China Drug Administration Approves Epclusa® (Sofosbuvir/Velpatasvir), Gilead's Pan-Genotypic Treatment for Chronic Hepatitis C Virus Infection

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– Epclusa is the First Approved Pan-Genotypic Once Daily Single Table Regimen for Chronic Hepatitis C Virus Infection in China –

FOSTER CITY, Calif.--(BUSINESS WIRE)--May 30, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) announced today that the China Drug Administration (CDA) has approved Epclusa® (sofosbuvir 400 mg/velpatasvir 100 mg) for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection. The CDA also approved Epclusa in combination with ribavirin (RBV) for adults with HCV and decompensated cirrhosis. Epclusa is the first pan-genotypic HCV single tablet regimen (STR) approved in China.

The approval of Epclusa in China is supported by five international Phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3, ASTRAL-4 and ASTRAL-5. High overall rates of SVR12 (defined as undetectable HCV RNA 12 weeks after completing therapy), ranging from 92-100 percent, were achieved across difficult-to-cure patient populations including treatment-experienced patients and those with compensated or decompensated cirrhosis.

"The safety and efficacy profile of Epclusa are supported by large clinical and real-world global datasets," said Professor Lai Wei, Peking University People's Hospital and Institute of Hepatology, Peking University. "With high cure rates across all HCV genotypes, Epclusa could increase HCV treatment in China by potentially eliminating the need for genotype testing, which can be a barrier to treatment in many settings."

HCV is the fourth-most commonly reported infectious disease in China, with approximately 10 million people infected. HCV genotypes 1, 2, 3 and 6 account for more than 96 percent of all cases.

In the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,035 treatment-naïve and treatment-experienced patients with genotype 1-6 HCV infection, without cirrhosis or with compensated cirrhosis, received 12 weeks of Epclusa. Ninety-eight percent (1,015/1,035) of patients achieved SVR12. In the ASTRAL-5 study, 106 treatment-naïve and treatment-experienced patients with genotype 1-6 HCV infection, without cirrhosis or with compensated cirrhosis, who were coinfected with HIV and on a stable antiretroviral therapy, received 12 weeks of Epclusa. Ninety-five percent (101/106) of patients achieved SVR12.

The ASTRAL-4 study assessed the safety and efficacy of 12 weeks of Epclusa with or without RBV or 24 weeks of Epclusa in 267 HCV-infected patients with genotypes 1-4 and 6 decompensated cirrhosis (Child-Pugh B). Patients with decompensated cirrhosis receiving Epclusa with RBV for 12 weeks achieved 94 percent (82/87) SVR12.

The most common adverse reactions (≥10 percent) experienced by patients treated with Epclusa in ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-5 were headache and fatigue. The placebo-treated patients in the ASTRAL-1 experienced headache and fatigue at a similar frequency. The most common adverse reactions (≥10 percent) experienced by HCV-infected patients with decompensated cirrhosis treated with Epclusa and RBV in ASTRAL-4 were fatigue, anemia, nausea, headache, diarrhea and insomnia. Four patients treated with Epclusa with RBV, discontinued treatment due to adverse events.

"As the first once-daily, interferon-free single tablet regimen for HCV patients regardless of genotype, Epclusa offers physicians in China an important new option for effectively treating their patients while potentially helping to reduce the significant burden of HCV at a population level," said John F. Milligan, PhD, Gilead's President and Chief Executive Officer. "Gilead has now launched two direct-acting antiviral treatments in China, and we are committed to supporting efforts to screen and link patients to treatment, to help address the country's HCV epidemic."

Epclusa received marketing approval from the U.S. Food and Drug Administration (FDA) and the European Commission

in 2016 as the first pan-genotypic STR for HCV infection. It is also approved for use in 54 countries.

Sovaldi (sofosbuvir) as a single agent received marketing approval from the China Food and Drug Administration in 2017 for the treatment of adults infected with HCV genotype 1, 2, 3, 4, 5 or 6 and for adolescents (aged 12 to 18 years) with HCV genotype 2 or 3, as a component of a combination antiviral treatment regimen.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR EPCLUSA IN U.S.

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED 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 coinfected 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 coinfected 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 cirrhosis 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.

Indication

EPCLUSA is indicated for the treatment of adults with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and in combination with ribavirin for those with decompensated cirrhosis.

About Gilead Sciences, Inc.

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 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. 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, 2018, 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 and Sovaldi, including **BOXED WARNING** 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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