European Medicines Agency Validates Gilead's Marketing Authorization Application for Investigational Chronic Hepatitis C Therapy Sofosbuvir/Velpatasvir/Voxilaprevir (SOF/VEL/VOX)

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– SOF/VEL/VOX Granted an Accelerated Assessment by the European Medicines Agency –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 20, 2017-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company's Marketing Authorization Application (MAA) for the 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 has been fully validated and is now under assessment by the European Medicines Agency (EMA).

"Direct-acting antiviral treatments have transformed our ability to treat hepatitis C; however, for some patients who have failed to achieve a cure with these regimens, effective and well-tolerated therapies are still needed," said Norbert Bischofberger, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. "The submission of this application reflects our continued commitment to provide treatment options for this life-threatening disease to as many patients as possible, including those who have failed previous direct-acting antiviral therapy, in Europe and around the world."

The MAA for SOF/VEL/VOX is supported by data from two Phase 3 studies (POLARIS-1 and POLARIS-4), which evaluated 12 weeks of the fixed-dose combination in direct-acting antiviral (DAA)-experienced patients with hepatitis C genotypes 1-6, including those who failed prior treatment with an NS5A inhibitor-containing regimen. Across the two studies, 97 percent of patients treated with SOF/VEL/VOX (n=430/445) achieved the primary efficacy endpoint of SVR12. The MAA also includes data from two additional phase 3 studies (POLARIS-2 and POLARIS-3), which evaluated 8 weeks of SOF/VEL/VOX in 611 DAA-naïve patients with genotypes 1-6. 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 were headache, fatigue, diarrhea and nausea.

SOF/VEL/VOX for the treatment of HCV will be reviewed by the EMA under the centralized licensing procedure for all 28 member states of the European Union, Norway and Iceland. The review will follow an accelerated procedure reserved for medicinal products expected to be of major public health interest. Gilead also submitted a New Drug Application to the U.S. Food and Drug Administration (FDA) for SOF/VEL/VOX on December 8, 2016.

SOF/VEL/VOX is an investigational product and its safety and efficacy has 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, 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 September 30, 2016, 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.

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Gilead Sciences, Inc.
Investors
Sung Lee, 650-524-7792
Media
Mark Snyder, 650-522-6167