Gilead Announces New Sustained Viral Response Data for Sofosbuvir-Based Regimens in Genotype 3-Infected Hepatitis C Patients

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-- Results from Phase 3 VALENCE Study Confirm Efficacy and Safety of All-Oral Sofosbuvir-Based Regimen in Hepatitis C Patients with Genotype 3 Infection --

WASHINGTON--(BUSINESS WIRE)--Nov. 2, 2013-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced results from two studies, the Phase 3 VALENCE study and the Phase 2 LONESTAR-2 study, evaluating the investigational once-daily nucleotide analogue sofosbuvir for the treatment of chronic hepatitis C virus (HCV) infection among patients infected with genotype 3 HCV. These data will be presented this week at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (The Liver Meeting 2013) taking place in Washington, D.C.

In the Phase 3 VALENCE study, 85 percent (n=212/250) of treatment-naïve or treatment-experienced patients with genotype 3 HCV who received a 24-week regimen of sofosbuvir plus ribavirin (RBV) achieved a sustained virologic response 12 weeks after treatment (SVR12). Patients who achieve SVR12 are considered cured of HCV infection.

“The VALENCE results demonstrate the high efficacy of a 24-week, sofosbuvir-based, interferon-free treatment regimen for genotype 3 HCV patients with and without liver cirrhosis,” said Stefan Zeuzem, MD, Professor of Medicine and Chief of the Department of Medicine, Goethe University Hospital, Frankfurt, Germany, and principal investigator for the VALENCE study. “Notably, the majority of these patients had failed prior therapy, and sofosbuvir was able to produce a sustained virologic response.”

Additionally, the Phase 2 LONESTAR-2 study evaluated 12 weeks of sofosbuvir, RBV and pegylated interferon (peg-IFN) among patients who had previously failed treatment with peg-IFN/RBV, approximately half of whom had cirrhosis. In this study, 83 percent (n=20/24) of genotype 3 patients achieved SVR12.

There were few discontinuations due to adverse events in VALENCE and LONESTAR-2. Sofosbuvir was well tolerated in VALENCE and adverse events in LONESTAR-2 were consistent with the safety profile of peg-IFN/RBV.

About VALENCE

VALENCE is an ongoing placebo-controlled Phase 3 study in which patients with genotype 2 and 3 HCV infection were originally randomized (4:1) to receive sofosbuvir 400 mg once-daily plus weight-based RBV twice-daily (1,000 or 1,200 mg/day) for 12 weeks (n=334) or placebo (n=85). The study was subsequently amended to extend the treatment duration for genotype 3 patients (n=250) to 24 weeks. Patients randomized to receive placebo were offered treatment in an alternative protocol. Fifty-eight percent of trial participants were treatment-experienced and 21 percent had cirrhosis.

Among genotype 2 HCV patients receiving a 12-week all-oral course of sofosbuvir plus RBV, 93 percent (n=68/73) achieved SVR12.

Two patients receiving sofosbuvir and one patient receiving placebo discontinued treatment due to adverse events. The most common adverse events occurring in ≥10 percent of patients receiving sofosbuvir were headache, fatigue, pruritus, asthenia and nausea.

About LONESTAR-2

LONESTAR-2 is an ongoing open-label Phase 2 study evaluating the efficacy and safety of a 12-week regimen of sofosbuvir 400 mg once-daily, weight-based RBV twice-daily (1,000 or 1,200 mg/day) and peg-IFN (180 µg/week) among 47 patients with genotype 2 or 3 HCV infection. All patients in the study had previously failed treatment with peg-IFN/RBV and 55 percent had cirrhosis.

Ninety-six percent (n=22/23) of genotype 2 HCV patients achieved SVR12 in the study.

Two patients receiving sofosbuvir discontinued treatment due to adverse events. The most common adverse events occurring in ≥15 percent of the patients were consistent with the safety profiles of peg-IFN and RBV and included flu-like symptoms, fatigue and anemia.

Further information about these studies can also be found at www.clinicaltrials.gov.

Sofosbuvir is an investigational product and its safety and efficacy have not 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 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 risks related to the possibility of unfavorable results from ongoing and subsequent clinical trials involving sofosbuvir, including in combination with other products, for the treatment of HCV, and the possibility that regulatory authorities may not approve sofosbuvir for HCV-related indications and any marketing approval may have substantial limitations on its use. As a result, sofosbuvir may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of sofosbuvir if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. 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.

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.

Source: Gilead Sciences, Inc.

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