**European Medicines Agency Validates Gilead's Type II Variation Application for Truvada® for Reducing the Risk of Sexually Acquired HIV**

February 1, 2016 9:04 AM ET

***– If Approved, Truvada Would be First Antiretroviral in Europe to be Indicated for Use in Combination with Safer Sex Practices to Reduce the Risk of HIV Infection in Adults –***

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 1, 2016-- Gilead Sciences, Inc. (NASDAQ:GILD) announced today that the company's Type II variation application for once-daily Truvada® (emtricitabine 200mg/tenofovir disoproxil fumarate 300mg) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection among uninfected adults at high risk, a strategy known as pre-exposure prophylaxis or PrEP, has been fully validated and is now under evaluation by the European Medicines Agency (EMA). Truvada was approved by the EMA in 2005 in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults, and is currently the most prescribed antiretroviral treatment in Europe.

"In Europe, 2014 saw the highest number of HIV diagnoses recorded in any given year – nearly 30,000 – highlighting the substantial need for additional strategies to help address the epidemic," said Sheena McCormack, Medical Research Council Clinical Trials Unit, University College London. "We are excited by the potential public health impact Truvada for PrEP may have, as part of a comprehensive HIV prevention strategy, in lowering transmission rates among at-risk populations across Europe."

The application is based on the results of two large placebo-controlled trials of Truvada for PrEP, the Pre-Exposure Prophylaxis Initiative (iPrEX) and Partners PrEP, sponsored by the U.S. National Institutes of Health (NIH) and the University of Washington, respectively. The indication extension will be reviewed by the EMA under the centralized procedure, which, when finalized, may lead to the granting of marketing authorization by the European Commission, which is valid in all 28 member states of the European Union (EU).

In all studies of Truvada for PrEP, the most commonly reported side effects included headache, stomach discomfort and weight loss. The incidence and types of side effects were consistent with Truvada's safety and tolerability profile when used as an HIV treatment.

"The EMA filing for Truvada for PrEP is timely given the growing body of evidence supporting its use in preventing HIV and the interest expressed by the medical and patient advocacy communities," said Norbert W. Bischofberger, PhD, Gilead's Executive Vice President, Research and Development and Chief Scientific Officer. "Appropriate use of Truvada for PrEP is supported by European AIDS Clinical Society and World Health Organization guidelines, and Gilead believes it is an important HIV prevention tool that, when taken as directed and used in combination with other prevention strategies, has the potential to help reduce new HIV infections."

Truvada was approved for PrEP in the United States in 2012, and in Kenya and South Africa in 2015; regulatory submissions are pending in Australia, Brazil, Canada, Peru and Thailand. Additionally, within the EU, Truvada for PrEP is currently available in France following a Temporary Recommendation for Use by the French regulatory agency (ANSM).

Truvada for PrEP is an investigational use in the EU and its safety and efficacy has not been established.

**About Gilead**

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. 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 Truvada for PrEP will not be approved by the European Commission or other regulatory authorities, and any marketing approvals, if granted, may have significant limitations on their use. 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 statements.

*The European SmPC for Truvada is available from the EMA website at www.ema.europa.eu.*

*Truvada 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*

View source version on businesswire.com: http://www.businesswire.com/news/home/20160201005686/en/

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Patrick O'Brien, +1 650-522-1936
Media (U.S.)
Ryan McKeel, +1 650-377-3548
Media (EU)
Stephen Head, +44 (0)7768 705945