Health Canada Issues Notice of Compliance for Gilead's Harvoni™ (Ledipasvir/Sofosbuvir), the First Once-Daily Single Tablet Regimen for the Treatment of Genotype 1 Chronic Hepatitis C

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-- Harvoni Provides High Cure Rates (SVR12), Shortens Treatment Duration and Eliminates Need for Interferon and Ribavirin --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 16, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that Health Canada has issued a Notice of Compliance for Harvoni™ (ledipasvir 90 mg/sofosbuvir 400 mg), the first once-daily single tablet regimen for the treatment of chronic hepatitis C genotype 1 infection in adults. Harvoni combines the NS5A inhibitor ledipasvir with the nucleotide analog polymerase inhibitor sofosbuvir, granted marketing authorization under the tradename Sovaldi® in December 2013. The efficacy of Harvoni has been established in patients with chronic hepatitis C virus (HCV) genotype 1 infection, with a treatment duration of eight, 12 or 24 weeks depending on prior treatment history, cirrhosis status and baseline viral load. Eight weeks of treatment with Harvoni can be considered for treatment-naïve patients without cirrhosis who have baseline HCV viral load below 6 million IU/mL.

Harvoni Product Photo (Photo: Business Wire)

"Chronic hepatitis C can lead to cirrhosis, liver cancer and liver transplantation and is a major cause of liver-related morbidity and mortality in Canada," said Dr. Robert Myers, Associate Professor and Director of the University of Calgary Viral Hepatitis Clinic. "With Harvoni, the majority of genotype 1 patients can be cured with a once-daily pill in as little as eight or 12 weeks without the need for interferon injections or ribavirin tablets, which are associated with significant side effects."

Gilead filed a New Drug Submission for Harvoni in Canada on March 19, 2014 and was granted Priority Review by Health Canada. Gilead has filed private and public payer reimbursement submissions for Harvoni and was granted a Priority Review under the Common Drug Review process on October 6, 2014. Harvoni was approved in the United States on October 10, 2014 and granted a positive opinion by the Committee for Medicinal Products for Human Use in the European Union on September 25, 2014. Applications are pending in Australia and New Zealand.

The marketing authorization for Harvoni is supported by data from three Phase 3 studies, ION-1, ION-2 and ION-3. These studies evaluated eight, 12 or 24 weeks of treatment with Harvoni, with or without ribavirin, among nearly 2,000 genotype 1 HCV patients with compensated liver disease. These studies included non-cirrhotic treatment-naïve patients (ION-3), cirrhotic and non-cirrhotic treatment-naïve patients (ION-1) and cirrhotic and non-cirrhotic patients who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor (ION-2). The primary endpoint for each study was sustained virologic response (HCV undetectable) 12 weeks after completing therapy (SVR12). Patients who achieve SVR12 are considered cured of HCV. In these studies, ribavirin was not shown to increase response rates. Trial participants in the ribavirin-free arms (n=863) achieved SVR12 rates of 94 to 99 percent. For full study details, see the Clinical Studies section of the Product Monograph.

Harvoni was well tolerated in the ION studies. Zero percent, less than 1 percent and 1 percent of patients treated for

eight, 12 and 24 weeks, respectively, discontinued treatment due to adverse events, and fewer adverse events were observed in the ribavirin-free arms compared to the ribavirin-containing arms in all ION studies. The most common adverse reactions among patients treated with Harvoni (≥ 5 percent) were fatigue, headache, nausea, diarrhea and insomnia. See below for Important Safety Information regarding warnings and precautions, adverse reactions and drug interactions.

Patient Assistance Program in Canada

To assist eligible hepatitis C patients in Canada with access to Harvoni, Gilead Sciences Canada, Inc. has added the medicine to the Gilead Momentum Support Program™, which provides an integrated offering of support services for patients and healthcare providers. The program provides access to dedicated case managers to help patients and their providers with insurance-related needs, including identifying their coverage options through either private insurance or publicly funded programs. In addition, the program provides financial assistance for eligible patients who need help paying for out-of-pocket medication costs.

For more information regarding the Momentum Program in Canada, please call 1-855-447-7977.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

General: The safety and efficacy of Harvoni in combination with other anti-HCV medicines has not been studied. The sustained virologic response of Harvoni is reduced in treatment-experienced patients with HCV containing certain NS5A baseline mutations.

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 leading to reduced therapeutic effect of Harvoni and potential loss of virologic response.

Patients with Other HCV Genotypes: The safety and efficacy of Harvoni have not been studied in patients infected with HCV genotype 2, 4, 5 or 6 and has not been fully established in patients infected with genotype 3.

Risk of Increase in Tenofovir Exposure: Harvoni has been shown to increase tenofovir exposure when used together with an HIV regimen containing tenofovir disoproxil fumarate and a pharmacokinetic enhancer (ritonavir or cobicistat). The safety of tenofovir in the setting of Harvoni and a pharmacokinetic enhancer has not been established. Patients receiving Harvoni concomitantly with Stribild or tenofovir DF and a boosted HIV protease inhibitor should be monitored for tenofovir-associated adverse reactions.

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 and headache.

Drug Interactions

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

The safety and efficacy of Harvoni in combination with simeprevir have not been established.

Consult the full Canadian Product Monograph 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 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 physicians may choose not to prescribe the product and payers may be reluctant to approve or provide reimbursement for the product. Further, pending marketing applications for Harvoni in the European Union and other territories may not be approved in the currently anticipated timelines or at all, and marketing approval, 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 Quarterly Report on Form 10-Q for the quarter ended June 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.

Canadian Product Monograph for HARVONI is available at www.Gilead.ca.

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.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20141016006163/en/

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