Gilead Announces SVR12 Rates From Phase 3 Study Evaluating Harvoni® for the Treatment of Chronic Hepatitis C in Patients Co-Infected With HIV

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– 96 Percent SVR12 Rate for Hepatitis C Genotypes 1 and 4 Among HIV-infected Patients on Antiretroviral Therapy –

SEATTLE--(BUSINESS WIRE)--Feb. 26, 2015-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced results from a Phase 3 study, ION-4, evaluating the once-daily single tablet regimen Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg) for the treatment of genotypes 1 or 4 chronic hepatitis C virus (HCV) infection among patients co-infected with HIV. In the trial, 96 percent (n=321/335) of HCV patients achieved a sustained virologic response 12 weeks after completing therapy (SVR12). Patients who achieve SVR12 are considered cured of HCV infection. These data were presented in a late-breaker oral session (Session 152LB) at the 22nd Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle.

“This trial provides strong evidence that people who are co-infected with HIV can achieve very high rates of hepatitis C cure with a combination direct-acting antiviral regimen,” said Susanna Naggie, MD, MHS, Director of Infectious Diseases Research at Duke Clinical Research Institute and Principal Investigator for the ION-4 study. “These high cure rates were observed in most of the historically difficult-to-treat sub-populations, including those who failed previous treatment and those with cirrhosis. We are greatly encouraged by these findings.”

ION-4 is a Phase 3, multicenter, open-label study investigating the efficacy, safety and tolerability of Harvoni treatment for 12 weeks in 335 patients with HCV genotype 1a (75 percent), 1b (23 percent) or 4 (2 percent) and HIV-1 co-infection. The study included HCV treatment-naïve (45 percent) and treatment-experienced (55 percent) patients, including patients with compensated cirrhosis (20 percent), whose HIV was suppressed using one of three HIV antiretroviral (ARV) regimens: tenofovir and emtricitabine with efavirenz (Atripla®), raltegravir or rilpivirine (Complera®).

SVR12 rates did not differ significantly by prior HCV treatment status, presence or absence of cirrhosis, or ARV regimen. No patients discontinued Harvoni due to an adverse event (AE). Of the 14 patients that did not achieve SVR12, two patients experienced virologic failure during treatment (likely due to non-compliance per physician reporting), 10 experienced virologic relapse post-treatment, one was lost to follow up and one died due to causes unrelated to study drug. The most common AEs reported were headache (25 percent), fatigue (21 percent) and diarrhea (11 percent).

Harvoni received regulatory approval for the treatment of chronic HCV genotype 1 infection in adults in the United States in October 2014. Based on the ION-4 trial results, Gilead plans to file a supplemental New Drug Application with the U.S. Food and Drug Administration for Harvoni to include the results from this study in the U.S. label. Harvoni received marketing authorization in Europe in November 2014, where data from a small study in HIV-HCV co-infected patients (ERADICATE) are included in the prescribing information.

Important Safety Information for Harvoni

Warnings and Precautions

- **Risk of Reduced Therapeutic Effect of Harvoni Due to P-gp Inducers:** Rifampin and St. John’s wort are not recommended for use with HARVONI as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations.
- **Related Products Not Recommended:** Harvoni is not recommended for use with other products containing sofosbuvir (Sovaldi®).

Adverse Reactions

Most common (≥10%, all grades) adverse reactions were fatigue and headache.

Drug Interactions

- In addition to rifampin and St. John's wort, coadministration of Harvoni is also not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of ledipasvir and sofosbuvir, reducing the therapeutic effect of Harvoni.
- Coadministration of Harvoni is not recommended with simeprevir due to increased concentrations of ledipasvir and simeprevir. Coadministration is also not recommended with rosuvastatin or co-formulated elvitegravir/cobicistat /emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of rosuvastatin and tenofovir, respectively.

Additionally, patients taking Harvoni concomitantly with the combination of efavirenz, emtricitabine and tenofovir disoproxil fumarate should be monitored for tenofovir-associated adverse events.

Consult the full Prescribing Information for Harvoni for more information on potentially significant drug interactions, including clinical comments.

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 the supplemental New Drug Application may not be approved. In addition, physicians and patients may not see advantages of Harvoni over other therapies and physicians may therefore be reluctant to prescribe the product and private and public payers may be reluctant to provide coverage or reimbursement for the product. Further, additional studies of Harvoni may produce unfavorable results. 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, 2014, 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 Harvoni and U.S. full Prescribing Information, including BOXED WARNING, for Atripla and Complera are available at www.gilead.com.

Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

Complera and Harvoni are registered trademarks of Gilead Sciences, Inc., or its related companies.

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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