FDA Advisory Committee Supports Approval of Gilead's Sofosbuvir for Chronic Hepatitis C Infection

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– Final FDA Decision on Sofosbuvir Anticipated by December 8, 2013 –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 25, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the Antiviral Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted unanimously (15-0) that the available data support approval of the once-daily nucleotide analogue sofosbuvir in combination with ribavirin for the treatment of chronic hepatitis C in adult patients with genotype 2 and 3 infection. Committee members also voted unanimously (15-0) that the available data support approval of sofosbuvir in combination with pegylated interferon and ribavirin for the treatment of chronic hepatitis C in treatment-naïve adult patients with genotype 1 and 4 infection.

The recommendations of the Advisory Committee are not binding, but will be considered by FDA as the agency completes its review of Gilead's New Drug Application (NDA) for sofosbuvir. Gilead submitted the NDA on April 8, 2013 and was granted a priority review. The FDA also granted sofosbuvir a Breakthrough Therapy designation. The FDA grants Breakthrough Therapy designation and priority review status to drug candidates that may offer major advances in treatment over existing options. A target review date of December 8, 2013 has been set under the Prescription Drug User Fee Act (PDUFA). Applications for marketing approval of sofosbuvir are also pending in the European Union, Australia, Canada, New Zealand, Switzerland and Turkey.

The sofosbuvir NDA is supported primarily by data from four Phase 3 studies, NEUTRINO, FISSION, POSITRON and FUSION, in which 12 or 16 weeks of sofosbuvir-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 (HCV undetectable) 12 weeks after completing therapy (SVR12). During the review, data from an additional Phase 3 study, VALENCE, were filed to the NDA. In this study, patients with genotype 3 HCV infection were treated with sofosbuvir and ribavirin for 24 weeks. Patients who achieve SVR12 are considered cured of HCV.

About Sofosbuvir

Sofosbuvir is a nucleotide analogue inhibitor of the HCV NS5B polymerase enzyme, which plays an essential role in HCV replication. Sofosbuvir is a direct-acting agent, meaning that it interferes directly with the HCV life cycle by suppressing viral replication. Sofosbuvir 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 that FDA, EMA and other regulatory agencies may not approve sofosbuvir in the currently anticipated timelines or at all, and that any marketing approvals, if granted, may have significant limitations on their use. In addition, future studies of sofosbuvir, including in combination with other products, may not produce favorable results. Further, even if approved, Gilead may not be able to successfully commercialize sofosbuvir, and may make a strategic decision to discontinue its development if, for example, the market for the product fails to materialize as expected. 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 Gilead's Quarterly Report on Form 10-Q for the quarter ended June 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.

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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