Gilead Announces Sustained Virologic Response Rate of 78% From Phase 3 Study of Sofosbuvir for Genotype 2/3 Hepatitis C Infected Patients

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-- POSITRON Demonstrates Efficacy of a 12-Week All-Oral Regimen of Sofosbuvir Plus Ribavirin for Chronic Hepatitis C Patients who are Unable or Unwilling to Take Interferon --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 27, 2012-- Gilead Sciences (Nasdaq:GILD) today announced topline results from the Phase 3 POSITRON study examining a 12-week course of once-daily sofosbuvir plus ribavirin (RBV) in patients with genotype 2 or 3 chronic hepatitis C virus (HCV) infection who are not candidates to take interferon (IFN). The study found that 78 percent of patients (n=161/207) remained HCV RNA undetectable 12 weeks after completing therapy (SVR12). The safety profile of sofosbuvir was similar to that observed in previous studies, and there were few treatment discontinuations due to adverse events.

POSITRON is the first of three Phase 3 studies to be completed that are evaluating sofosbuvir therapy in HCV genotype 2 or 3 infected patient populations.

“Achieving a sustained virologic response in three quarters of patients is an impressive result for a sofosbuvir-based, all-oral treatment in a group of individuals for which no suitable alternative therapy exists. These patients by definition had previously declined interferon-based therapy, were ineligible to receive interferon, or were interferon intolerant,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer, Gilead Sciences. “We look forward to sharing data from additional Phase 3 studies in early 2013, and expect to submit our first regulatory filings for sofosbuvir by mid-2013.”

In POSITRON, HCV genotype 2 or 3 patients who were interferon intolerant, interferon ineligible or unwilling to take interferon were randomized (3:1) to receive 12 weeks of either sofosbuvir 400 mg once daily plus weight-based RBV twice daily (n=207) or matching placebo (n=71). Of the 207 patients randomized to the sofosbuvir/RBV arm, 15 percent had compensated cirrhosis (more advanced liver disease) and 53 percent were infected with genotype 2. SVR12 rates were 93 percent in genotype 2 and 61 percent in genotype 3. In the small percentage of patients with cirrhosis at baseline who received sofosbuvir/RBV, 61 percent achieved SVR12. All patients receiving sofosbuvir/RBV became HCV RNA negative on treatment and relapse accounted for all virologic failures. No patient in the placebo group achieved an SVR12. The most common adverse events reported in greater than 10 percent of patients in the study were fatigue, nausea, headache, insomnia, pruritis and anemia.

Full data from the study will be submitted for presentation at a future scientific conference.

The Phase 3 clinical trial program for sofosbuvir includes two additional studies evaluating 12 and 16 weeks of therapy with sofosbuvir plus RBV in HCV genotype 2 and 3 infected patients. A fourth Phase 3 clinical trial is evaluating sofosbuvir combined with RBV and peg-IFN among patients with HCV genotypes 1, 4, 5 and 6. Pending the results, these studies will support initial regulatory filings in mid-2013 for an all-oral therapy with sofosbuvir plus RBV among genotype 2/3 treatment-naïve, treatment-experienced and interferon-intolerant patients, and for sofosbuvir in combination with RBV and peg-IFN among treatment-naïve patients with HCV genotypes 1, 4, 5 and 6.

About Sofosbuvir

Sofosbuvir (formerly referred to as GS-7977) is a once-daily nucleotide analog polymerase inhibitor for the treatment of HCV infection. Sofosbuvir is being evaluated as part of multiple therapeutic regimens, including the programs outlined above in combination with RBV and peg-IFN. Additionally, sofosbuvir is being studied as a once-daily fixed-dose combination containing sofosbuvir and the NS5A inhibitor GS-5885, with the added goal of creating a potent, tolerable and convenient all-oral treatment for genotype 1 infected HCV patients that may eliminate the need for interferon and/or RBV.

Sofosbuvir and GS-5885 are investigational products and their 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 additional clinical trials involving sofosbuvir and the fixed-dose combination of sofosbuvir and GS-5885. As a result, sofosbuvir and GS-5885 as single agents or as a fixed-dose combination may never be successfully commercialized. Further, Gilead may make a strategic decision to discontinue development of the compounds or the fixed-dose combination regimen if, for example, Gilead 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, 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.

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