# Gilead Files for U.S. Approval of Ledipasvir/Sofosbuvir Fixed-Dose Combination Tablet for Genotype 1 Hepatitis C

Press Release
Date(s): 10-Feb-2014 4:05 PM

-- If Approved, Fixed-Dose Combination Would be First Oral Treatment Regimen for Patients with Genotype 1 HCV Infection, Eliminating Need for Both Interferon and Ribavirin --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 10, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for a once-daily fixed-dose combination of the NS5A inhibitor ledipasvir (LDV) 90 mg and the nucleotide analog polymerase inhibitor sofosbuvir (SOF) 400 mg for the treatment of chronic hepatitis C genotype 1 infection in adults. The data submitted in the NDA support the use of LDV/SOF in patients with genotype 1 hepatitis C virus (HCV) infection, with a treatment duration of eight or 12 weeks depending on prior treatment history and whether they have cirrhosis. Approximately 75 percent of people infected with HCV in the United States have the genotype 1 strain of the virus.

"Today's filing brings us one step closer to our goal of offering all patients with hepatitis C a simple, safe and highly effective all-oral treatment regimen," said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer. "Based on the data from the Phase 3 ION studies, the LDV/SOF combination may have the potential to cure HCV in genotype 1 patients in as little as eight weeks and without the need for interferon injections or ribavirin."

The FDA has assigned LDV/SOF a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options. The NDA for LDV/SOF is supported by three Phase 3 studies, ION-1, ION-2 and ION-3, in which nearly 2,000 genotype 1 HCV patients were randomized to receive the fixed-dose combination, with or without RBV, for treatment durations of eight, 12 or 24 weeks. Trial participants included patients who were treatment-naïve or who had failed previous treatment, including protease inhibitor-based regimens, and also included patients with compensated cirrhosis.

Gilead plans to file for regulatory approval of LDV/SOF in other geographies, including the European Union, in the first quarter of 2014. Gilead has submitted an application to the European Medicines Agency (EMA) for accelerated assessment of LDV/SOF, a designation that is granted to new therapies and medicines of major public health interest. If accepted, accelerated assessment could shorten the EMA's review time of LDV/SOF by two months, although it does not guarantee a positive opinion from the Committee for Medicinal Products for Human Use or approval by the European Commission.

LDV/SOF is an investigational product and its safety and efficacy has not yet been established.

SOF as a single agent was approved by the FDA under the tradename Sovaldi® on December 6, 2013 and by the European Commission on January 17, 2014.

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. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia Pacific.

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 FDA may not approve the LDV/SOF fixed-dose combination, and that any marketing approvals, if granted, may have significant limitations on its use. In addition, Gilead may be unable to file for regulatory approval of LDV/SOF in other geographies in the currently anticipated timelines. Further, additional clinical studies of LDV/SOF, including results from the 24-week arms of ION-1, may produce unfavorable results. As a result, Gilead may not be able to successfully commercialize LDV/SOF, and may make a strategic decision to discontinue its development if, for example, the market for the product fails to materialize as expected. 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, 2013, 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 is available at www.Gilead.com.