies who were receiving a four-drug regimen of GS 9190, an investigational HCV NS5B polymerase inhibitor; pegylated interferon and ribavirin; and one of two protease inhibitors (GS 9451 in one study and GS 9256 in the second study). Patient safety is Gilead's top priority, and the company will therefore immediately halt the dosing of GS 9190 in patients receiving this combination of medications.

Pegylated interferon in combination with ribavirin is currently part of the standard of care treatment for patients with chronic hepatitis C. Because of the side effects that can be associated with interferon, Gilead is working to develop multiple oral antivirals that, when used in combination, may be able to reduce or eliminate the need for interferon.

Gilead does not anticipate any impact on the timelines for or goals of its planned and ongoing clinical studies evaluating an "all oral" regimen for the treatment of chronic hepatitis C. Studies that include GS 9190 but do not include pegylated interferon will continue as planned. Similarly, studies that include the combination of GS 9451 (an investigational protease inhibitor), GS 5885 (an investigational NS5A) and pegylated interferon and ribavirin will continue.

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 that could cause actual results to differ materially from those referred to in the forward-looking statements, including the risk that further analysis of the laboratory abnormalities, adverse events and other data obtained to date may not support the continued development of GS 9190 and the risk that further clinical testing of Gilead's developmental compounds (including GS 9190, GS 9451, GS 5885 and GS 9256) and all oral regimens containing such compounds result in laboratory abnormalities, adverse events and other clinical data that may not support the continued development of such compounds or regimens. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter 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.

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.

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