**Health Canada Issues Notice of Compliance for Sovaldi™ (Sofosbuvir) for the Treatment of Chronic Hepatitis C**

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***– Sovaldi Receives Marketing Authorization for Patients with Genotypes 1, 2, 3 or 4 HCV –***

***– High Cure Rates (SVR 12) and Therapy Shortened to Just 12 Weeks for Many Patients –***

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 16, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that Health Canada has issued a Notice of Compliance for Sovaldi™ (sofosbuvir) 400 mg tablets, a once-daily oral nucleotide analog polymerase inhibitor for the treatment of chronic hepatitis C (CHC) infection. Sovaldi is indicated for use in adult patients with compensated liver disease, including cirrhosis, for the treatment of genotype 1 or 4 CHC in combination with pegylated interferon and ribavirin, and for the treatment of genotype 2 or 3 CHC in combination with ribavirin. The recommended dose and treatment duration for Sovaldi combination therapy is as follows:

| | **Treatment** | **Duration** |
|---|---|---|
| Treatment-naïve patients with genotype 1 or 4 CHC | Sovaldi + peginterferon alfa + ribavirin | 12 weeks |
| Patients with genotype 2 CHC | Sovaldi + ribavirin | 12 weeks |
| Patients with genotype 3 CHC | Sovaldi + ribavirin | 16 weeks* |

** Consideration should be given to extending the duration of therapy beyond 16 weeks and up to 24 weeks guided by an assessment of the potential benefits and risks for the individual patient (these factors may include cirrhosis status and treatment history).*

Treatment regimen, duration and response to Sovaldi are dependent on viral genotype and patient population, and associated baseline factors. Sovaldi must not be administered as monotherapy. The Canadian Product Monograph is available at www.Gilead.ca.

Gilead submitted the marketing application for Sovaldi in Canada on May 17, 2013 and was granted Priority Review by Health Canada. Gilead is awaiting federal and provincial reimbursement review for Sovaldi under the Canadian Common Drug Review process. Gilead anticipates that Sovaldi will be available to patients in Canada early next year. Sovaldi was approved in the United States on December 6, 2013 and applications are pending in the European Union, Australia and New Zealand, Switzerland and Turkey.

“I believe sofosbuvir has the potential to transform HCV treatment in Canada as it addresses many unmet patient needs,” said Jordan Feld, MD, MPH, Staff Hepatologist, Toronto Western Hospital, Department of Medicine, Division of Gastroenterology. “The high cure rates, shortened treatment duration, and potential to eliminate or reduce interferon injections give us our best opportunity to successfully treat Canadians with hepatitis C.”

An estimated 250,000 Canadians are living with chronic hepatitis C virus (HCV), but because the disease can progress for many years without causing noticeable symptoms, about 35 percent of these individuals do not know they are infected. HCV disproportionately impacts “baby boomers,” individuals born between 1945 and 1965, and the Canadian Liver Foundation now recommends that all Canadian baby boomers be tested for the virus. The current standard of care for HCV in Canada involves up to 48 weeks of therapy with a pegylated interferon (peg-IFN)/ribavirin (RBV)-containing regimen, which may not be suitable for certain types of patients.

The marketing authorization is supported primarily by data from four Phase 3 studies, NEUTRINO, FISSION, POSITRON and FUSION, which evaluated 12 or 16 weeks of treatment with Sovaldi combined with either RBV or RBV plus peg-IFN. Three of these studies evaluated Sovaldi plus RBV in genotype 2 or 3 patients who were either treatment-naïve (FISSION), treatment-experienced (FUSION) or peg-IFN intolerant, ineligible or unwilling (POSITRON). NEUTRINO evaluated Sovaldi in combination with peg-IFN/RBV in treatment naïve patients with genotypes 1, 4, 5 or 6. Patients who achieve SVR12 are

considered cured of HCV. Trial participants taking Sovaldi-based therapy achieved SVR12 rates of 50-90 percent. For full study details, see the Clinical Studies section of the Product Monograph.

Sovaldi combination therapy was well tolerated in clinical studies. Adverse events were generally mild and there were few treatment discontinuations due to adverse events. The most common adverse reaction occurring in at least 5 percent of patients receiving Sovaldi in combination with ribavirin was fatigue. Among patients receiving Sovaldi in combination with RBV and peg-IFN, the most common adverse reactions occurring in at least 5 percent of patients were fatigue, anemia, neutropenia, insomnia, headache and nausea. See below for Important Safety Information regarding contraindications, warnings and precautions, adverse reactions and drug interactions.

**Patient Assistance Program in Canada**

As part of its commitment to ensuring that people with hepatitis C can access Sovaldi, Gilead Sciences Canada has developed the Momentum Support Program™, which will launch on January 6, 2014. The program is designed to provide an integrated offering of support services for patients and healthcare providers, including:

- Access to dedicated case managers to help patients and their providers with insurance-related needs, including identifying alternative coverage options such as federal and provincially-insured programs.
- The Sovaldi Co-pay assistance program, which will provide financial assistance for eligible patients who need help paying for out-of-pocket medication costs.

For more information regarding Sovaldi or the Momentum Program in Canada, please call the Gilead Sciences Canada medical information line at 1-866-207-4267.

**About Sovaldi**

Sovaldi is an oral nucleotide analog inhibitor of the HCV NS5B polymerase enzyme, which plays an essential role in HCV replication. Sovaldi is a direct-acting agent, meaning that it interferes directly with the HCV life cycle by suppressing viral replication. Treatment regimen and duration for Sovaldi are dependent on both viral genotype and patient population. Treatment response varies based on baseline host and viral factors. Sovaldi must not be administered as monotherapy.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**

Sovaldi combination treatment with ribavirin or with peginterferon alfa plus ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risk for birth defects and fetal death associated with ribavirin. Contraindications to ribavirin or with peginterferon alfa plus ribavirin also apply to Sovaldi combination treatment. Refer to the Product Monographs of peginterferon alfa and ribavirin for a list of their contraindications.

**Warnings and Precautions**

Sovaldi must not be administered as a monotherapy and must only be used in combination with either peginterferon alfa/ribavirin or ribavirin for the treatment of hepatitis C infection.

Pregnancy: Use with Ribavirin or Peginterferon Alfa/Ribavirin: Ribavirin therapy should not be started unless a report of a negative pregnancy test has been obtained immediately prior to initiation of therapy. Female patients of childbearing potential and their male partners must use two forms of non-hormonal contraception during treatment and for at least 6 months after treatment has concluded. Routine monthly pregnancy tests must be performed during this time. Refer to the prescribing information for ribavirin.

Use with Potent P-gp Inducers: Rifampin and St. John’s wort should not be used with Sovaldi as they may significantly decrease sofosbuvir plasma concentration, reducing its therapeutic effect.

**Adverse Reactions**

Most common (≥20%, all grades) adverse reactions for:

- Sovaldi + peginterferon alfa + ribavirin combination therapy were fatigue, headache, nausea, insomnia, and anemia
- Sovaldi + ribavirin combination therapy were fatigue and headache

**Drug Interactions**

In addition to rifampin and St. John's wort, coadministration of Sovaldi is not recommended with carbamazepine, modinafil, oxcarbazepine, phenobarbital, phenytoin, and rifabutin. Such coadministration is expected to decrease the concentration of sofosbuvir, reducing its therapeutic effect.

**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.

**About Gilead Sciences Canada, Inc.**

Gilead Sciences Canada, Inc. is the Canadian affiliate of Gilead Sciences, Inc. and was established in Mississauga, Ontario in 2006.

**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 Sovaldi may not be available to patients in Canada in the currently anticipated timelines. In addition, physicians and patients may not see advantages of Sovaldi over other therapies and may therefore be reluctant to prescribe the product, and the risk that public payers may be reluctant to approve or provide reimbursement for the product. Further, pending marketing applications for Sovaldi 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 September 30, 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.

*Canadian Product Monograph for Sovaldi is available at www.Gilead.ca.*

*U.S. full prescribing information for Sovaldi is available at www.Gilead.com.*

*Sovaldi is a 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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