Gilead Announces Early Sustained Virologic Response Rates for GS-7977 Plus Ribavirin in Genotype 1 Treatment-Naïve Hepatitis C Patients

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- Interim Results Reported from ELECTRON and QUANTUM Studies -

BARCELONA, Spain, Apr 19, 2012 (BUSINESS WIRE) --Gilead Sciences, Inc. (Nasdaq: GILD) today announced interim data from the Phase 2 ELECTRON study examining the investigational once-daily oral agent GS-7977 plus ribavirin (RBV) in treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection. Of the 25 patients who completed 12 weeks of treatment with the GS-7977-based regimen, 88 percent of patients (n=22/25) remained HCV RNA undetectable four weeks after completion of treatment. Three patients experienced viral relapse. These findings are being presented this week during a poster session (Poster #1113) at the 47th Annual Meeting of the European Association for the Study of the Liver (International Liver Congress 2012) in Barcelona, Spain.

"These preliminary results suggest that 12 weeks of therapy with once-daily oral GS-7977 and ribavirin may be enough to cure hepatitis C in many genotype 1 patients, including those who are currently not candidates to receive interferon," said Professor Edward Gane, MD, Deputy Director and Hepatologist, New Zealand Liver Transplant Unit, Auckland City Hospital in New Zealand, and principal investigator of the ELECTRON study. "Further investigation of GS-7977 in a variety of patient populations and combinations will be important in assessing the drug's potential as part of an all-oral regimen for hepatitis C."

Results from three additional arms of the ELECTRON study examining GS-7977-based therapy in various patient populations are also being presented this week at the International Liver Congress. These include null responder genotype 1 patients, and genotype 2 and genotype 3 patients, both treatment-naïve and prior non-responders.

Overall, GS-7977 was well tolerated and exhibited a favorable safety profile. No patients experienced viral rebound during treatment. No patients discontinued therapy due to an adverse event. The most common adverse events were fatigue, dizziness and headache, and two grade 3/4 laboratory abnormalities were reported.

Gilead today also announced interim results from a second Phase 2 trial (QUANTUM) examining a 12- and 24-week duration of GS-7977 plus RBV in treatment-naïve patients. Twenty-five patients were randomized to the 12-week treatment arm: 19 genotype 1 patients; four genotype 3 patients; and two genotype 2 patients. Two genotype 1 patients discontinued therapy prematurely during the 12-week treatment period. At the four-week post-treatment time period, data were available for 17 genotype 1 patients. Of these, 10/17 (59 percent) remained HCV RNA undetectable. Seven patients (41 percent) experienced viral relapse. Additionally, seven of the patients who have reached the eight week post-treatment time period, and who achieved SVR4, remain HCV RNA undetectable.

The overall safety and efficacy profile of GS-7977 was consistent with that seen in ELECTRON. No patients experienced viral rebound while on treatment and no patients discontinued therapy due to an adverse event.

Eleven of the 25 patients (44 percent) in ELECTRON and three of 19 patients (16 percent) in QUANTUM had the IL28B C/C genetic polymorphism. Each of the three patients who relapsed in the ELECTRON study had a different IL28B polymorphism (C/C, C/T or T/T). The seven patients who relapsed in the QUANTUM study either had IL28B C/T (n=4) or IL28B T/T (n=3) genetic polymorphisms. Patients in both studies will continue to be observed to determine sustained virologic response rates at weeks 12 and 24 of follow-up (SVR12 and SVR24).

"The early results from these studies confirm that GS-7977 has the potential to become the cornerstone of an efficacious, all-oral combination regimen for many patients with chronic hepatitis C infection," said John McHutchison, MD, Senior Vice President, Liver Disease Therapeutics, Gilead Sciences. "We look forward to more data unfolding as our trials progress and we expect to initiate additional studies with GS-7977 in combination with other oral antivirals in our pipeline in the coming months. Our goal is to develop a short, simple, safe and effective single tablet regimen for HCV patients throughout the world."

About ELECTRON

ELECTRON is an ongoing Phase 2 randomized open-label clinical study evaluating GS-7977 for the treatment of chronic HCV

infection. The primary endpoint of the trial is the safety and tolerability of GS-7977 400 mg once-daily for 8 or 12 weeks, with and without RBV and/or Peg-IFN in HCV patients with genotypes 1, 2 or 3. Study populations include treatment-naïve non-cirrhotic patients and those who have failed prior interferon based therapies or "null" responders.

About QUANTUM

QUANTUM is a Phase 2 randomized double-blind placebo-controlled clinical study evaluating GS-7977 for the treatment of chronic HCV infection. The current active arms of the trial are examining GS-7977 400 mg once-daily plus RBV for 12 or 24 weeks in cirrhotic and non-cirrhotic treatment-naïve HCV patients with genotypes 1, 2 and 3. The results announced today are for the cohort of patients who have received and completed 12 weeks of therapy with GS-7977 plus RBV (n=25).

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 the possibility that the proportion of patients who maintain a sustained virologic response 12 and 24 weeks post-treatment will not be as favorable as the sustained virologic response rates reported in this press release and the possibility of unfavorable results from additional arms of the ELECTRON and QUANTUM studies and subsequent clinical trials involving GS-7977 and RBV. As a result, GS-7977, including in combination with other oral antivirals in Gilead's pipeline, may never be successfully commercialized. Further, Gilead may make a strategic decision to discontinue development of the compounds if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. In addition, Gilead may be unable to develop an all-oral antiviral regimen for HCV genotype 1 patients or a pangenotypic regimen for all HCV patients. 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, 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.

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