Gilead Announces Sustained Virologic Response Rates from Two Phase 3 Studies of Sofosbuvir for Hepatitis C

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-- FISSION and NEUTRINO Studies Both Meet Primary Endpoints and Will Support Regulatory Filing for Sofosbuvir --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 4, 2013-- Gilead Sciences (Nasdaq:GILD) today announced topline results from two Phase 3 studies, FISSION and NEUTRINO, evaluating a 12-week course of the once-daily nucleotide sofosbuvir in combination with ribavirin (FISSION) and in combination with ribavirin and pegylated interferon (NEUTRINO) among treatment-naïve patients with chronic hepatitis C virus (HCV) infection.

In the FISSION study, patients with genotype 2 or 3 HCV infection were randomized to receive either a 12-week course of sofosbuvir plus ribavirin (RBV) or standard of care with 24 weeks of pegylated interferon alfa-2a (peg-IFN) plus RBV. The study met its primary efficacy endpoint of non-inferiority of sofosbuvir plus RBV to peg-IFN plus RBV, with 67 percent (170/253) of patients achieving a sustained virologic response (SVR) in the sofosbuvir plus RBV treatment group versus 67 percent (162/243) in the peg-IFN plus RBV treatment group (95 percent CI for the difference: -7.5 to +8.0 percent for sofosbuvir plus RBV versus peg-IFN plus RBV; predefined criterion for non-inferiority was a lower bound of a two sided 95 percent CI of -15 percent). All common adverse events (≥10 percent in any group) occurred more frequently in subjects receiving peg-IFN and RBV as compared to sofosbuvir and RBV. The most common adverse events in the sofosbuvir plus RBV arm occurring in ≥10 percent of the patients were fatigue, headache, nausea, insomnia and dizziness.

In the NEUTRINO study, patients with genotype 1, 4, 5 or 6 HCV infection were treated with a 12-week course of sofosbuvir, RBV and peg-IFN. This study met its primary efficacy endpoint of superiority compared to a predefined historic control SVR rate of 60 percent with 90 percent (295/327) of patients achieving SVR12 after completing therapy (P<0.001).

In the NEUTRINO study the most common adverse events that occurred in ≥20 percent of patients were fatigue, headache, nausea, insomnia and anemia.

“These data support the favorable clinical profile of sofosbuvir as the backbone of a potent, safe and well-tolerated treatment regimen that is effective across a broad range of HCV patient genotypes,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer, Gilead Sciences. “The sofosbuvir regimens in these trials allowed us to shorten the duration of effective hepatitis C therapy to just 12 weeks for treatment-naïve patients with genotypes 1 through 6.”

About FISSION

In FISSION, treatment-naïve HCV genotype 2 and 3 patients were randomized (1:1) to receive either 12 weeks of sofosbuvir 400 mg once daily plus RBV (1,000 or 1,200 mg/day) (n=256) or 24 weeks of peg-IFN (180 µg/week) plus RBV (800 mg/day) (n=243). Overall, 20 percent of patients had compensated cirrhosis (advanced liver disease) and 72 percent had genotype 3 infection. The SVR12 rates in patients receiving sofosbuvir plus RBV were 97 percent for genotype 2 patients and 56 percent for genotype 3 patients. The SVR12 rates in patients receiving peg-IFN plus RBV in this study were 78 percent for genotype 2 patients and 63 percent for genotype 3 patients. Among patients with cirrhosis at baseline who received sofosbuvir/RBV, 47 percent achieved SVR12; 38 percent of cirrhotics who received peg-IFN plus RBV achieved SVR12.

With the exception of one patient who was non-compliant, all patients in the sofosbuvir/RBV arm became HCV negative on treatment and relapse accounted for the virologic failures.

Three patients (1 percent) receiving sofosbuvir discontinued treatment due to adverse events compared to 26 patients (11 percent) receiving peg-IFN/RBV.

About NEUTRINO

In NEUTRINO, 327 treatment-naïve HCV genotype 1, 4, 5 and 6 patients were treated for 12 weeks with sofosbuvir 400 mg once daily in combination with RBV (1,000 or 1,200 mg/day) and peg-IFN (180 µg/week). Seventeen percent of patients had

compensated cirrhosis and 89 percent were infected with genotype 1. Among genotype 1 patients, 89 percent achieved SVR12. Of the 35 patients with genotypes 4, 5 or 6, 97 percent achieved SVR12. Among patients with cirrhosis at baseline, 80 percent achieved SVR12. All patients in this study became HCV RNA negative on treatment and relapse accounted for all virologic failures.

Five patients (2 percent) receiving sofosbuvir in combination with peg-IFN and RBV discontinued treatment due to adverse events.

FISSION, NEUTRINO, POSITRON and FUSION are the pivotal Phase 3 studies designed to support an initial regulatory filing for sofosbuvir as part of all-oral therapy with RBV for genotype 2 and 3 treatment-naïve, treatment-experienced and interferon-intolerant HCV patients, and for sofosbuvir in combination with RBV and peg-IFN for genotype 1, 4, 5 and 6 treatment-naïve patients. Topline results from the POSITRON study were announced in November 2012, and topline results from the last Phase 3 study, FUSION, are anticipated later this quarter. Full results from all four studies will be presented at a future scientific conference.

Additional information about these and other ongoing clinical studies 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 in the FISSION and NEUTRINO trials will not maintain SVR with longer follow up as favorable as the SVR12 rates reported in this press release. In addition, there is the possibility of unfavorable results from additional clinical trials involving sofosbuvir, including the FUSION trial. Further, we may not release topline results from the FUSION study or file for regulatory approval of sofosbuvir in the timelines currently contemplated. As a result, sofosbuvir may never be successfully commercialized. Further, 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. 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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