Gilead Announces Phase 2 Results for Two Investigational All-Oral Sofosbuvir-Based Regimens for the Treatment of Chronic Hepatitis C

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-- Data Support Efficacy of Ledipasvir/Sofosbuvir Fixed-Dose Combination with Ribavirin in Genotype 3 HCV; Product Under Regulatory Review for Genotype 1 in U.S., Europe --

-- Combination of Sofosbuvir and GS-5816 Demonstrates Efficacy Against HCV Genotypes 1-6 --

LONDON--(BUSINESS WIRE)--Apr. 10, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced data from two Phase 2 studies evaluating investigational all-oral regimens containing the nucleotide analog polymerase inhibitor sofosbuvir (SOF) for the treatment of chronic hepatitis C virus (HCV) infection. These data are being presented this week at the 49th Annual Meeting of the European Association for the Study of the Liver (The International Liver Congress 2014) in London.

The first study, ELECTRON2 (Oral #6), is an ongoing, open-label Phase 2 clinical trial evaluating a once-daily fixed-dose combination of SOF 400 mg and the NS5A inhibitor ledipasvir (LDV) 90 mg, with and without ribavirin (RBV) twice-daily (1,000 or 1,200 mg/day), among HCV-infected patient populations.

In this study, 100 percent (n=26/26) of treatment-naïve genotype 3 patients receiving 12 weeks of LDV/SOF plus RBV and 64 percent (n=16/25) of treatment-naïve genotype 3 patients receiving 12 weeks of LDV/SOF without RBV achieved a sustained virologic response 12 weeks after completing therapy (SVR12). Among genotype 1-infected patients who had failed prior treatment with SOF plus RBV, 100 percent (19/19) achieved SVR12 following 12 weeks of LDV/SOF plus RBV. Additionally, 65 percent (n=13/20) of genotype 1-infected patients with decompensated or Child-Turcotte-Pugh Class B cirrhosis receiving 12 weeks of LDV/SOF without RBV achieved SVR12. LDV/SOF with and without RBV was well-tolerated, including among patients with more advanced liver disease.

“The ELECTRON2 data suggest that an all-oral regimen of LDV/SOF plus RBV has the potential to provide high cure rates for genotype 3 patients in just 12 weeks – half the duration of current all-oral treatment regimens,” said Professor Edward Gane, MD, Deputy Director and Hepatologist, New Zealand Liver Transplant Unit, Auckland City Hospital in New Zealand, and principal investigator of the ELECTRON2 study. “These results also suggest that LDV/SOF may be an effective treatment regimen for HCV genotype 1-infected patients who have failed a previous sofosbuvir-based regimen and those with advanced liver disease, including decompensated cirrhosis.”

A second study, Study GS-US-342-0102 (Oral #111), is an ongoing randomized Phase 2 clinical trial in which treatment-naïve, non-cirrhotic patients with genotypes 1-6 HCV infection received a 12-week course of SOF plus the pan-genotypic NS5A inhibitor GS-5816. Patients received SOF 400 mg and either GS-5816 25 mg (n=77) or GS-5816 100 mg (n=77). In this study, 94.8 percent (n=73/77) of patients receiving the 25 mg dose of GS-5816 and 96.1 percent (n=74/77) of patients receiving the 100 mg dose achieved SVR12.

“The results of this study of sofosbuvir with a new pan-genotype NS5A inhibitor demonstrate the curative potential of this combination,” said Gregory T. Everson, MD, Professor of Medicine and Director, Section of Hepatology, University of Colorado, Denver, and principal investigator of Study GS-US-342-0102. “The combination was not only effective across all genotypes and patient subgroups, but also was well tolerated. These results warrant additional study in future trials, with the hope of providing a potent, pan-genotypic combination with few side effects and a high chance for cure.”

The most common adverse events occurring in more than 10 percent of patients were fatigue, headache and nausea. There were no treatment discontinuations due to adverse events, and no evidence of treatment-related laboratory abnormalities.

Additional information about ELECTRON2 and GS-US-342-102 can be found at www.clinicaltrials.gov.

About SOF-Based Fixed-Dose Combinations

Full data from three Phase 3 clinical trials of the LDV/SOF fixed-dose combination (ION-1, ION-2 and ION-3) are also being presented at The International Liver Congress 2014. Gilead announced topline results from the ION studies on December 18,

2013. On February 10, 2014, Gilead submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the LDV/SOF fixed-dose combination tablet for the treatment of genotype 1 HCV infection in adults. The FDA has assigned the product a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options. On April 7, 2014, the company announced that the FDA has granted the application a priority review, setting a target action date under the Prescription Drug User Fee Act (PDUFA) of October 10, 2014.

On March 27, 2014, the European Medicines Agency (EMA) accepted Gilead's request for accelerated assessment for LDV/SOF, a designation that is granted to new medicines of major public health interest. Accelerated assessment could shorten the EMA's review time of LDV/SOF by two months, although it does not guarantee a positive opinion from the Committee for Medicinal Products for Human Use, or final approval by the European Commission.

Gilead has developed a once-daily fixed-dose combination tablet containing SOF and GS-5816. A second Phase 2 clinical trial (Study GS-US-342-0109) evaluating 12 weeks of SOF plus GS-5816, with or without RBV, among treatment-experienced cirrhotic and non-cirrhotic patients with genotypes 1 or 3 HCV infection is ongoing. Pending full results from Studies GS-US-334-102 and GS-US-342-0109, Gilead plans to initiate Phase 3 studies evaluating the efficacy and safety of the SOF/GS-5816 fixed-dose combination.

LDV/SOF and SOF/GS-5816 are investigational products and their safety and efficacy have not yet been established.

SOF as a single agent is approved as Sovaldi® in the United States, European Union, Canada, New Zealand and Switzerland.

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 risk that the FDA, European Commission and other regulatory agencies may not approve the LDV/SOF fixed-dose combination in the currently anticipated timelines or at all, and that any marketing approvals, if granted, may have significant limitations on its use. Further, additional clinical studies of LDV/SOF, including subsequent results from ELECTRON2, may produce unfavorable results. As a result, Gilead may not be able to successfully commercialize LDV/SOF, and may make a strategic decision to discontinue its development if, for example, the market for the product fails to materialize as expected. Additional risks include the possibility of unfavorable results from additional studies of SOF/GS-5816 and the possibility that Gilead may make a strategic decision to discontinue development of the fixed-dose combination of SOF/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 Annual Report on Form 10-K for the year ended December 31, 2013, 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.

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