Data from Phase 3 Studies of Gilead's Sofosbuvir for Hepatitis C To Be Presented at 48th Annual EASL Meeting; Findings Published Online Today in *The New England Journal of Medicine*

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AMSTERDAM--(BUSINESS WIRE)--Apr. 23, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that detailed results from four Phase 3 clinical trials (NEUTRINO, FISSION, POSITRON and FUSION) evaluating sofosbuvir, the company's investigational once-daily nucleotide NS5B inhibitor for the treatment of chronic hepatitis C virus (HCV) infection, will be presented this week in oral sessions at the 48th Annual Meeting of the European Association for the Study of the Liver (International Liver Congress 2013) in Amsterdam, The Netherlands. In addition, detailed results from the four clinical studies have also been published online in two papers, ahead of print, in *The New England Journal of Medicine (NEJM).*

In the four trials, sofosbuvir was administered to nearly 1,000 patients with chronic HCV infection as part of an all-oral 12-week or 16-week treatment regimen in combination with ribavirin (RBV) in genotypes 2 and 3, or with RBV and pegylated interferon (peg-IFN) for 12 weeks in genotypes 1, 4, 5 and 6. Overall SVR12 rates (sustained viral response 12 weeks after completing therapy) from 50 to 90 percent were observed. Patients who achieve SVR12 are considered cured of their HCV infection.

A description of the four Phase 3 studies and SVR12 results are summarized in the table below. Detailed results from the Phase 3 studies of sofosbuvir are available at www.nejm.org/online-first.

Sofosbuvir Phase 3 Studies

Study	Population	Treatment groups	SVR12 Rates
NEUTRINO	Genotype 1/4/5/6 treatment-naïve	Sofosbuvir + RBV + Peg-IFN for 12 weeks	90% (295/327)
FISSION	Genotype 2/3 treatment-naïve	Sofosbuvir + RBV for 12 weeks **or**	67% (107/253)
		Peg-IFN + RBV for 24 weeks	67% (162/243)
POSITRON	Genotype 2/3, IFN intolerant, ineligible or unwilling	Sofosbuvir + RBV for 12 weeks **or**	78% (161/207)
		Placebo for 12 weeks	0% (0/71)
FUSION	Genotype 2/3 treatment-experienced	Sofosbuvir + RBV for 12 weeks **or**	50% (50/100)
		Sofosbuvir + RBV for 16 weeks	73% (69/95)

"There remains an urgent unmet medical need for individuals diagnosed with chronic hepatitis C infection," commented Ira Jacobson, MD, Chief of the Division of Gastroenterology and Hepatology, Vincent Astor Distinguished Professor of Medicine, The Joan Sanford I. Weill Medical College of Cornell University, Attending Physician, New York-Presbyterian Hospital Cornell Campus. "The breadth of data from the Phase 3 program evaluating sofosbuvir will help physicians understand how to treat the disease in the future across various HCV genotypes and patient populations."

"In these particular studies, sofosbuvir-based HCV therapy demonstrated high efficacy rates and a favorable safety profile while reducing the need for interferon injections to 12 weeks, or eliminating interferon completely from the regimen," said Eric Lawitz, MD, President and Medical Director, The Texas Liver Institute, University of Texas Health Science Center, San Antonio. "Based on these findings, sofosbuvir, once approved, has the potential to play an important role in addressing the global hepatitis C epidemic."

The NS5b region of the HCV viral genome for all patients who relapsed was sequenced and no S282T mutations were observed by population or deep sequencing (1 percent cutoff). There was no change in susceptibility to sofosbuvir or RBV observed by phenotypic analyses.

With the exception of one patient in FISSION who was non-compliant, relapse accounted for all virologic failures. Adverse events were generally mild and included fatigue, nausea, headache, insomnia, pruritis, anemia and dizziness. Less than 2 percent of patients in the sofosbuvir treatment groups discontinued due to adverse events.

On April 8, Gilead submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for sofosbuvir for the treatment of HCV infection. The data submitted in the NDA support the use of sofosbuvir and RBV as an all-oral therapy

for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with RBV and peg-IFN for treatment-naïve patients with genotype 1, 4, 5 and 6 HCV infection.

Gilead plans to file for regulatory approval of sofosbuvir in other geographies, including the European Union, in the second quarter of 2013. The European Medicines Agency (EMA) has accepted Gilead's request for accelerated assessment for sofosbuvir, a designation that is granted to new medicines of major public health interest. Accelerated assessment could shorten the EMA's review time of sofosbuvir by two months. Granting of accelerated assessment does not guarantee a positive opinion from the CHMP or approval by the European Commission.

About Sofosbuvir

Sofosbuvir is a nucleotide analogue inhibitor of the HCV NS5B protein, which plays an essential role in HCV replication. Sofosbuvir is a direct-acting agent, meaning that it interferes directly with the HCV life cycle by suppressing viral replication. Sofosbuvir is intended to become a cornerstone of interferon-free, all-oral treatment regimens for HCV that achieve higher cure rates more rapidly and with fewer side effects than current therapeutic options. Sofosbuvir is an investigational product and its safety and efficacy have not yet been established.

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 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 and other regulatory agencies may not approve sofosbuvir, and that any marketing approvals, if granted, may have significant limitations on its use. Additional clinical studies of sofosbuvir, including in combination with other compounds, may not produce favorable results. As a result, Gilead may not be able to successfully commercialize sofosbuvir, 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 Annual Report on Form 10-K for the year ended December 31, 2012, 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.

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

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