U.S. Food and Drug Administration Approves Gilead's Epclusa® (Sofosbuvir/Velpatasvir) for the Treatment of All Genotypes of Chronic Hepatitis C

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– Epclusa is the First and Only All-Oral, Pan-genotypic Single Tablet Regimen for Chronic Hepatitis C Virus Infection and Gilead's Third Sofosbuvir-Based Regimen –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 28, 2016-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Epclusa® (sofosbuvir 400 mg/velpatasvir 100 mg), the first all-oral, pan-genotypic, single tablet regimen for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection. Epclusa is also the first single tablet regimen approved for the treatment of patients with HCV genotype 2 and 3, without the need for ribavirin. Epclusa for 12 weeks was approved in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A), and in combination with ribavirin (RBV) for patients with decompensated cirrhosis (Child-Pugh B or C).

"The approval of Epclusa represents an important step forward in the global effort to control and potentially eliminate HCV as it provides a safe, simple and effective cure for the majority of HCV-infected patients, regardless of genotype," said Ira Jacobson, MD, Chairman of the Department of Medicine at Mount Sinai Beth Israel, New York City and a principal investigator in the Epclusa clinical trials. "Building on the established backbone of sofosbuvir, Epclusa demonstrated consistently high cure rates across all genotypes, including among patients with genotype 2 and 3, who traditionally have required ribavirin or other multi-pill regimens."

Photos and multimedia gallery available at www.GileadHCVMedia.com.

The FDA granted Epclusa a Priority Review and Breakthrough Therapy designation, which is given to investigational medicines that may offer major advances in treatment over existing options.

Epclusa's approval is supported by data from four international Phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-4. In the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,035 patients with genotype 1-6 chronic HCV infection, without cirrhosis or with compensated cirrhosis received 12 weeks of Epclusa. The ASTRAL-4 study randomized 267 patients with genotype 1-6 HCV infection, with decompensated cirrhosis (Child-Pugh B), to receive 12 weeks of Epclusa with or without RBV or 24 weeks of Epclusa. The primary endpoint for all studies was SVR12.

Of the 1,035 patients treated with Epclusa for 12 weeks in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,015 (98 percent) achieved SVR12. In ASTRAL-4, patients with decompensated cirrhosis receiving Epclusa with RBV for 12 weeks achieved a high SVR12 rate (94 percent) compared to those who received Epclusa for 12 weeks or 24 weeks (83 percent and 86 percent, respectively).

Headache and fatigue were the most common adverse reactions (≥10 percent) experienced by HCV-infected patients treated with Epclusa in ASTRAL-1, ASTRAL-2 and ASTRAL-3 and occurred at a similar or higher frequency in placebo-treated patients. In the 87 HCV-infected patients with decompensated cirrhosis treated with Epclusa and ribavirin in the ASTRAL-4 study, fatigue, anemia, nausea, headache, insomnia and diarrhea were the most common adverse reactions (≥10 percent). Two and four patients treated with Epclusa and Epclusa with RBV respectively discontinued treatment due to adverse events.

"Today's approval represents a significant advance for patients with HCV genotypes 2 and 3, who previously required more complex and costly regimens," said John Milligan, Ph.D., President and Chief Executive Officer of Gilead. "As the first and only pan-genotypic cure for hepatitis C, Epclusa has the potential to eliminate the need for genotype testing, which can be a barrier to treatment in certain resource-constrained settings. We look forward to making Epclusa available to patients around the world as quickly as possible."

Epclusa should not be administered with ribavirin in patients for whom ribavirin is contraindicated. See below for Important Safety Information for Epclusa.

U.S. Patient Support Program

To assist eligible hepatitis C patients in the United States with access to Epclusa, Gilead has added the medicine to its Support Path® (www.MySupportPath.com) program. The program consists of an integrated offering of support services for patients and providers, among them:

- Call center staffed with associates trained to help patients and their providers with insurance-related needs.
- Education and support, including a 24/7 nursing support service line.
- The Epclusa Co-pay Coupon Programs, which provide co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than $5 per co-pay.
- The Support Path Patient Assistance Program, which will provide Epclusa at no charge for eligible patients with no other insurance options.

Gilead also provides support to independent non-profit organizations that provide assistance for eligible federally-insured and privately-insured patients who need help covering out-of-pocket medication costs.

To learn more about Support Path for Epclusa, please visit www.MySupportPath.com or call 1-855-769-7284 between 9:00 a.m. – 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 eliminates 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, the Medicines Patent Pool and other stakeholders to expand treatment globally. Epclusa is already licensed to Gilead's 11 Indian manufacturing partners who may now begin production and distribution of a generic version of this medicine for 101 developing countries.

IMPORTANT SAFETY INFORMATION

Contraindications

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

Warnings and Precautions

Risk of Serious Symptomatic Bradycardia When Sofosbuvir Is Coadministered with Amiodarone and Another HCV Direct Acting Antiviral: 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. 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 risks that physicians and patients may not see advantages of Epclusa over other therapies and may therefore be reluctant to prescribe the product, and the risk that payers may be reluctant to approve or provide reimbursement for the product. 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, 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.

U.S. Full Prescribing Information for Epclusa 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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