Gilead Reports Interim Data From Phase 2 LONESTAR Study

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-- Company Plans to Initiate Phase 3 Study Evaluating Eight and 12 Weeks of Therapy with Sofosbuvir and Ledipasvir for the Treatment of Chronic Hepatitis C --

FOSTER CITY, Calif.--(BUSINESS WIRE)--May. 2, 2013-- Gilead Sciences (Nasdaq: GILD) today announced plans to initiate a third Phase 3 clinical trial of the company's investigational fixed-dose combination tablet of sofosbuvir and ledipasvir for the treatment of chronic hepatitis C virus (HCV) infection. The study, called ION-3, will evaluate the once-daily fixed-dose combination of sofosbuvir and ledipasvir for eight weeks with and without ribavirin (RBV) and for 12 weeks without RBV in 600 non-cirrhotic, treatment-naïve genotype 1 HCV-infected patients.

The design of ION-3 was based on interim results from the Phase 2 LONESTAR study, which evaluated eight- and 12-week courses of therapy with the once-daily fixed-dose combination of sofosbuvir and ledipasvir with and without RBV in 60 treatment-naïve, non-cirrhotic patients.

In this study, 19/19 patients in the 12-week arm had a sustained virologic response four weeks after completing therapy (SVR4) and 40/41 in the eight-week arms had a sustained virologic response eight weeks after stopping therapy (SVR8), with one relapse occurring in the arm receiving sofosbuvir/ledipasvir without RBV.

Two additional cohorts in the LONESTAR study evaluated a 12-week course of the fixed-dose combination of sofosbuvir and ledipasvir with or without RBV in 40 patients who had previously failed therapy with an HCV-specific protease inhibitor-based regimen. Half of these treatment-experienced patients have documented, compensated cirrhosis. Ninety-five percent of patients in both arms achieved SVR4, one cirrhotic patient in the sofosbuvir and ledipasvir arm relapsed and one patient in the sofosbuvir and ledipasvir plus RBV arm was lost to follow-up.

Interim results from LONESTAR are summarized in the table below. Further details from this study will be presented at a future scientific meeting.

Treatment	Treatment Duration	Population	Results
Sofosbuvir + ledipasvir	8 weeks	GT 1 treatment-naïve	95% (19/20) SVR 8
Sofosbuvir + ledipasvir + RBV	8 weeks	GT 1 treatment-naïve	100% (21/21) SVR 8
Sofosbuvir + ledipasvir	12 weeks	GT 1 treatment-naïve	100% (19/19) SVR 4
Sofosbuvir + ledipasvir	12 weeks	GT 1 treatment-experienced	95% (18/19) SVR 4
Sofosbuvir + ledipasvir + RBV	12 weeks	GT 1 treatment-experienced	95% (20/21) SVR 4

"The LONESTAR results suggest that once-daily all-oral therapy with the nucleotide NS5B inhibitor sofosbuvir and the NS5A inhibitor ledipasvir may have the potential to cure most genotype 1 HCV infected patients with a remarkably short treatment duration," said Eric Lawitz, MD, President and Medical Director, The Texas Liver Institute, University of Texas Health Science Center, San Antonio, and Principal Investigator for the LONESTAR study.

Both sofosbuvir in combination with ledipasvir, and sofosbuvir in combination with ledipasvir and RBV were well tolerated in the LONESTAR study.

"Based upon the encouraging data derived from LONESTAR, we are continuing to advance our research evaluating new drug combinations and shorter durations of all-oral therapy that have the potential to simplify treatment for those living with hepatitis C," commented Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer at Gilead Sciences.

About ION-3

ION-3 is a randomized, open label Phase 3 clinical trial evaluating the efficacy and safety of sofosbuvir and ledipasvir for the

treatment of chronic HCV in non-cirrhotic, treatment-naïve genotype 1 infected patients. Participants will be randomized to receive sofosbuvir and ledipasvir for eight weeks (n=200), sofosbuvir and ledipasvir plus RBV for eight weeks (n=200), or sofosbuvir and ledipasvir for 12 weeks (n=200). The primary endpoint of the study is SVR12, defined as maintaining undetectable HCV RNA 12 weeks post-treatment and considered a cure for HCV infection. The study is designed to assess non-inferiority of the eight-week treatment duration arms to the 12-week treatment duration arm.

Two other ongoing Phase 3 studies are examining all-oral HCV therapy with sofosbuvir and ledipasvir. ION-1 and ION-2 are testing 12- and 24-week courses of the fixed-dose combination with and without RBV among treatment-naïve and treatment-experienced genotype 1 HCV patients, including those with compensated cirrhosis. Based on the results of the LONESTAR trial, Gilead has amended ION-2 to shorten the duration of therapy in one of the two fixed-dose combination arms without RBV from 24 to 12 weeks.

Additional information about ION-1, ION-2, ION-3 and LONESTAR can be found at www.clinicaltrials.gov.

Sofosbuvir, ledipasvir and the fixed-dose combination tablet are investigational products and their 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 possibility of unfavorable results from the clinical studies evaluating sofosbuvir and the sofosbuvir and ledipasvir fixed-dose combination, including from the ION-1, ION-2 and ION-3 and LONESTAR studies. Gilead also faces risks related to its ability to enroll patients in the ION-3 study, the need to modify or delay the study and the risk of failing to obtain approval of sofosbuvir and/or the sofosbuvir and ledipasvir fixed-dose combination from regulatory authorities. As a result, sofosbuvir and the sofosbuvir and ledipasvir fixed-dose combination may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of these products 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 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 1-80-GILEAD-5 or 1-650-574-3000.

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