U.S. Food and Drug Administration Approves Gilead's Vosevi™ (Sofosbuvir/Velpatasvir/Voxilaprevir) for Re-Treatment of Adults with Chronic Hepatitis C Virus

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- Vosevi is the First Once-daily Single-Tablet HCV Regimen Approved as Salvage Therapy for Certain Patients and Completes Gilead's Portfolio of Sofosbuvir-based HCV Direct-acting Antiviral (DAA) Treatments -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 18, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Vosevi™ (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) tablets, a single-tablet regimen for the re-treatment of chronic hepatitis C virus (HCV) infection in adults with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. The approval is based on data from the Phase 3 POLARIS-1 and POLARIS-4 studies, which evaluated 12 weeks of Vosevi in direct-acting antiviral-experienced chronic HCV-infected patients without cirrhosis or with compensated cirrhosis.

"Direct-acting antiviral regimens have transformed HCV treatment and have allowed health care providers the fortunate opportunity to cure many patients. However, for patients who require re-treatment, there remains an unmet clinical need for an effective and well-tolerated option," said Ira Jacobson, MD, Chairman of the Department of Medicine at Mount Sinai Beth Israel, New York City and a principal investigator in the Vosevi clinical trials. "Treatment with Vosevi resulted in high cure rates in clinical studies of patients who were not previously cured with several widely-prescribed DAA regimens and will provide physicians with an important new therapeutic option that could offer hope for their hardest-to-treat patients."

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

Vosevi is the latest single-tablet regimen in Gilead's portfolio of sofosbuvir-based DAA treatments that offer people living with HCV a short course of therapy to cure their HCV, with the convenience associated with once-daily single-tablet regimens. Since 2013, Gilead has brought to market four HCV treatments, including 3 single-table regimens. To date, more than an estimated 1.4 million patients worldwide have been treated with sofosbuvir-based regimens.

"The evolution of Gilead's portfolio of HCV single-tablet regimens has been driven by our commitment to address previously unmet needs and put the possibility of cure within reach for as many HCV patient populations as possible," said John F. Milligan, PhD, Gilead's President and Chief Executive Officer. "The approval of Vosevi completes our portfolio by fulfilling the unmet need for an effective regimen for patients who could not be cured, despite prior treatment with certain DAA regimens."

The approval of Vosevi is supported by data from the POLARIS-1 study evaluating 12 weeks of treatment among adults with HCV genotype 1, 2, 3, 4, 5 or 6 with or without compensated cirrhosis who had failed prior treatment with an NS5A inhibitor-containing regimen, as well as data from the POLARIS-4 study evaluating 12 weeks of treatment among adults with HCV genotypes 1a and 3 with or without compensated cirrhosis who had failed prior treatment with a sofosbuvir-containing regimen that did not include an NS5A inhibitor. In these populations across the two studies, 340 of the 353 patients treated with Vosevi (96 percent) achieved the primary endpoint of SVR12, defined as maintaining undetectable viral load 12 weeks after completing therapy.

The most common adverse events (≥10% of patients) among patients who received Vosevi were headache, fatigue, diarrhea and nausea. The proportion of subjects who permanently discontinued treatment due to adverse events was 0.2% for subjects who received Vosevi for 12 weeks.

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 Gilead HCV medications, including Vosevi. Support Path conducts benefits investigations and provides patients with information regarding their insurance options.

Further, the Vosevi 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 Vosevi, 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.

IMPORTANT SAFETY INFORMATION

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 Vosevi. 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

- Vosevi is contraindicated with rifampin.

Warnings and Precautions

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with Vosevi 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 Vosevi with P-gp Inducers and/or Moderate to Potent Inducers of CYP2B6, CYP2C8 or CYP3A4:** St. John's wort and carbamazepine are not recommended for use with Vosevi as they may significantly decrease sofosbuvir, velpatasvir, and/or voxilaprevir plasma concentrations.

Adverse Reactions

- The most common adverse reactions (≥10%, all grades) with Vosevi were headache, fatigue, diarrhea, and nausea.

Drug Interactions

- Coadministration of Vosevi is not recommended with phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, rosuvastatin, pitavastatin, and cyclosporine due to changes (decreased or increased) in concentrations of sofosbuvir, velpatasvir, voxilaprevir, and/or the other agent.

Consult the full Prescribing Information for Vosevi 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 Vosevi for the treatment of adults with chronic HCV infection. 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 Vosevi, including **BOXED WARNING**, is available at www.gilead.com.*

Vosevi is a 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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