European Commission Grants Marketing Authorization for Gilead's Once-Daily Truvada® For Reducing the Risk of Sexually Acquired HIV-1

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– Truvada is the First Antiretroviral Medicine to be Licensed in Europe for Pre-Exposure Prophylaxis, in Combination with Safer-Sex Practices, to Reduce the Risk of Sexually Acquired HIV-1 in Adults at High Risk –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Aug. 22, 2016-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted marketing authorization for once-daily Truvada® (emtricitabine 200 mg/tenofovir disoproxil 245 mg; FTC/TDF) 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. Truvada was approved by the European Medicines Agency in 2005 for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults aged 18 years and over, and is currently the most prescribed antiretroviral medicine in Europe as part of combination therapy.

The marketing authorization allows for the marketing of Truvada for PrEP in all 28 countries of the European Union, subject to national regulatory authority approval of required pharmacovigilance materials in each country.

"In the past 30 years, we have seen significant progress in the way we treat HIV; however, infection rates have continued to rise. In 2014, we saw the highest number of newly diagnosed cases in the European Union ever recorded, with 94 percent of those with known cause transmitted through sexual contact," said Professor Jean-Michel Molina, MD, PhD, Hôpital Saint Louis in Paris and University of Paris 7. "Truvada for PrEP provides an additional prevention tool, which when used with safer-sex practices, will help uninfected adults at high risk of HIV protect themselves against the virus."

The marketing authorization is based on the results of two large placebo-controlled trials of Truvada, the Pre-Exposure Prophylaxis Initiative (iPrEX) and Partners PrEP, sponsored by the U.S. National Institutes of Health and the University of Washington, respectively. In these studies, 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 part of an HIV treatment regimen.

"The approval of Truvada for PrEP represents an important step forward in addressing the incidence of HIV in Europe" said Norbert W. Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "When taken as directed and used in combination with other prevention strategies, Gilead believes Truvada for PrEP can have a meaningful impact on public health by helping to reduce HIV transmission rates across Europe."

Worldwide, clinical guidelines support the use of PrEP, in combination with other existing prevention measures such as condoms, to prevent the sexual transmission of HIV in adults at high risk of HIV infection. Truvada should not be used in individuals with unknown or positive HIV-1 status, as Truvada alone does not constitute a complete regimen for the treatment of HIV-1 and HIV-1 resistance mutations have emerged in individuals with undetected HIV-1 infection who are only taking Truvada.

In addition to the European Union, Truvada is also authorized for PrEP in Australia, Canada, Kenya, Peru, South Africa and the United States.

For important safety information for Truvada, including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European SmPC, available from the EMA website at www.ema.europa.eu.

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 that physicians may not see the benefits of prescribing Truvada for PrEP. 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 June 30, 2016, 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

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