

European Commission Grants Marketing Authorization for Gilead's Vosevi® (Sofosbuvir/Velpatasvir /Voxilaprevir) for the Treatment of All Genotypes of Chronic Hepatitis C

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-- Vosevi is the First and Only Single Tablet Regimen for Patients Who Have Previously Failed Therapy with Direct-Acting Antivirals --

-- European Commission Also Extends Marketing Authorization for Harvoni® (sofosbuvir/ledipasvir), Enabling First Direct-Acting Antiviral Regimen for Adolescent Hepatitis C Patients --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 28, 2017-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the European Commission has granted marketing authorization for Vosevi® (sofosbuvir 400mg/velpatasvir 100mg/voxilaprevir 100mg), as a once-daily single tablet regimen for the treatment of adults with genotype 1-6 chronic hepatitis C virus (HCV) infection.

Vosevi was authorized as a 12-week treatment regimen for patients with any genotype of chronic HCV infection, without cirrhosis or with compensated cirrhosis, who have previously failed therapy with a direct-acting antiviral (DAA)-containing regimen. A 12-week regimen was also authorized for use in DAA-naïve patients with compensated cirrhosis infected with any HCV genotype, with an option to shorten therapy to 8 weeks for those infected with genotype 3. For DAA-naïve patients without cirrhosis, the recommended treatment duration is 8 weeks.

“DAA-based therapies have transformed our ability to treat hepatitis C. However, until now we have had limited options for patients who have failed to achieve cure with these regimens,” said Professor Michael Manns, Director of the Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany. “Vosevi has demonstrated high cure rates across a range of DAA-experienced patients, with a simple 12-week single tablet regimen. Availability of Vosevi will have a significant impact for this group of patients, offering them the opportunity to be cured of this disease.”

Gilead also today announced an extension of the marketing authorization for Harvoni® (ledipasvir 90mg/sofosbuvir 400mg). Previously authorized for the treatment of adults with chronic HCV genotype 1, 3, 4, 5 or 6 infection, the indication for Harvoni has been extended to include the treatment of chronic HCV genotype 1, 3, 4, 5 and 6 infection in adolescents aged 12 to < 18 years. Harvoni is the first direct-acting antiviral regimen to receive marketing authorization in the European Union extended for use in the adolescent population.

“The authorization of Vosevi and the extended indication for Harvoni demonstrate our ongoing commitment to bring therapies with high cure rates to all HCV-infected patients,” said John Milligan, PhD, Gilead's President and Chief Executive Officer. “We look forward to working with healthcare providers and governments to ensure Vosevi is made available to patients who would benefit the most from it, while continuing to expand the benefits of our other approved medicines for patients with chronic HCV infection across Europe.”

Sofosbuvir-based regimens are recommended by global guidelines across HCV genotypes and disease severities and have been used to treat more than 1.5 million patients worldwide. Vosevi is Gilead's fourth sofosbuvir-based treatment to be granted marketing authorization by the European Commission for the treatment of chronic HCV infection. The marketing authorization of Vosevi follows an accelerated review procedure by the European Medicines Agency, reserved for medicinal products expected to be of major public health interest. It allows for the marketing of Vosevi in all 28 countries of the European Union. Gilead will now work diligently with national pricing and reimbursement agencies across Europe to make Vosevi available to patients.

The approval of Vosevi is supported by data from four Phase 3 studies. Two studies (POLARIS-1 and POLARIS-4) evaluated 12 weeks of the single tablet regimen in patients with hepatitis C genotypes 1-6 previously treated

unsuccessfully with DAA-containing regimens, including NS5A inhibitors. Two other studies (POLARIS-2 and POLARIS-3) evaluated 8 weeks of Vosevi in DAA-naïve patients with hepatitis C genotypes 1-6. Across POLARIS-1 and POLARIS-4, 97 percent of patients treated with Vosevi (n=431/445) achieved the primary efficacy endpoint of SVR12. In POLARIS-2, 95 percent of patients with hepatitis C genotypes 1-6 with and without cirrhosis treated with Vosevi (n=477/501) achieved the primary efficacy endpoint of SVR12. In POLARIS-3, 96 percent of patients with genotype 3 infection and compensated cirrhosis treated with Vosevi (n=106/110) achieved the primary efficacy endpoint of SVR12. The most common adverse drug reactions among patients who received Vosevi in the POLARIS studies were headache, diarrhea and nausea.

Sofosbuvir as a single agent was granted marketing authorization in the European Union on January 16, 2014, under the trade name Sovaldi[®], for use in combination with other agents for the treatment of adults with chronic HCV infection. The single tablet regimen, Harvoni, received marketing authorization in the European Union on November 18, 2014. The single tablet regimen of sofosbuvir (400mg) and velpatasvir (100mg) received marketing authorization in the European Union on July 8, 2016, under the trade name Epclusa[®] for the treatment of adults with chronic HCV infection.

Vosevi was approved by the U.S. Food and Drug Administration on July 18, 2017 for the re-treatment of adults with genotype 1-6 chronic HCV infection.

Important Safety Information for Vosevi

Contraindications include hypersensitivity to the active substances or to any of the excipients. Co-administration with strong P-glycoprotein (P-gp) and/or strong cytochrome P450 (CYP) inducers (e.g. rifampicin, rifabutin, St. John's wort [*Hypericum perforatum*], carbamazepine, phenobarbital and phenytoin) are contraindicated. Co-administration with strong OATP1B inhibitors (e.g. ciclosporin), rosuvastatin, dabigatran etexilate and ethinylestradiol-containing medicinal products is also contraindicated.

Patients co-infected with hepatitis C and hepatitis B are at risk of hepatitis B virus reactivation and should therefore be monitored and managed according to current clinical guidelines.

Caution and frequent renal monitoring is recommended for co-administration with certain HIV antiretroviral treatments (e.g. tenofovir disoproxil fumarate- and efavirenz-containing regimens). Safety has not been established in patients with severe renal impairment (glomerular filtration rate <30ml/min).

Monitoring of digoxin and amiodarone is recommended when used with sofosbuvir/velpatasvir/voxilaprevir.

The “interaction with other medicinal products and other forms of interaction” section of the Vosevi EU Summary of Product Characteristics (SmPC) should be consulted before starting therapy with sofosbuvir/velpatasvir/voxilaprevir.

Sofosbuvir/velpatasvir/voxilaprevir should not be administered concomitantly with other medicinal products containing sofosbuvir.

In clinical studies, headache, diarrhoea and nausea were the most commonly reported adverse drug reactions.

Important Safety Information for Harvoni

Contraindications include hypersensitivity to the active substances or to any of the excipients. Co-administration with rosuvastatin or St. John's wort (*Hypericum perforatum*) is contraindicated. Co-administration with certain P-glycoprotein (P-gp) inducers (e.g. rifampicin, carbamazepine and phenytoin) is not recommended. For patients on statins dose reduction should be considered and careful monitoring for statin adverse events (myopathy and rhabdomyolysis) should be undertaken.

Patients co-infected with hepatitis C and hepatitis B are at risk of hepatitis B virus reactivation and should therefore be

monitored and managed according to current clinical guidelines.

Caution and frequent renal monitoring is recommended for co-administration with certain HIV antiretroviral regimens. Safety has not been established in patients with severe renal impairment.

Monitoring of digoxin and dabigatran is recommended when used with ledipasvir/sofosbuvir.

Ledipasvir/sofosbuvir should not be administered concomitantly with other medicinal products containing sofosbuvir.

In clinical studies headache, fatigue and nausea were more common in patients treated with ledipasvir/sofosbuvir compared to placebo.

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 worldwide. 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 or Harvoni for the treatment of adolescents 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.

Full European Summary of Product Characteristics for Vosevi, Sovaldi, Harvoni and Epclusa are available from the EMA website at www.ema.europa.eu.

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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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Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.

Investors:

Sung Lee, +1 650-524-7792

or

Media

Mark Snyder, +1 650-522-6167