

Gilead Announces Top-Line Results From Two Phase 3 Studies Evaluating Tenofovir Alafenamide (TAF) for Patients With Chronic Hepatitis B Infection

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-- U.S. and EU Filings Planned for Q1 2016 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 5, 2016-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that two Phase 3 clinical trials (Studies 108 and 110) evaluating investigational use of once-daily tenofovir alafenamide (TAF) 25 mg in treatment-naïve and treatment-experienced adults with HBeAg-negative and HBeAg-positive chronic hepatitis B virus (HBV) infection met their primary objectives. The studies demonstrated that TAF was non-inferior to Gilead's Viread® (tenofovir disoproxil fumarate, TDF) based on the percentage of patients with HBV DNA levels below 29 IU/mL at 48 weeks of therapy. In addition, TAF demonstrated improved renal and bone laboratory safety parameters compared to Viread.

“An estimated 350 million people are living with chronic hepatitis B worldwide, and Viread is an effective treatment option for those appropriate to receive therapy,” said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. “We are pleased that the TAF Phase 3 study results reflect high efficacy and improved renal and bone safety parameters similar to those seen in clinical studies evaluating TAF-based regimens for HIV. Like HIV, HBV is a chronic condition that requires prolonged therapy and we look forward to the opportunity to offer patients an improved option that has the potential to advance the long-term treatment of HBV.”

In Study 108, evaluating HBeAg-negative patients, 94.0 percent (n=268/285) of patients receiving TAF and 92.9 percent (n=130/140; CI -3.6 percent to +7.2 percent, p=0.47) of patients receiving Viread achieved HBV DNA below 29 IU/mL at week 48. In Study 110, evaluating HBeAg-positive patients, 63.9 percent (n=371/581) of TAF patients and 66.8 percent (n=195/292; CI -9.8 percent to +2.6 percent, p=0.25) of Viread patients achieved HBV DNA below 29 IU/mL at week 48. Two criteria were used to evaluate normalization of serum ALT levels: a central laboratory cut-off value and the American Association for the Study of Liver Diseases (AASLD) criteria. In both studies, treatment with TAF showed a statistically significant increase in ALT normalization relative to the Viread arms when using the AASLD criteria. The ALT normalization was not statistically significant using the central laboratory cut-off value, which defines normalization at a higher ALT level. Discontinuations due to adverse events were uncommon in both treatment arms (0.7 percent (n=2) for TAF vs. 0.7 percent (n=1) for Viread in Study 108, and 1.0 percent (n=6) for TAF vs. 1.0 percent (n=3) for Viread in Study 110). The most commonly reported adverse events in both studies included headache, upper respiratory tract infection, nasopharyngitis and cough, and occurred at similar rates in patients receiving either TAF or Viread.

Changes in bone and renal laboratory parameters favored the TAF regimen. In both studies, patients receiving TAF experienced a significantly smaller mean percentage decrease from baseline in hip and spine bone mineral density at week 48 (p<0.001) compared to patients receiving Viread. Smaller increases in serum creatinine were observed in patients receiving TAF in Study 110 (p=0.02). Additionally, the median change in estimated glomerular filtration rate (eGFR) from baseline to week 48 favored TAF in both studies (p<0.01).

Based on the results of Studies 108 and 110, Gilead plans to submit regulatory applications for TAF for chronic HBV in the United States and the European Union in the first quarter of 2016. Gilead also plans to submit data from both studies for presentation to a scientific conference in 2016.

About Studies 108 and 110

Studies 108 and 110 are randomized, double-blind, 96-week clinical trials among 1,298 treatment-naïve and treatment-experienced patients with chronic HBV. In Study 108, 425 HBeAg-negative patients were randomized 2:1 to receive TAF (n=285) or Viread (n=140). In Study 110, 873 HBeAg-positive patients were randomized 2:1 to receive TAF (n=581) or Viread (n=292).

The primary efficacy endpoint of the studies is the proportion of subjects with plasma HBV DNA levels below 29 IU/mL. Key secondary endpoints include change from baseline in bone mineral density at the hip and spine at week 48, and change from baseline in serum creatinine at week 48. Other secondary endpoints include ALT normalization and change from baseline in eGFR at week 48.

TAF as a single-agent for chronic HBV 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. 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 Gilead may be unable to submit regulatory applications for TAF for chronic HBV treatment in the United States and the European Union in the currently anticipated timelines. In addition, the regulatory filings may not be approved by the regulatory authorities, and marketing approvals, if granted, may have significant limitations on their use. As a result, TAF may never be successfully commercialized. Further, there is a possibility of unfavorable results from other clinical trials involving TAF regimens for the treatment of HBV. 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, 2015, 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 statement.

*U.S. full prescribing information for Viread, including **BOXED WARNING**, is available at www.gilead.com.*

Viread is a registered trademark 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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