Gilead Announces U.S. FDA Priority Review Designation for Sofosbuvir/Velpatasvir for Treatment of All Genotypes of Chronic Hepatitis C Infection

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-- Final FDA Decision Anticipated by June 28, 2016 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 4, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted priority review to the company's New Drug Application (NDA) for an investigational, once-daily fixed-dose combination of the nucleotide analog polymerase inhibitor sofosbuvir (SOF), approved as Sovaldi® in December 2013, and velpatasvir (VEL), an investigational pan-genotypic NS5A inhibitor, for the treatment of chronic genotype 1-6 hepatitis C virus (HCV) infection. Gilead filed the NDA for SOF/VEL on October 28, 2015, and FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 28, 2016.

The FDA has assigned SOF/VEL a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options. The NDA for SOF/VEL is supported by data from four Phase 3 ASTRAL trials, which evaluated the fixed-dose combination in hepatitis C genotypes 1-6. A marketing application for SOF/VEL is also under review in the European Union, and was validated by the European Medicines Agency (EMA) in December. The SOF/VEL fixed-dose combination 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. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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. 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, 2015, 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 statement.

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.

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