China Food and Drug Administration Approves Gilead's Sovaldi® (Sofosbuvir) for Treatment of Chronic Hepatitis C Virus Infection

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- Sovaldi-based Regimens Demonstrated High Rates of Sustained Virologic Response or Cure for Chinese Hepatitis C Infected Patients -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 25, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) announced today that the China Food and Drug Administration (CFDA) has approved Sovaldi® (sofosbuvir 400mg), a once-daily oral nucleotide analog polymerase inhibitor for the treatment of chronic hepatitis C virus (HCV) infection. Sovaldi was approved for the treatment of adults and adolescents (aged 12 to 18 years) infected with HCV genotype 1, 2, 3, 4, 5 or 6 as a component of a combination antiviral treatment regimen. Sovaldi is the first Gilead HCV medicine approved in China.

The approval of Sovaldi is supported by a Phase 3 study conducted in China, presented earlier this year at the Asian Pacific Association for the Study of the Liver (APASL) meeting. SVR12 (HCV RNA undetectable 12 weeks after completing therapy) rates for Chinese HCV patients with genotype 1, 2, 3 or 6 ranged from 92-100 percent. The study evaluated Sovaldi in combination with ribavirin (RBV) or pegylated interferon+ribavirin (PegIFN+RBV) across a range of difficult-to-cure patient populations, including treatment-experienced patients and those with compensated cirrhosis. In this study, the safety profiles of the regimens were consistent with the known side effects of pegylated interferon and/or ribavirin. The most common adverse events were hematological abnormalities and pyrexia.

Professor Lai Wei, the principal investigator of Sovaldi's Phase 3 study and former Chairman of the Chinese Society of Hepatology of the Chinese Medical Association said, "The approval of sofosbuvir in China provides more treatment options for Chinese HCV patients. The clinical trials in China and around the world provide evidence that the treatment is effective for multiple genotypes, which offers HCV patients in China a better chance at curing their disease."

HCV is the fourth-most commonly reported infectious disease in China, with approximately 10 million people infected. HCV genotypes 1, 2, 3 and 6 account for more than 96 percent of all cases. Less than one percent of HCV patients are currently treated, using interferon-based regimens that have lower efficacy, longer treatment duration and less favorable safety profiles than more recent regimens that contain direct-acting antiviral medicines.

"With the approval of Sovaldi, there is now the potential opportunity to transform treatment for HCV patients in China," said John F. Milligan, PhD, Gilead's President and Chief Executive Officer. "Medicines are one part of the solution but, as we have seen in other countries around the world, there are many other challenges that impact diagnosis, linkage to care and treatment. Gilead is committed to working with the government and other stakeholders with the goal to help reduce the significant burden of HCV disease in China."

Sovaldi received marketing approval from the U.S. Food and Drug Administration (FDA) in 2013 and the European Commission in 2014. It is also approved for use in 79 countries including Australia, India, Indonesia, the Philippines, New Zealand, Canada, Egypt, Switzerland and Turkey.

Gilead Sciences in China

Gilead has been present in China since 2007, starting with manufacturing and growing over time to include the establishment of commercial operations based in Shanghai in 2016.

Beyond the approval of Sovaldi, Gilead is studying its HCV single-tablet regimens Harvoni® (ledipasvir/sofosbuvir) and Epclusa® (sofosbuvir/velpatasvir) at clinical trials sites across China, with the aim of providing important new treatment options to Chinese HCV patients.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR SOVALDI IN U.S.

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 SOVALDI. 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

- Contraindications to peginterferon alfa and ribavirin also apply to SOVALDI combination treatment. Refer to the Prescribing Information for peginterferon alfa and ribavirin for a list of their contraindications.

Warnings and Precautions

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with SOVALDI 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 Use with P-gp Inducers:** Rifampin and St. John's wort are not recommended for use with SOVALDI as they may significantly decrease sofosbuvir plasma concentrations.
- **Risk Associated with Combination Treatment:** Because SOVALDI is used in combination with other antiviral drugs for the treatment of HCV infection, consult the Prescribing Information for these drugs.

Adverse Reactions

Most common adverse reactions (≥20%, all grades) for:

- SOVALDI + peginterferon alfa + ribavirin combination therapy were fatigue, headache, nausea, insomnia, and anemia.
- SOVALDI + ribavirin combination therapy were fatigue and headache.

Drug Interactions

- In addition to rifampin and St. John's wort, coadministration of SOVALDI is not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of sofosbuvir, reducing its therapeutic effect.

Indication:

SOVALDI is indicated for the treatment of chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen:

- genotype (GT) 1 or 4 infected adults without cirrhosis or with compensated cirrhosis, in combination with pegylated interferon and ribavirin.
- GT 2 or 3 infected patients at least 12 years of age (or ≥35 kg) without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

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 in China may not see the benefits of prescribing Sovaldi for the treatment 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 June 30, 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 Sovaldi, including **BOXED WARNING** is available at www.gilead.com*

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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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