Gilead Submits New Drug Application to U.S. Food and Drug Administration for Tenofovir Alafenamide (TAF) for the Treatment of Chronic Hepatitis B

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-- High Rates of Viral Suppression and Improved Renal and Bone Safety Parameters Compared to Viread in Phase 3 Studies --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 12, 2016-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tenofovir alafenamide (TAF) 25 mg, an investigational, once-daily treatment for adults with chronic hepatitis B virus (HBV) infection.

TAF is a novel, targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of Gilead's Viread® (tenofovir disoproxil fumarate, TDF), as well as improvements in surrogate laboratory markers of renal and bone safety as compared to Viread.

"Chronic hepatitis B is a potentially life-threatening disease that impacts millions of people worldwide and often requires prolonged therapy," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Given its lower dose, efficacy and safety profile, TAF has the potential to offer patients an improved treatment option that may advance their long-term care of chronic HBV."

The NDA for TAF is supported by 48-week data from two Phase 3 studies, which met their primary objective of non-inferiority in efficacy compared to Gilead's Viread among treatment-naïve and treatment-experienced adults with HBeAg-negative and HBeAg-positive chronic HBV. In both studies, changes in renal and bone laboratory safety parameters favored the TAF regimen. Overall, patients receiving TAF experienced a significantly smaller mean percentage decrease from baseline in hip and spine bone mineral density at week 48 compared to patients receiving Viread. Additionally, the overall median change in serum creatinine from baseline to week 48 favored TAF. Rates of discontinuations due to adverse events and the most commonly reported adverse events were similar in patients receiving TAF or Viread.

Gilead plans to submit a regulatory application for TAF in the European Union in the first quarter of 2016.

TAF as a single agent treatment for 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 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.

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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