Gilead Submits New Drug Application to U.S. Food and Drug Administration for the Investigational Single Tablet Regimen Sofosbuvir/Velpatasvir/Voxilaprevir

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- If Approved, SOF/VEL/VOX Would Be the First Once-Daily Single Tablet Regimen Available as a Salvage Therapy for Patients Infected with HCV Genotype 1-6 Who Have Failed Prior Treatment with DAA Regimens Including NS5A Inhibitors -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 8, 2016-- 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 single tablet regimen containing sofosbuvir 400 mg, velpatasvir 100 mg, and voxilaprevir 100 mg (SOF/VEL/VOX) for the treatment of direct-acting antiviral (DAA)-experienced chronic hepatitis C virus (HCV)-infected patients. The data submitted in the NDA support the use of the regimen for 12 weeks in DAA-experienced patients with genotype 1 to 6 HCV infection without cirrhosis or with compensated cirrhosis.

“The remaining clinical need to treat HCV patients is a safe and effective cure for patients who have failed previous therapy with DAA regimens, including those with NS5A inhibitors,” said Norbert Bischofberger, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. “SOF/VEL/VOX has the potential to fill that need by offering single tablet dosing and high cure rates across all HCV genotypes for patients with and without cirrhosis, who have failed prior treatment with other highly effective regimens.”

The NDA for SOF/VEL/VOX is based on data from two Phase 3 studies (POLARIS-1 and POLARIS-4), which evaluated 12 weeks of the fixed-dose combination in DAA-experienced patients with hepatitis C genotypes 1-6, including those who failed prior treatment with an NS5A-containing regimen. Of the 445 patients treated with SOF/VEL/VOX, 430 (97 percent) achieved the primary efficacy endpoint of SVR12. The NDA is further supported by two additional Phase 3 studies (POLARIS-2 and POLARIS-3) in which 611 DAA-naïve HCV-infected patients received 8 weeks of SOF/VEL/VOX. The most common adverse events among patients who received SOF/VEL/VOX were headache, fatigue, diarrhea and nausea. These data were presented at the American Association for the Study of Liver Diseases (AASLD) annual meeting in November 2016.

About SOF/VEL/VOX

The SOF/VEL/VOX fixed-dose combination is an investigational product and its safety and efficacy have not been established. It has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration for the treatment of chronic genotype 1 HCV patients who have previously failed an NS5A inhibitor-containing regimen.

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 the FDA and other regulatory agencies may not approve the SOF/VEL/VOX fixed-dose combination, and any marketing approvals, if granted, may have significant limitations on its use. 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, 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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