CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION APPROVES HARVONI® (LEDIPASVIR/SOFOSBUVIR) FOR TREATMENT OF CHRONIC HEPATITIS C VIRUS GENOTYPE 1-6

Dec.14th, 2018

--Harvoni Offers Highly Effective, Short-Duration, Pan-Genotypic Treatment for Chinese Patients with HCV Infection--

--Harvoni Achieved Cure Rate (SVR12) of 100% Percent in Clinical Trial of Chinese Patients with Genotype 1--

Foster City, Calif. – **December 4, 2018** – Gilead Sciences, Inc. (NASDAQ: GILD) announced today that the National Medical Products Administration (NMPA) has approved Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg) in China for the treatment of chronic hepatitis C virus (HCV) genotype 1- 6 infection in adults and adolescents aged 12 to 18 years.

Hepatitis C is a significant public health challenge. Nearly 10 million people in China are estimated to have chronic HCV, with approximately 58 percent having HCV genotype 1 infection.

"The multicenter clinical trials in China have shown that the once-daily single-tablet treatment regimen of Harvoni® achieved a 100% SVR12 (defined as undetectable HCV RNA 12 weeks after completing therapy) rate in treatment patients with genotype 1 HCV infection", said Professor Lai Wei, Peking University People's Hospital and Institute of Hepatology, Beijing.

"Gilead has continued to develop and deliver new treatments for HCV to help enable people with HCV the potential to be cured," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. "We are pleased to offer an important new treatment option that can help patients achieve HCV cure and further support efforts to stem the epidemic in China."

The approval of Harvoni® in China is supported by an open-label, phase 3b study, which was conducted at 18 study centers in mainland China between May 2016 and July 2017. The study evaluated 12 weeks of treatment with Harvoni in 206 genotype 1 HCV patients, including treatment-naïve and treatment-experienced patients without cirrhosis or with compensated cirrhosis.

In the study, 100 percent of patients achieved SVR12. The most common adverse reactions (≥10 percent) experienced by patients treated with Harvoni were viral upper respiratory tract infection and upper respiratory tract infection.

- more -

Harvoni US 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 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 posttreatment 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
- **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 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.

Adverse Reactions
- Most common adverse reactions (≥10%, all grades) 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.

US Indication

HARVONI is indicated for the treatment of chronic hepatitis C virus (HCV) genotype (GT) 1, 4, 5, or 6 infection in patients at least 12 years of age (or ⩾35 kg) without cirrhosis or with compensated cirrhosis. HARVONI is used with ribavirin in GT 1 adults with decompensated cirrhosis and in GT 1 or 4 adult liver transplant recipients without cirrhosis or with compensated cirrhosis.

About Gilead Sciences

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 Harvoni in 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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, including ***BOXED WARNING*** for Harvoni® *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.