

## European Commission Grants Marketing Authorization for Gilead's Sovaldi® (Sofosbuvir) for the Treatment of Chronic Hepatitis C Infection

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– *Sovaldi Approved For Use in Genotypes 1-6* –

– *High Cure Rates and Shortened, 12-Week Course of Therapy for Treatment-Naïve Patients* –

– *First All-Oral Treatment Option for Patients Who Cannot Take Interferon* –

– *First Regimen for Patients Awaiting Liver Transplantation to Prevent HCV Recurrence* –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 17, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted marketing authorization for Sovaldi® (sofosbuvir) 400 mg tablets, a once-daily oral nucleotide analogue polymerase inhibitor for the treatment of chronic hepatitis C (CHC) infection in adults, in combination with other antiviral agents (ribavirin (RBV) and pegylated interferon alpha (peg-IFN)). Today's marketing authorization follows an accelerated assessment by the European Medicines Agency, a designation that is granted to new medicines of major public health interest, and allows for the marketing of Sovaldi in all 28 countries of the European Union (EU).

Sovaldi has been studied in hepatitis C virus (HCV) genotypes 1-6. The efficacy of Sovaldi has been established in patients with genotypes 1-4, in those awaiting liver transplantation and those with HCV/HIV-1 co-infection. The clinical data supporting the use of Sovaldi in patients with genotypes 5 and 6 is limited. Recommended regimens and treatment duration for Sovaldi combination therapy in HCV mono-infected or HCV/HIV-1 co-infected patients follow:

<b>Patient population</b>	<b>Treatment</b>	<b>Duration</b>
	Sovaldi + RBV + peg-IFN	12 weeks
	Sovaldi + RBV	
Genotype 1, 4, 5 or 6 CHC		24 weeks
	Only for use in patients ineligible or intolerant to peg-IFN	
Genotype 2 CHC	Sovaldi + RBV	12 weeks
	Sovaldi + RBV + peg-IFN	12 weeks
Genotype 3 CHC		
	Sovaldi + RBV	24 weeks
Patients with CHC awaiting liver transplantation	Sovaldi + RBV	Until liver transplantation

Monotherapy is not recommended. The Summary of Product Characteristics is available at [www.ema.europa.eu](http://www.ema.europa.eu).

“Unlike many chronic diseases, hepatitis C can be cured. However, for a number of reasons, many HCV patients have not currently achieved a cure and often progress to end-stage liver disease or liver cancer,” said Graham Foster, MD, Professor of Hepatology, Queen Mary University of London. “With high cure rates across a broad range of patients and a short duration of therapy, Sovaldi is a very welcome therapeutic advance that will increase the number of patients who can be treated and ultimately cured.”

Approximately nine million people in Europe are infected with HCV, a major cause of liver cancer and liver transplantation. The societal, clinical and economic burden of untreated HCV is substantial, with HCV-related healthcare costs directly related to disease severity. The current standard of care for HCV involves up to 48 weeks of therapy with a peg-IFN/RBV-containing regimen, which may not be suitable for certain types of patients.

“The marketing authorization of Sovaldi is an important step forward in the management of hepatitis C in Europe, enabling many more patients the opportunity of cure,” said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences. “We are committed to working with local governments and health systems to make Sovaldi available in Europe as quickly as possible.”

The European Commission marketing authorization for Sovaldi is supported primarily by data from four Phase 3 studies, NEUTRINO, FISSION, POSITRON and FUSION in which 12 or 16 weeks of Sovaldi-based therapy was found to be superior or non-inferior compared with the currently available treatment options RBV/peg-IFN or historical controls, based on the proportion of patients who had a sustained virologic response (where HCV becomes 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 Summary of Product Characteristics at [www.ema.europa.eu](http://www.ema.europa.eu).

During the regulatory review, data from two additional Phase 3 studies, VALENCE and PHOTON-1 were added to the marketing authorization application. In the VALENCE study, patients with genotype 3 HCV infection were treated with Sovaldi and RBV for 24 weeks. The PHOTON-1 study evaluated Sovaldi and RBV for 12 weeks in patients with genotype 2 or 3 HCV infection co-infected with HIV-1 and for 24 weeks in patients with genotype 1 HCV co-infected with HIV-1. 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 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 10 percent of patients were consistent with the safety profiles of peg-IFN and RBV and included fatigue, headache, nausea, insomnia, dizziness, pruritis (severe itching) and anemia.

Sovaldi was approved in the United States on December 6, 2013 and in Canada on December 13, 2013. Applications are pending in Australia and New Zealand, Switzerland and Turkey.

### **Important Safety Information**

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use: The summary of product characteristics of co-prescribed medicinal products should be consulted before starting therapy with Sovaldi. When Sovaldi is used in combination with RBV or peg-IFN/RBV, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and for a period of time after the treatment as recommended in the Summary of Product Characteristics for ribavirin. Refer to the Summary of Product Characteristics for ribavirin for additional information.

Use with potent P gp inducers: Medicinal products that are potent P glycoprotein (P gp) inducers in the intestine (e.g. rifampicin, St. John's wort [*Hypericum perforatum*], carbamazepine and phenytoin) may significantly decrease Sovaldi plasma concentration leading to reduced therapeutic effect of Sovaldi. Such medicinal products should not be used with Sovaldi.

For the Summary of Product Characteristics please visit [www.ema.europa.eu](http://www.ema.europa.eu).

### **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 government reimbursement and pricing approval may take longer than anticipated. In addition, pending marketing applications for Sovaldi in 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.

*Sovaldi is a registered 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](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at +1 (650) 574-3000.*

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