

## **GILEAD SUBMITS NEW DRUG APPLICATION TO U.S. FDA FOR SOFOSBUVIR FOR THE TREATMENT OF HEPATITIS C**

For Immediate Release

-- Sofosbuvir Would Form Basis of First All-Oral Regimen for HCV Genotype 2 and 3 Patients, and Interferon-Sparing Regimen for Genotype 1 Patients --

Foster City, CA, April 8, 2013 - Gilead Sciences (Nasdaq: GILD) today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of sofosbuvir, a once-daily oral nucleotide analogue for the treatment of chronic hepatitis C virus (HCV) infection. The data submitted in this NDA support the use of sofosbuvir and ribavirin (RBV) as an all-oral therapy for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with RBV and pegylated interferon (peg-IFN) for treatment-naïve patients with genotype 1, 4, 5 and 6 HCV infection.

Chronic HCV infection affects up to four million Americans, particularly individuals born between 1946 and 1964. The disease is the leading cause of liver cancer and liver transplantation in the United States. Treatment for HCV currently includes 24-48 weeks of therapy with peg-IFN, which has to be injected and is associated with significant side effects, leaving some patients unable to complete therapy. If approved, sofosbuvir would shorten HCV therapy to 12 to 16 weeks, and depending on the genotype, would either eliminate or reduce the duration of peg-IFN injections.

"Current therapies are not suitable for large numbers of patients with HCV infection, and are challenging to take and tolerate," said John C. Martin, PhD, Chairman and Chief Executive Officer of Gilead Sciences. "Sofosbuvir's antiviral potency, safety profile and once-daily administration have the potential to improve cure rates by simplifying and shortening therapy for patients with this disease."

The sofosbuvir NDA is supported primarily by data from four phase 3 studies, NEUTRINO, FISSION, POSITRON and FUSION, in which 12 or 16 weeks of sofosbuvir-based therapy was found to be superior or non-inferior to currently available treatment options or historical controls, based on the proportion of patients who had a sustained virologic response (HCV undetectable) 12 weeks after completing therapy (SVR12). Patients who achieve SVR12 are considered cured of HCV.

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. Unlike ribavirin and pegylated interferon, 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 has not yet been established.

For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.