U.S. FDA Approves Expanded Labeling for Epclusa® (Sofosbuvir/Velpatasvir) for the Treatment of Chronic Hepatitis C in Patients Co-Infected with HIV

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– New Data for First Approved Pan-genotypic Once-Daily Single Tablet Regimen for Chronic Hepatitis C Virus Infection –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Aug. 1, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved updated labeling for Epclusa® (sofosbuvir 400mg/velpatasvir 100mg), the first all-oral, pan-genotypic, once-daily single tablet regimen (STR) for the treatment of adults with chronic hepatitis C virus (HCV) infection, to include use in patients co-infected with HIV. Epclusa received regulatory approval for the treatment of adults with genotype 1-6 chronic HCV infection without cirrhosis or with compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin, in the United States on June 28, 2016.

Epclusa has a boxed warning in its product label regarding the risk of hepatitis B virus (HBV) reactivation in HCV/HBV co-infected patients. See below for important safety information.

“HCV co-infection remains a major cause of morbidity in HIV-infected individuals. With this expanded use, Epclusa provides co-infected patients with a much needed one-pill-a-day regimen that works across all HCV genotypes and is compatible with widely-used antiretroviral regimens,” said David Wyles, M.D., Chief, Division of Infectious Disease, Denver Health Medical Center; Associate Professor of Medicine, University of Colorado School of Medicine. “With Epclusa, physicians have an important new treatment option for their HCV/HIV co-infected patients.”

The supplemental new drug application (sNDA) was supported by data from the open-label, Phase 3 ASTRAL-5 study, which evaluated 12 weeks of treatment with Epclusa in 106 subjects with genotype 1-4 HCV infection who were co-infected with HIV and on stable antiretroviral therapy. In the study, 95 percent (101/106) of patients achieved the primary endpoint of SVR12, defined as an undetectable viral load 12 weeks after completing therapy.

The safety profile of Epclusa in HCV/HIV co-infected patients was similar to that observed in HCV mono-infected patients. The most common adverse events (in at least 10 percent of subjects) were fatigue (22 percent) and headache (10 percent).

“Epclusa has already helped further simplify HCV treatment among mono-infected patients, and we are pleased that HCV/HIV co-infected patients can benefit from this pan-genotypic single tablet regimen,” said John F. Milligan, PhD, Gilead’s President and Chief Executive Officer. “This approval advances the commitment we’ve made to the HCV and HIV communities to deliver innovative new treatments that address their unmet medical needs.”

U.S. Patient Support Program

To support these patients and their families, Gilead’s U.S. Support Path® program provides information regarding access and reimbursement coverage options to patients in the United States who need assistance with coverage for their medications, including Epclusa. Support Path conducts benefits investigations and provides patients with information regarding their insurance options.

Further, the Epclusa Co-pay Coupon Program offers co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs.

To learn more about Support Path for Epclusa, please visit www.MySupportPath.com or call 1-855-7-MYPATH (1-855-769-7284) between 9:00 a.m. and 8:00 p.m. (Eastern), Monday through Friday.

Global Availability

The prevalence of HCV genotypes varies regionally throughout the world. In resource-limited settings genotype testing can often be costly or unreliable, posing yet another barrier to treatment. As a pan-genotypic therapeutic option, Epclusa may help eliminate the need for genotype testing and has the potential to accelerate access to treatment for patients worldwide.

Gilead is committed to helping enable access to Epclusa around the world. Gilead works with a network of regional business partners, generic licensing partners and other stakeholders to expand treatment globally. Epclusa is already licensed to Gilead's 11 Indian manufacturing partners who produce and distribute generic versions of this medicine for 101 developing countries.

Important U.S. Safety Information for Epclusa

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV CO-INFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with Epclusa. HBV reactivation has been reported in HCV/HBV co-infected patients who were undergoing or had completed treatment with HCV direct acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV co-infected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Contraindications

- If Epclusa is used in combination with ribavirin (RBV), all contraindications, warnings and precautions, in particular pregnancy avoidance, and adverse reactions to RBV also apply. Refer to RBV prescribing information.

Warnings and Precautions

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with Epclusa due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir containing regimen. In patients without alternative, viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.
- **Risk of Reduced Therapeutic Effect Due to Concomitant Use of Epclusa with P-gp Inducers and/or Moderate to Potent Inducers of CYP2B6, CYP2C8 or CYP3A4:** Rifampin, St. John's wort, and carbamazepine are not recommended for use with Epclusa as they may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

Adverse Reactions

- The most common adverse reactions (≥10%, all grades) with Epclusa were headache and fatigue; and when used with RBV in decompensated cirrhotics were fatigue, anemia, nausea, headache, insomnia, and diarrhea.

Drug Interactions

- Coadministration of Epclusa is not recommended with topotecan due to increased concentrations of topotecan.
- Coadministration of Epclusa is not recommended with proton-pump inhibitors, oxcarbazepine, phenobarbital,

phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for Epclusa for more information on potentially significant drug interactions, including clinical comments.

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 physicians may not see the benefits of prescribing Epclusa for the treatment of adults with chronic HCV infection, for expanded use in patients co-infected with HIV. 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 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.

*U.S. Full Prescribing Information for Epclusa, including **BOXED WARNING**, is available at www.gilead.com.*

Epclusa is a registered trademark of Gilead Sciences, Inc., or its related companies.

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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