Gilead Announces Phase 2 Data for Investigational All-Oral Regimen of Sofosbuvir Plus GS-5816 for the Treatment of Chronic Hepatitis C

November 11, 2014 8:01 AM ET

-- Once-Daily Combination Achieves High SVR12 Rates Across Multiple HCV Genotypes --

BOSTON--(BUSINESS WIRE)--Nov. 11, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced data from three Phase 2 open-label studies evaluating the safety and efficacy of an investigational all-oral pan-genotypic regimen containing the nucleotide analog polymerase inhibitor sofosbuvir (SOF), approved as Sovaldi® by the U.S. Food and Drug Administration in December 2013, and the investigational NS5A inhibitor GS-5816 for the treatment of chronic hepatitis C virus (HCV) infection. These data are being presented this week at the 65th Annual Meeting of the American Association for the Study of Liver Diseases (The Liver Meeting® 2014) in Boston.

All three studies evaluated SOF 400 mg plus GS-5816 25 or 100 mg, with and without ribavirin (RBV), for eight or 12 weeks. Rates of sustained virologic response (SVR12) ranged from 88 percent to 100 percent among those receiving SOF plus GS-5816 100 mg for 12 weeks – the regimen selected for Phase 3 studies. Patients who achieve SVR12 are considered cured of HCV infection.

“There continues to be a need for simple, interferon- and ribavirin-free treatment regimens that are effective for all hepatitis C patients, regardless of genotype,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer, Gilead Sciences. “These data demonstrate the high efficacy and tolerability of sofosbuvir plus GS-5816 among patients with varying genotypes and disease progression and we look forward to providing Phase 3 data on the combination across all six genotypes.”

The first study, GS-US-342-0109 (Oral #197), evaluated 12 weeks of SOF plus GS-5816 with and without RBV in treatment-experienced genotype 1 and 3 patients with and without cirrhosis. The genotype 1 patients had all failed a prior treatment course that included a protease inhibitor. The number and proportion of patients achieving SVR12 are summarized in the table below.

SVR12 Rates Among Treatment-Experienced Patients in Study GS-US-342-0109

Regimen	**GT1 without cirrhosis**	**GT1 with cirrhosis**	**GT3 without cirrhosis**	**GT3 with cirrhosis**
SOF+GS-5816 100 mg	100% (n=20/20)	100% (n=7/7)	100% (n=27/27)	88% (n=23/26)
SOF+GS-5816 100 mg +RBV	100% (n=18/18)	90% (n=9/10)	100% (n=26/26)	96% (n=25/26)

The second study, ELECTRON 2 (Oral #79), evaluated the same combination of SOF plus GS-5816, with and without RBV, for eight weeks in non-cirrhotic, treatment-naïve genotype 3 patients. Patients receiving SOF with GS-5816 100 mg achieved SVR12 rates of 100 percent (n=26/26) with RBV and 96 percent (n=26/27) without RBV.

The third study, GS-US-342-0102, evaluated SOF plus GS-5816, with and without RBV, among non-cirrhotic treatment-naïve patients. The results of Part A of the study evaluating 12 weeks of therapy were presented at the 49th Annual Meeting of the European Association for the Study of the Liver (The International Liver Congress 2014) in April 2014.

The results of Part B, presented at the Liver Meeting this week (Oral #80), evaluated eight weeks of SOF plus GS-5816, with and without RBV, in patients with genotype 1 or 2 HCV infection. Among genotype 1 patients receiving SOF plus GS-5816 100 mg, SVR12 rates were 81 percent (n=25/31) and 90 percent (n=26/29), with and without RBV, respectively. Genotype 2 patients achieved SVR12 rates of 88 percent (n=23/26) with RBV and 88 percent (n=23/26) without RBV.

SOF plus GS-5816 was well tolerated in over 800 patients with HCV infection evaluated in these three studies. There was a low incidence of serious adverse effects and few discontinuations due to adverse events. The most frequently reported adverse events (>10%) were fatigue, headache, nausea and insomnia. The most frequently observed hematologic abnormality was hemoglobin decrease in the RBV-containing treatment groups.

GS-5816 is an investigational product and its safety and efficacy have not been established.

Additional information about these studies can be found at www.clinicaltrials.gov.

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 and South 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 of unfavorable longer-term results from these studies and other ongoing and subsequent clinical trials involving sofosbuvir plus GS-5816, alone or in combination with other products, for the treatment of HCV. In addition, Gilead may make a strategic decision to discontinue development of GS-5816 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, 2014, 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.

U.S. Full Prescribing Information for Sovaldi is available at www.gilead.com.

Sovaldi is a registered trademark of Gilead Sciences, Inc.

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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