

U.S. Food and Drug Administration Approves Gilead's Sovaldi™ (Sofosbuvir) for the Treatment of Chronic Hepatitis C

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- *Sovaldi Approved for Use in Genotypes 1, 2, 3 or 4* –
- *High Cure Rates (SVR12) and Shortened, 12-Week Course of Therapy for Many Patients* –
- *First Ever Oral Treatment Regimen for Genotypes 2 or 3* –
- *First Regimen for Patients Awaiting Liver Transplantation to Prevent HCV Recurrence* –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 6, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Sovaldi™ (sofosbuvir) 400 mg tablets, a once-daily oral nucleotide analog polymerase inhibitor for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Sovaldi's efficacy has been established in subjects with hepatitis C virus (HCV) genotypes 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. Recommended regimens and treatment duration for Sovaldi combination therapy in HCV mono-infected or HCV/HIV-1 co-infected patients follows:

	Treatment	Duration
Genotype 1 or 4	Sovaldi + peg-interferon alfa + ribavirin	12 weeks
Genotype 2	Sovaldi + ribavirin	12 weeks
Genotype 3	Sovaldi + ribavirin	24 weeks

Sovaldi in combination with ribavirin for 24 weeks can be considered for CHC patients with genotype 1 infection who are interferon ineligible. Additionally, Sovaldi should be used in combination with ribavirin for treatment of CHC patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation to prevent post-transplant HCV infection. Treatment regimen, duration and response to Sovaldi are dependent on viral genotype and patient population, and associated baseline factors. Monotherapy is not recommended. Full Prescribing Information will be available on www.Gilead.com.

The FDA granted Sovaldi Priority Review and Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options.

"I believe that Sovaldi will have a major impact on public health by significantly increasing the number of Americans who are cured of hepatitis C," said Ira Jacobson, MD, Chief of the Division of Gastroenterology and Hepatology, Weill Cornell Medical College, New York City and a principal investigator in the Sovaldi clinical trials. "In clinical studies, Sovaldi in combination with other agents achieved very high cure rates while shortening the duration of treatment to as little as 12 weeks and reducing or completely eliminating the need for interferon injections, depending on the viral genotype."

Chronic hepatitis C affects an estimated 4 million people in the United States, the majority of whom are "baby boomers" – individuals born between 1945 and 1965. The disease is the nation's leading cause of liver cancer and liver transplantation, and in recent years has surpassed HIV/AIDS as a cause of death. The current standard of care for HCV 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.

"It is our hope that Sovaldi will mark the beginning of a new era in hepatitis C treatment. Gilead is proud to have played a role in bringing about this important therapeutic advance and we would like to extend our thanks to the many patients and physicians who partnered with us on Sovaldi's clinical studies," said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences.

Sovaldi's approval 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. In these studies, Sovaldi-based therapy was found to be superior to historical controls (NEUTRINO and FUSION) or to placebo (POSITRON), or non-inferior to currently available treatment options (FISSION) based on the proportion of patients who had a sustained virologic response (HCV undetectable) 12 weeks after completing therapy (SVR12). 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 full Prescribing Information.

During the FDA's review, data from two additional Phase 3 studies, VALENCE and PHOTON-1, were added to the NDA as a result of the Breakthrough Designation status. In the VALENCE study, patients with genotype 3 HCV infection were treated with Sovaldi and RBV for 24 weeks. Eighty-four percent of patients in this trial achieved SVR12. The PHOTON-1 study evaluated Sovaldi and RBV for 12 weeks in patients with genotype 2 HCV infection co-infected with HIV-1 and for 24 weeks in patients with genotypes 1 or 3 HCV co-infected with HIV-1. Trial participants achieved SVR12 rates of 76-92 percent. In all Phase 3 studies of Sovaldi, no viral resistance to the drug was detected among patients who relapsed following completion of therapy.

To date, nearly 3,000 patients have received at least one dose of Sovaldi in Phase 2 or 3 studies. 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 events occurring in at least 20 percent of patients receiving Sovaldi in combination with Peg-IFN/RBV were fatigue, headache, nausea, insomnia and anemia; see below for Important Safety Information regarding contraindications, warnings and precautions, adverse reactions and drug interactions.

On November 22, 2013, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion on Gilead's application for marketing authorization for Sovaldi. The CHMP opinion was adopted following an accelerated review procedure, which is reserved for medicinal products that are expected to be of major public health interest. This assessment does not guarantee marketing authorization by the European Commission. If approved, Sovaldi could be available in the European Union in the first quarter of 2014. Applications for marketing approval of Sovaldi are also pending in Australia, Canada, New Zealand, Switzerland and Turkey.

Dr. Jacobson is a paid consultant to Gilead.

The Wholesaler Acquisition Cost (WAC) of a 28-tablet bottle of Sovaldi in the United States is \$28,000.

U.S. Patient Assistance Program

Gilead is committed to ensuring that people with hepatitis C can access Sovaldi and has launched Support Path™ (www.MySupportPath.com) to provide assistance to patients who are uninsured, underinsured or who need financial assistance to pay for the medicine. The program consists of an integrated offering of support services for patients and providers, including:

- Access to dedicated case managers to help patients and their providers with insurance-related needs, including identifying alternative coverage options such as federally-insured programs (e.g., Medicaid, Medicare) and health exchanges.
- Education and support, including a 24/7 nursing support service line and the ability to schedule an onsite visit from a clinical educator.
- The Sovaldi Co-pay Coupon Program, which provides co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than \$5 per co-pay. Co-pay assistance can also be applied toward deductibles and co-insurance obligations.
- Gilead will provide support to the Patient Access Network (PAN) Foundation, an independent non-profit organization that provides assistance for eligible federally-insured and privately-insured patients who need help covering out-of-pocket medication costs.
- The Support Path Patient Assistance Program will provide Sovaldi at no charge for eligible patients with no other insurance options.

Information about how to apply for any of these forms of assistance can be found at www.MySupportPath.com or by calling 1-855-7MyPath (1-855-769-7284) between 9 a.m. - 8 p.m. EST.

Global Availability

Gilead is committed to helping ensure access to Sovaldi in resource-limited settings. The company is developing a hepatitis C treatment access program, focusing on those countries with the greatest HCV burden. Full program details will be announced in the coming months.

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. Monotherapy is not recommended for treatment of CHC.

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 peginterferon alfa and ribavirin also apply to Sovaldi combination treatment. Refer to the prescribing information of peginterferon alfa and ribavirin for a list of their contraindications.

Warnings and Precautions

- **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 ($\geq 20\%$, 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, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. 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.

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 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. In addition, 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.

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

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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/20131206005775/en/>

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