

Gilead Announces Results From Phase 3 Study of Sofosbuvir Among Hepatitis C Patients in Japan

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– Results Confirm Efficacy and Safety of All-Oral Sofosbuvir-Based Regimen for Genotype 2 HCV Patients –

– Japanese Regulatory Filing Planned for Mid-Year –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 2, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced topline results from a Phase 3 clinical trial (Study GS-US-334-0118) in Japan evaluating the once-daily nucleotide analog polymerase inhibitor sofosbuvir in combination with ribavirin (RBV) for the treatment of genotype 2 chronic hepatitis C virus (HCV) infection. The study met its primary efficacy endpoint of superiority compared to a predefined historical control sustained virologic response (SVR) rate. In the study, 97 percent (n=148/153) of genotype 2 HCV-infected patients receiving 12 weeks of an all-oral regimen of sofosbuvir plus RBV achieved a sustained virologic response 12 weeks after completing therapy (SVR12). SVR12 rates among treatment-naïve and treatment-experienced patients were 98 percent (n=88/90) and 95 percent (n=60/63), respectively. Of the 153 patients who received treatment, 11 percent (n=17) had documented cirrhosis.

Japan has one of the highest rates of liver cancer of any industrialized country, and the majority of cases are due to chronic HCV infection. An estimated two million people in Japan are living with HCV infection, and approximately 20-30 percent have the genotype 2 strain of the virus. Current treatment options for genotype 2 HCV infection in Japan involve up to 48 weeks of therapy with pegylated interferon injections, which may not be suitable for certain patients.

In Study GS-US-334-0118, 153 patients (100%) became HCV undetectable by treatment Week 4 and remained undetectable through the remainder of the 12-week treatment period. Post-treatment relapse accounted for five virologic failures. There were no treatment discontinuations due to adverse events and all patients completed the 12 week post-treatment follow-up visit. The most common side effects observed in the study, consistent with the population and safety profile of RBV, included nasopharyngitis, anemia, headache, malaise and pruritis. Full study results will be presented at a future scientific meeting.

“This study confirms the high efficacy of all-oral therapy with sofosbuvir among genotype 2 hepatitis C patients in Japan, regardless of whether they are treatment experienced or new to treatment,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer, Gilead Sciences. “Based on these trial results, Gilead anticipates submitting a New Drug Application for sofosbuvir to the Japanese Pharmaceutical and Medical Devices Agency (PMDA) by mid-2014.”

Gilead established operations in Japan with the formation of Gilead K.K. in Tokyo in September 2012. If approved by the PMDA, sofosbuvir would be the first product to be launched and marketed by Gilead in Japan.

Gilead is also conducting a Phase 3 study in Japan evaluating the efficacy and safety of a once-daily fixed-dose combination of the NS5A inhibitor ledipasvir 90 mg and sofosbuvir 400 mg with and without ribavirin for the treatment of patients with genotype 1 chronic HCV infection, the most common strain of HCV in Japan. SVR12 results are expected in the second half of 2014.

Sofosbuvir is an investigational product in Japan and its safety and efficacy has not yet been established. The compound has been approved by regulatory authorities in the United States, European Union and Canada and is commercialized under the tradename Sovaldi®. The ledipasvir/sofosbuvir fixed-dose combination 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 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 results from additional clinical trials involving sofosbuvir or the ledipasvir/sofosbuvir fixed-dose combination in Japan, and the possibility we may not file for regulatory approval of sofosbuvir in Japan in the currently anticipated timelines. Further, the PMDA may not approve these products in Japan, and any marketing approvals, if granted, may have significant limitations on its 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, 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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