European CHMP Adopts Positive Opinion for Gilead's Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) for the Treatment of All Chronic Hepatitis C Genotypes

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– Vosevi is Gilead's Fourth Sofosbuvir-Based Treatment to Receive CHMP Positive Opinion for the Treatment of Chronic HCV Infection –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 23, 2017-- 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 Authorization Application (MAA) for Vosevi®, an investigational, once-daily, single tablet regimen of sofosbuvir 400 mg, velpatasvir 100 mg, and voxilaprevir 100 mg (SOF/VEL/VOX) for the treatment of chronic hepatitis C virus (HCV)-infected patients. The data included in the application support the use of SOF/VEL/VOX in patients with and without compensated cirrhosis, with all genotypes (GT1-6) of HCV infection regardless of prior therapy, including 8 weeks of treatment for HCV direct-acting antiviral (DAA)-naïve patients without cirrhosis, as well as 12 weeks of treatment for patients who have previously failed therapy with a DAA-containing regimen.

The CHMP positive opinion was adopted following an accelerated assessment procedure, reserved for medicinal products expected to be of major public health interest. The 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, Norway and Iceland.

The MAA for SOF/VEL/VOX is supported by data from four Phase 3 studies. Two studies (POLARIS-1 and POLARIS-4), evaluated 12 weeks of the single tablet regimen in patients with genotypes 1-6 HCV infection previously treated unsuccessfully with DAA-containing regimens, including NS5A inhibitors. Two other studies (POLARIS-2 and POLARIS-3) evaluated 8 weeks of SOF/VEL/VOX in DAA-naïve patients with genotypes 1-6 HCV infection. Across POLARIS-1 and POLARIS-4, 97 percent of patients treated with SOF/VEL/VOX (n=431/445) achieved the primary efficacy endpoint of SVR12. In POLARIS-2, 95 percent of patients with genotypes 1-6 HCV infection with and without cirrhosis treated with SOF/VEL/VOX (n=477/501) achieved the primary efficacy endpoint of SVR12. In POLARIS-3, 96 percent of patients with genotype 3 infection and cirrhosis treated with SOF/VEL/VOX (n=106/110) achieved the primary efficacy endpoint of SVR12. The most common adverse events among patients who received SOF/VEL/VOX in the POLARIS studies were headache, fatigue, diarrhea and nausea.

Sofosbuvir as a single agent was granted marketing authorization in the European Union on January 16, 2014, under the trade name Sovaldi®, for use in combination with other agents. The single tablet regimen of sofosbuvir (400 mg) and ledipasvir (90 mg) received marketing authorization in the European Union on November 18, 2014, under the trade name Harvoni®. The single tablet regimen of sofosbuvir (400 mg) and velpatasvir (100 mg) received marketing authorization in the European Union on July 8, 2016, under the trade name Epclusa®.

Gilead has also submitted a regulatory application for SOF/VEL/VOX in the United States. Gilead filed the New Drug Application for SOF/VEL/VOX on December 8, 2016, and the Food and Drug Administration (FDA) has set a target action date under the Prescription Drug User Fee Act of August 8, 2017.

SOF/VEL/VOX is an investigational product and its safety and efficacy has not been established and is not approved anywhere globally.

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 40 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, including the risk that the European Commission or other regulatory agencies, including the FDA, may not approve SOF/VEL/VOX for the treatment of chronic hepatitis C and that any marketing approvals, if granted, may have significant limitations on its use. As a result, Gilead may not be able to successfully commercialize SOF/VEL/VOX for chronic hepatitis C. 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 10Q for the quarter ended March 31, 2017, 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.

Full European Summary of Product Characteristics for Sovaldi, Harvoni and Epclusa are available from the EMA website at www.ema.europa.eu.

Vosevi, Sovaldi, Harvoni and Epclusa are registered trademarks of Gilead Sciences, Inc. or its related companies.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-650-574-3000.

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