European CHMP Adopts Positive Opinion for Gilead Sciences' Sovaldi® for the Treatment of Chronic Hepatitis C Infection

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 22, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion on the company's Marketing Authorisation Application (MAA) for Sovaldi® (sofosbuvir 400 mg tablets), an investigational once-daily oral nucleotide analogue polymerase inhibitor for the treatment of chronic hepatitis C virus (HCV) infection in adults. The CHMP opinion supports the approval of Sovaldi for the treatment of HCV in combination with other agents. The CHMP's recommendation will now be reviewed by the European Commission, which has the authority to approve medicines for use in the 28 countries of the European Union (EU).

Chronic HCV is a major cause of liver cancer and liver transplantation in Europe and around the world. The current standard of care for HCV involves up to 48 weeks of therapy with a pegylated interferon (peg-IFN)/ ribavirin (RBV)-containing regimen. These regimens are not always effective and are associated with significant side effects and contraindications with other medicines. Many HCV patients in Europe are not considered appropriate candidates for current treatment options.

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 authorisation by the European Commission. However, if approved, Sovaldi could be available in the EU in the first quarter of 2014.

The MAA 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 to currently available treatment options or historical controls, based on the proportion of patients who had a sustained virologic response (were HCV undetectable) 12 weeks after completing therapy (SVR12). Patients who achieve SVR12 are considered cured of HCV. During the European review, data from two additional Phase 3 studies, VALENCE and PHOTON-1 were filed to the MAA. 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 HCV infection co-infected with HIV-1 and for 24 weeks in patients with genotypes 1 or 3 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.

In the United States, an expert advisory committee of the U.S. Food and Drug Administration (FDA) voted unanimously (15-0) on October 25, 2013 that the available data support approval of sofosbuvir. A final decision from the FDA is anticipated by December 8, 2013.

Sovaldi is an investigational product and its safety and efficacy have not 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 risk of unfavorable results from ongoing and subsequent clinical trials of Sovaldi for HCV. The European Commission, FDA and other regulatory agencies may not approve Sovaldi in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on

their use. As a result, Sovaldi may never be successfully commercialized. Further, Gilead may make a strategic decision to discontinue development of Sovaldi if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. 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.

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.

Source: Gilead Sciences, Inc.

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