Gilead Announces Multiple Scientific Presentations Demonstrating Broad Utility of Sofosbuvir-Based Hepatitis C Therapies

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– Studies Highlight Progress with Approved Therapies and Investigational Pangenotypic Regimens, Including Sofosbuvir/Velpatasvir (SOF/VEL) and SOF/VEL Plus GS-9857 –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 16, 2016-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced results from several Phase 2 and Phase 3 studies evaluating its two investigational, pangenotypic, fixed-dose combination therapies for the treatment of chronic hepatitis C virus (HCV) infection, as well as new data highlighting the potential use of Harvoni® (ledipasvir/sofosbuvir) in adolescents aged 12 to 17. Data were presented this week at The International Liver Congress™ 2016 in Barcelona, Spain.

"The data presented this week continue to underscore the high cure rates and safety of our sofosbuvir-based HCV therapies, and support their utility across all patient HCV genotypes and disease stages," said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. "We are pleased to have the opportunity to further characterize the pangenotypic profiles of our two new investigational fixed-dose combinations, sofosbuvir/velpatasvir and sofosbuvir/velpatasvir plus GS-9857, and to highlight results from the first study to evaluate interferon-free HCV therapy in adolescents."

Sofosbuvir/Velpatasvir (SOF/VEL)

Results from the open-label, Phase 3 ASTRAL-5 study (PS104), led by David L. Wyles, MD, Associate Professor of Medicine, Division of Infectious Diseases, University of California, San Diego, California, evaluating once-daily SOF/VEL for 12 weeks among patients with HCV genotype 1-6 who are co-infected with HIV demonstrated that SOF/VEL was well-tolerated and resulted in high SVR12 rates. The SVR12 rate was 95 percent (n=99/104) overall, and 100 percent (n=19/19) and 97 percent (n=28/29) in patients with cirrhosis and prior treatment-failure, respectively. Two patients relapsed, while three patients were lost to follow up or withdrew consent. Two patients achieved SVR4 but have not yet returned for the post-treatment week 12 visit. The most common adverse events (>10 percent) were fatigue and headache.

SOF/VEL is currently being evaluated by regulatory agencies in the United States, Europe and Canada.

Sofosbuvir/Velpatasvir (SOF/VEL) Plus GS-9857

Data from three Phase 2 trials evaluating SOF/VEL plus GS-9857, a pangenotypic protease inhibitor, (Studies GS-US-367-1168 and GS-US-367-1169 and TRILOGY-3) also were selected for presentation.

Studies 1168 and 1169

Studies 1168 and 1169 evaluated 6 and 8 weeks of SOF/VEL plus GS-9857, with or without ribavirin (RBV), among treatment-naïve patients and 12 weeks of SOF/VEL plus GS-9857 among patients who failed prior treatment including those previously exposed to a direct acting antiviral (DAA) regimen. Study 1168 evaluated 197 genotype 1 patients and Study 1169 evaluated 128 genotype 2-6 patients.

- Treatment-naïve patients: Poster SAT-138 highlighted combined safety and efficacy results from Studies 1168 and 1169 evaluating SOF/VEL plus GS-9857, with or without ribavirin, in genotype 1-6, treatment-naïve patients, with and without cirrhosis. SVR12 rates were:

	SOF/VEL plus GS-9857		SOF/VEL plus GS-9857 with RBV
	6 weeks	8 weeks	8 weeks
SVR12	79% (n=53/67)	96% (n=95/99)	81% (n=25/31)

The most common adverse events (>10 percent) across the three study arms were headache, nausea, fatigue, diarrhea and anemia.

- Treatment-experienced patients: Oral presentation PS008 highlighted combined safety and efficacy results from Studies 1168 and 1169 evaluating 12 weeks of SOF/VEL plus GS-9857 in genotype 1-6, treatment-experienced patients. Twenty-seven percent of patients were NS5A inhibitor-experienced, 52 percent were non-NS5A inhibitor, DAA-experienced and 21 percent failed interferon-based treatment without a DAA. Overall, the SVR12 rate was 99 percent (n=127/128). One genotype 3 patient with cirrhosis who had failed prior treatment with sofosbuvir plus pegylated interferon/ribavirin relapsed. Frequently reported adverse events (>10 percent) were headache, fatigue, diarrhea and nausea.

Studies 1168 and 1169 were led by Edward J. Gane, MD, Auckland City Hospital, Auckland, New Zealand (SAT-138); and Eric Lawitz, MD, Texas Liver Institute, University of Texas Health Science Center, San Antonio, Texas (PS008), respectively.

TRILOGY-3

A late-breaker oral presentation (PS021) featuring data from a Phase 2 trial, led by Dr. Lawitz, evaluated 12 weeks of a fixed-dose combination of SOF/VEL/GS-9857, with or without RBV, among genotype 1, DAA-experienced, HCV-infected patients, including patients with cirrhosis. One hundred

percent (n=24/24) of patients receiving 12 weeks of therapy with SOF/VEL/GS-9857 and 96 percent (n=24/25) of patients receiving SOF/VEL /GS-9857 plus RBV achieved SVR12. Among the 49 patients in this trial, 41 percent had prior exposure to an NS5A inhibitor and 47 percent previously received at least two classes of DAA. The most common adverse events (>10 percent) across both treatment arms were fatigue and anemia.

Based on these data a fixed-dose combination of SOF/VEL/GS-9857 is being evaluated in four Phase 3 studies (POLARIS-1, POLARIS-2, POLARIS-3 and POLARIS-4). SOF/VEL/GS-9857 has been granted a Breakthrough Therapy designation by the U.S. Food and Drug Administration for the treatment of chronic genotype 1 HCV patients who have previously failed an NS5A inhibitor-containing regimen.

Harvoni

Harvoni is the first single tablet HCV regimen approved in the United States for use in a broad range of patient populations, including HCV genotypes 1, 4, 5 and 6, HCV/HIV-1 coinfection, HCV genotype 1 and 4 liver transplant recipients and genotype 1-infected patients with decompensated cirrhosis.

Data from an evaluation of Harvoni in genotype 1 HCV-infected adolescents aged 12 to 17 have been selected for presentation in a late breaker oral session (LB-4597). Presented by Sanjay Bansal, MD, MRCPCH, Kings College Hospital, London, United Kingdom, and led by Kathleen B. Schwarz, MD, Pediatric Liver Center, Johns Hopkins University School of Medicine, Baltimore, Maryland, the Phase 2 study demonstrated that Harvoni is well tolerated and results in high SVR12 in this population. Of the 100 patients enrolled, 97 percent (n=97/100) achieved SVR12. The three patients who did not achieve SVR12 were lost to follow up; no patients experienced virologic failure. The most common adverse events were headache, diarrhea and fatigue. Further evaluation of Harvoni in a pediatric population of children aged 3 to 11 is ongoing.

Further information about the clinical studies described above can be found at www.clinicaltrials.gov.

Uses for Harvoni in certain HCV patient populations highlighted above are investigational and have not been determined to be safe or efficacious. SOF/VEL and SOF/VEL/GS-9857 are investigational products and have not been determined to be safe or efficacious.

Important Safety Information for Harvoni

Contraindications

If Harvoni is used in combination with ribavirin (RBV), all contraindications, warnings and precautions, in particular pregnancy avoidance, and adverse reactions to RBV also apply. Refer to RBV prescribing information.

Warnings and Precautions

Risk of Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Amiodarone is not recommended for use with Harvoni due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. In patients without alternative, viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.

Risk of Reduced Therapeutic Effect of Harvoni Due to P-gp Inducers: Rifampin and St. John's wort are not recommended for use with Harvoni as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations.

Related Products Not Recommended: Harvoni is not recommended for use with other products containing sofosbuvir (Sovaldi).

Adverse Reactions

Most common (≥10%, all grades) adverse reactions were fatigue, headache and asthenia.

Drug Interactions

In addition to rifampin and St. John's wort, co-administration of Harvoni is also not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such co-administration is expected to decrease the concentration of ledipasvir and sofosbuvir, reducing the therapeutic effect of Harvoni.

Co-administration of Harvoni is not recommended with simeprevir due to increased concentrations of ledipasvir and simeprevir. Co-administration is also not recommended with rosuvastatin or co-formulated elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of rosuvastatin and tenofovir, respectively.

Consult the full Prescribing Information for Harvoni for more information on potentially significant drug interactions, including clinical comments.

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. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 risk that Gilead may observe unfavorable results from additional clinical trials involving SOF/VEL, SOF/VEL/GS-9857 and Harvoni in certain patient populations, including adolescents aged 12 to 18. In addition, the regulatory filings for SOF/VEL and SOF/VEL/GS-9857 may not be approved by regulatory agencies, and marketing approvals, if granted, may have significant limitations on their 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 Annual Report on Form 10-K for the year ended December 31, 2015, 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 Harvoni is available at www.gilead.com.

Harvoni is a registered trademark of Gilead Sciences, Inc. or its related companies.

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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