

Gilead Announces Update on Phase 3 Study of Oral Fixed-Dose Combination of Sofosbuvir and Ledipasvir for Genotype 1 Hepatitis C Patients

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-- Enrollment in ION-1 Study Continues Following Planned DSMB Review --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 26, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today provided an update on ION-1, a Phase 3 clinical trial evaluating a once-daily fixed-dose combination of the nucleotide sofosbuvir and the NS5A inhibitor ledipasvir with and without ribavirin (RBV) for 12 or 24 weeks among treatment-naïve genotype 1 patients with hepatitis C virus (HCV) infection (n=800). A planned review by the study's Data and Safety Monitoring Board (DSMB) of safety data from 200 patients in all four arms and of SVR4 rates (sustained virologic response four weeks after completion of therapy) from 100 patients in the two 12-week duration arms concluded that the trial should continue without modification. This recommendation is based upon the observed SVR4 rates exceeding the predefined threshold of 60 percent and the absence of significant safety issues. Enrollment of the remaining 600 patients in ION-1 is now underway.

Sofosbuvir/ledipasvir is also being evaluated in a second Phase 3 study, ION-2, initiated in January 2013, which is now fully enrolled. ION-2 is evaluating sofosbuvir/ledipasvir with RBV for 12 weeks, and with and without RBV for 24 weeks, among 400 treatment-experienced genotype 1 HCV patients. Participants in this study failed to respond to past therapy containing pegylated interferon (peg-IFN) or peg-IFN plus a protease inhibitor.

Sofosbuvir, ledipasvir and the sofosbuvir/ledipasvir fixed-dose combination 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 longer-term results from the ION-1 study, the possibility that the proportion of patients who maintain a sustained virologic response with longer follow up will not be as favorable as the SVR4 rates observed in the study, and the possibility of unfavorable results from ION-2 and other ongoing and subsequent clinical trials involving sofosbuvir and the fixed-dose combination of sofosbuvir/ledipasvir. In addition, Gilead may make a strategic decision to discontinue development of sofosbuvir, ledipasvir and/or the fixed-dose combination regimen if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, these compounds may never be successfully commercialized. 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 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

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