Gilead Announces Scientific Presentations Demonstrating Efficacy of Harvoni® (Ledipasvir/Sofosbuvir) in Special Patient Populations With HCV Infection

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-- Results Presented at The International Liver Congress™ 2017 Highlight Progress for the Treatment of Pediatric HCV and Adult HCV/HBV Co-Infected Patient Populations --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 21, 2017-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from two Phase 2 studies evaluating Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg, LDV/SOF) tablets in chronic hepatitis C virus (HCV)-infected patient populations not previously studied in dedicated clinical trials with direct-acting antiviral therapies. The studies demonstrated HCV cure rates of 99 percent in children aged 6 to 11 years (#PS-101), and 100 percent in adult patients co-infected with HCV and hepatitis B virus (HBV) (#PS-098). Detailed results from these studies were presented this week at The International Liver Congress™ 2017 in Amsterdam.

Harvoni is approved in the United States for the treatment of genotype 1, 4, 5, or 6 chronic HCV infection in adults and pediatric patients 12 years of age or older or weighing at least 35 kilograms. Harvoni is indicated with ribavirin (RBV) for the treatment of chronic HCV genotype 1 or 4 HCV infection in liver transplant recipients without cirrhosis or with compensated cirrhosis and for genotype 1 HCV-infected patients with decompensated cirrhosis.

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

“Gilead continues to study the safety and efficacy of our medicines in HCV-infected patients with unmet medical need, to help realize the potential for cure,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer, Gilead Sciences. “In these studies of younger children with hepatitis C and HCV/HBV co-infected patients, Harvoni achieved high cure rates and demonstrated safety consistent with the known profile of the drug.”

Children Aged 6 to 11 Years with Chronic HCV

The estimated prevalence of HCV infection in children is up to 0.4 percent in Europe and the United States and up to 6 percent in resource-limited countries. For children 6-11 years of age weighing less than 35 kilograms, interferon plus RBV for up to 48 weeks remains the standard of care.

Results from an open-label Phase 2 study, led by Karen F. Murray, MD, Professor of Pediatrics at Seattle Children’s Hospital in Seattle, Washington, evaluating an investigational dosage strength of a once-daily single tablet of Harvoni (ledipasvir 45 mg/sofosbuvir 200 mg) in HCV-infected children aged 6 to 11 years, demonstrated cure rates of 99 percent (n=89/90). Genotype 1 patients received 12 weeks of treatment (n=85); one genotype 1 patient who had cirrhosis and prior treatment failure with pegylated interferon plus RBV received 24 weeks of treatment; genotype 3 patients (n=2) received Harvoni plus RBV for 24 weeks; genotype 4 patients (n=2) received Harvoni for 12 weeks. One treatment-naïve genotype 1 patient relapsed; all other patients achieved SVR12, the primary efficacy endpoint. The most common adverse events (>10 percent) all of which were mild to moderate in severity, were abdominal pain, headache, diarrhea, vomiting, nausea, fatigue, pyrexia, cough and oropharyngeal pain. No patients discontinued therapy.

HCV/HBV Co-infected Patients

The global prevalence of HCV/HBV co-infection is estimated to be 1.7–3.9 million. Reactivation of HBV infection during treatment of HCV infection with direct-acting antiviral agents has been reported in the postmarketing setting. However, clinical trials to more systematically assess the safety and efficacy of direct-acting antiviral therapy in HCV/HBV co-infected patients with active HBV infection have not been conducted.

This Phase 2, open-label study led by Chun-Jen Liu, Professor of Medicine at National Taiwan University in Taipei, Taiwan, evaluated 12 weeks of Harvoni in 111 genotype 1 or 2 HCV-infected patients in Taiwan with active HBV co-infection (hepatitis B surface antigen positive), who were not receiving HBV treatment. All patients achieved SVR12 (100 percent, 111/111) including 68 genotype 1 HCV-infected patients, 43 genotype 2 HCV-infected patients, 17 patients with compensated cirrhosis and 37 with prior HCV treatment failure.

Three patients had serious adverse events that were not considered to be drug-related, including optic neuritis, post-procedural bleeding and duodenal ulcer bleeding. The most common adverse events reported (≥5 percent of patients) were headache, upper respiratory infection and fatigue.

Of the 111 patients enrolled, 23 (21 percent) experienced an increase in HBV DNA of at least 2 log10 IU/mL during or following Harvoni treatment. However, no patient experienced a grade 3 or 4 ALT increase or any clinical manifestations suggestive of HBV reactivation. There were two patients that started HBV treatment based on increases in HBV DNA and mild elevations in ALT without symptoms.

Further information about the clinical studies described above can be found at www.clinicaltrials.gov.

Certain uses for Harvoni highlighted above are investigational and have not been determined to be safe or efficacious.

U.S. Important Safety Information for Harvoni

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HBV/HCV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with Harvoni.

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 Harvoni 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

- **Risk of Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with Harvoni 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 of Harvoni Due to P-gp Inducers:** Rifampin and St. John's wort are not recommended for use with Harvoni as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations.
- **Related Products Not Recommended:** Harvoni is not recommended for use with other products containing sofosbuvir.

Adverse Reactions

Most common (≥10%, all grades) adverse reactions were fatigue, headache and asthenia.

Drug Interactions

- In addition to rifampin and St. John's wort, coadministration of Harvoni is also not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of ledipasvir and sofosbuvir, reducing the therapeutic effect of Harvoni.
- Coadministration of Harvoni is not recommended with simeprevir due to increased concentrations of ledipasvir and simeprevir. Coadministration is also not recommended with rosuvastatin or co-formulated elvitegravir/cobicistat /emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of rosuvastatin and tenofovir, respectively.

Consult the full Prescribing Information for Harvoni 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 Harvoni in special patient populations with 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 Annual Report on Form 10-K for the year ended December 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 Harvoni, including **BOXED WARNING**, is available at www.gilead.com.*

Harvoni 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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