

Treatment with Gilead’s Investigational Single Tablet Regimen Ledipasvir/Sofosbuvir Resulted in A Cure Rate Of 100 Percent in Chinese Chronic Hepatitis C Patients

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- Results from 12-week Study of Ledipasvir/Sofosbuvir in Patients with the Most Prevalent HCV Genotype (GT1) in China to be Presented at The Liver Meeting® 2017-

SHANGHAI -- Oct. 20, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced results of a Phase 3 study of the investigational once-daily, single tablet regimen ledipasvir 90mg/sofosbuvir 400mg (LDV/SOF) in Chinese patients with genotype 1 chronic hepatitis C virus (HCV) infection, with or without compensated cirrhosis. Patients were recruited from 18 sites in China. Treatment with LDV/SOF for 12 weeks resulted in 100 percent (n=206) of patients achieving sustained virologic response, defined as an undetectable viral load 12 weeks after completing therapy. Data from the study will be presented tomorrow during a poster session at The Liver Meeting® 2017 in Washington, DC (Poster #1191).

“Of the approximately 10 million people infected with HCV in China, more than half are infected with HCV genotype 1. Effective and well-tolerated HCV therapies are needed for this patient population to help address the significant burden of disease in China,” said Professor Lai Wei, the principal investigator for the study and former chairman of the Chinese Society of Hepatology of the Chinese Medical Association. “In this study, ledipasvir/sofosbuvir cured 100 percent of genotype 1 patients, regardless of prior treatment experience, baseline presence of resistance mutations, and cirrhosis status, with few adverse events.”

Treatment-emergent adverse events (AEs) reported in greater than five percent of patients in this study were viral upper respiratory tract infection (18 percent, n=36) and upper respiratory tract infection (14 percent, n=28). There were no discontinuations due to AEs, no serious or severe AEs related to study drug, and no deaths.

“Ledipasvir/sofosbuvir has achieved high cure rates with simple, well-tolerated once-daily dosing both in clinical studies and the real-world experience of patients around the world,” said Norbert Bischofberger, PhD, executive vice president of research and development and chief scientific officer at Gilead. “The results of this Phase 3 study of ledipasvir/sofosbuvir in China are consistent with international experience and will be the foundation for a planned new drug application filing with China FDA.”

LDV/SOF is an investigational medicine in China and has not been determined to be safe or efficacious in Chinese patients.

Gilead Sciences in China

Gilead is committed to address the unmet medical need in China through bringing forward our innovative products to the patients here. The company 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. In September 2017, the China Food and Drug Administration (CFDA) approved Gilead’s Sovaldi® (sofosbuvir 400mg), for the treatment of chronic HCV infection as a component of a combination antiviral treatment regimen. Sovaldi is the first Gilead HCV medicine to be approved in China. Along with LDV/SOF, Gilead is also studying its HCV single-tablet regimen sofosbuvir/velpatasvir in clinical trials at sites across China.

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.

For more information on Gilead Sciences, please visit the company's Chinawebsite at www.gileadchina.com, contact Gilead Public Affairs at infochina@gilead.com, or follow Gilead on WeChat by scanning the QR code below:

