Gilead's Sofosbuvir for Hepatitis C Meets Primary Endpoint in Fourth Pivotal Phase 3 Study

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-- Initial Regulatory Filings Planned for Q2 2013 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 19, 2013-- Gilead Sciences (Nasdaq:GILD) today announced topline results from the Phase 3 FUSION study evaluating 12- and 16-week courses of therapy with the once-daily nucleotide sofosbuvir plus ribavirin (RBV) in treatment-experienced patients with genotype 2 or 3 chronic hepatitis C virus (HCV) infection who failed prior treatment. The study met its primary efficacy endpoint of superiority compared to a predefined historic control sustained virologic response (SVR) rate of 25 percent. In FUSION, 50 percent of patients (n=50/100) in the 12-week arm and 73 percent of patients (n=69/95) in the 16-week arm achieved SVR12 ($p<0.001$ for both arms).

"This study demonstrates that all-oral therapy with sofosbuvir provides significant efficacy among difficult-to-treat hepatitis C patients who could not be cured by prior regimens containing pegylated interferon and now have limited treatment options," said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer. "With positive results from all four Phase 3 trials now in hand, Gilead is on track to meet its goal of filing regulatory applications in the United States and Europe in the second quarter."

In the FUSION study, HCV genotype 2 or 3 patients who failed prior interferon-based therapy were randomized (1:1) to receive either a 12-week (n=103) or 16-week (n=98) course of sofosbuvir 400 mg once daily plus RBV (1,000 or 1,200 mg/day). Sixty-three percent of patients were infected with genotype 3. In the 12-week arm, SVR12 rates were 86 percent among genotype 2 and 30 percent among genotype 3 patients. In the 16-week arm, SVR12 rates were 94 percent among genotype 2 and 62 percent among genotype 3 patients. Among the 34 percent of FUSION participants who had compensated cirrhosis at baseline, 31 percent achieved SVR12 in the 12-week arm, and 66 percent achieved SVR12 in the 16-week arm. All patients in the study became HCV negative on treatment, and relapse accounted for all virologic failures.

No patients discontinued sofosbuvir or RBV due to adverse events. The most common adverse events reported in ≥15 percent of patients in the study were fatigue, headache, insomnia and nausea.

Results from all four pivotal Phase 3 studies of sofosbuvir – FUSION, POSITRON, FISSION and NEUTRINO – will support the initial regulatory filing for sofosbuvir as part of all-oral therapy with RBV among genotype 2 and 3 treatment-naïve, treatment-experienced and interferon-intolerant HCV patients, and for sofosbuvir in combination with RBV and pegylated interferon among treatment-naïve patients with genotypes 1, 4, 5 and 6.

Full results from these studies will be presented at a future scientific conference. Additional information about these and other ongoing clinical studies of sofosbuvir can be found at www.clinicaltrials.gov. Sofosbuvir 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 the possibility that the proportion of patients who maintain a sustained virologic response with longer follow up will not be as favorable as the sustained virologic response rates reported in this press release, and the possibility of unfavorable results from other clinical trials involving sofosbuvir. As a result, sofosbuvir may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of the compound if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. Further, Gilead may be unable to file for regulatory approval of sofosbuvir in the currently anticipated timelines or at all. If marketing approval is granted for this product, there may be significant limitations on its use. 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, 2012, 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, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

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