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

– 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.