Gilead Submits New Drug Application to U.S. Food and Drug Administration for Fixed-Dose Combination of Sofosbuvir/Velpatasvir for Treatment of All Six Genotypes of Hepatitis C

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-- If Approved, Combination Would Be First All-Oral, Pan-Genotypic Single-Tablet Regimen for Chronic HCV Infection --

-- Filing is Company's Third in Three Years for a New HCV Medicine --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 28, 2015-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) 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. The NDA is supported by clinical studies exploring the use of 12 weeks of SOF/VEL for patients with genotype 1-6 HCV infection, including patients with compensated cirrhosis and 12 weeks of SOF/VEL with ribavirin for patients with decompensated cirrhosis.

"As the first fixed-dose combination of two pan-genotypic, direct-acting antivirals, SOF/VEL represents an important step forward in the treatment of patients with hepatitis C," said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. "Genotype 1 is the most prevalent form of HCV in the United States, but worldwide, more than half of people living with HCV are infected with other genotypes. SOF/VEL complements our current HCV portfolio of Sovaldi and Harvoni, offering high cure rates and the potential to simplify treatment and eliminate the need for HCV genotype testing."

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. Of the 1,035 patients treated with SOF/VEL for 12 weeks in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,015 (98 percent) achieved the primary efficacy endpoint of SVR12. The ASTRAL-4 study randomized 267 patients with decompensated cirrhosis (Child-Pugh class B) to receive 12 weeks of SOF/VEL with or without ribavirin (RBV), or 24 weeks of SOF/VEL. Those who received SOF/VEL plus RBV for 12 weeks achieved an SVR12 rate of 94 percent, while those who received SOF/VEL for 12 weeks and 24 weeks achieved SVR12 rates of 83 percent and 86 percent, respectively.

Patients treated with SOF/VEL for 12 weeks in ASTRAL-1, ASTRAL-2 and ASTRAL-3 had similar adverse events compared with placebo-treated patients in ASTRAL-1. The most common adverse events were headache, fatigue and nausea. The most common adverse events in ASTRAL-4 were fatigue, nausea and headache.

Gilead plans to submit a regulatory application for approval of SOF/VEL in the European Union by the end of the year.

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. 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 FDA may not approve the

SOF/VEL fixed-dose combination, and that any marketing approvals, if granted, may have significant limitations on its use. In addition, Gilead may be unable to file for regulatory approval of SOF/VEL in other geographies in the currently anticipated timelines. Further, additional clinical studies of SOF/VEL may produce unfavorable results. As a result, Gilead may not be able to successfully commercialize SOF/VEL. 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 June 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 statements.

U.S. full prescribing information for Sovaldi and Harvoni is available at www.gilead.com.

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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:
Patrick O'Brien, 650-522-1936
or
Media:
Cara Miller, 650-522-1616