Gilead Announces Sustained Virologic Response Data for 12-Week Regimen of GS-7977 Plus Pegylated Interferon and Ribavirin in Genotype 1 Hepatitis C Patients

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- ATOMIC Data Demonstrate High Cure Rates in Genotype 1 Patients With 12 Weeks of Treatment -

BARCELONA, Spain, Apr 19, 2012 (BUSINESS WIRE) --Gilead Sciences, Inc. (Nasdaq:GILD) today announced interim data from a Phase 2 trial (ATOMIC) examining a 12-week course of treatment with the once-daily nucleotide GS-7977 plus pegylated interferon (Peg-IFN) and ribavirin (RBV) in treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection. The study found that 90 percent of patients (n=47/52, missing data equals failure analysis) achieved a 12-week sustained virologic response (SVR12), defined as maintaining undetectable viral load (HCV RNA <25 IU/mL) 12 weeks after the completion of therapy. These findings will be presented today during an oral session at the 47th Annual Meeting of the European Association for the Study of the Liver (International Liver Congress 2012) in Barcelona, Spain.

"These data suggest that this GS-7977-based regimen could offer most patients with genotype 1 a simple, short, three-month course of treatment with very high cure rates," said Kris Kowdley, MD, Director of the Liver Center of Excellence at the Virginia Mason Medical Center in Seattle and the study's principal investigator. "An all-oral regimen for HCV remains the ultimate treatment goal. In the interim, these results suggest that we may soon be able to end the complex process of response-guided HCV therapy and shorten the duration of treatment, which would be a significant advance for patients and for physicians who manage their care."

In this study, 52 patients were randomized to the 12-week treatment arm. One patient was lost to follow up during the course of treatment. At the end of treatment, 51/51 patients (100 percent) were HCV RNA undetectable. At the 12-week, post-treatment time period, data were available for 50/51 patients, as one patient was lost to follow up during the post-treatment time period. Of the 50 patients, 47 (94 percent) remained HCV RNA undetectable. Three patients experienced viral relapse after the end of treatment.

Overall, GS-7977 was well tolerated. The frequency and severity of adverse events were consistent with the historical safety profile of Peg-IFN and RBV and included fatigue, headache, nausea, chills and insomnia.

About ATOMIC

ATOMIC is an ongoing Phase 2 randomized open-label clinical trial evaluating the efficacy, safety and tolerability of a regimen containing GS-7977 (400 mg once daily), Peg-IFN (180 ug weekly injection) and RBV (500 mg twice daily) for the treatment of chronic HCV infection in treatment-naïve patients. Patients with genotype 1 HCV (n=316) who were non-cirrhotic and had HCV RNA of at least 50,000 IU/mL were randomized (1:2:3) to receive the regimen for 12 weeks (n=52), 24 weeks (n=109) or 12 weeks followed by re-randomization (1:1) to receive an additional 12 weeks of either GS-7977 alone or GS-7977 plus RBV (n=155). Additionally, 16 patients with HCV genotypes 4 and 6 received the 24-week regimen of GS-7977, Peg-IFN and RBV.

Four-week response rates following completion of therapy from two additional arms of ATOMIC also were presented at the International Liver Congress. Patients in all arms of the study will be followed to determine their 12- and 24-week sustained virologic response rates.

Additional information about the study can be found at www.clinicaltrials.gov. GS-7977 is an investigational product and its safety and efficacy has 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 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 ATOMIC study and subsequent clinical trials involving GS-7977 plus Peg-IFN and RBV. As a result, GS-7977 may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of GS-7977 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. Further, 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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