Gilead Announces New Data on the Impact of Truvada® (Emtricitabine and Tenofovir Disoproxil Fumarate) for Pre-Exposure Prophylaxis (PrEP) on the Number of HIV Diagnoses in the United States

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– Data Show That States with Highest Use of Truvada for PrEP® Had Significant Declines in New HIV Infections –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 24, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced results of a retrospective nationwide analysis of the impact of Truvada (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg tablets) for pre-exposure prophylaxis (PrEP) use across all 50 U.S. states and the District of Columbia. Conducted in collaboration with researchers at Emory University Rollins School of Public Health and the Centers for Disease Control and Prevention (CDC), these data demonstrate that use of once-daily oral Truvada for PrEP has had an independent and significant impact on the number of new HIV infections diagnosed in the United States from 2012 to 2016. The data were presented at the 22nd International AIDS Conference (AIDS 2018) in Amsterdam.

Truvada for PrEP is indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg. To take Truvada for PrEP, individuals must be confirmed to be HIV-negative and be tested for HIV immediately prior to initiating and at least every 3 months while taking Truvada for PrEP. Truvada has a boxed warning in its product label regarding the risks of drug resistance with the use of Truvada for PrEP in undiagnosed early HIV infection and post treatment acute exacerbation of hepatitis B. Further important safety information, adverse drug reactions and prescribing considerations are included below.

In the analysis, states with the highest utilization of Truvada for PrEP during this five year period (2012 to 2016) had significant declines in the average number of HIV diagnoses, while there was an average increase for the states with the lowest use. The impact of Truvada for PrEP use occurred even after controlling for the effect of antiretroviral therapy use in those living with HIV, known as treatment as prevention (TasP), in a subset of 38 states and Washington, D.C., where virologic suppression data was available.

“These data further validate the potential for significant public health impacts of Truvada for PrEP to help reduce HIV transmission in the U.S.,” said Patrick Sullivan, Professor of Epidemiology at Rollins School of Public Health, Emory University, and lead study author. “By documenting significant declines in average new cases of HIV in states where Truvada for PrEP has been most widely adopted, our analysis emphasizes the importance of improving access to HIV screening and a full range of prevention tools, including PrEP, in U.S. states.”

The analysis of state-level data was based on National HIV Surveillance System and national pharmacy data on HIV diagnoses and prevalence of use of Truvada for PrEP from 2012 to 2016. Across all 50 states and Washington, D.C., Truvada for PrEP use prevalence increased from 7.0 to 68.5 per 1,000 people at highest risk of HIV acquisition during the five-year period, and the rate of new HIV diagnoses decreased significantly from 15.7 to 14.5 per 100,000 people among the general population.

In the ten states with the highest prevalence of Truvada for PrEP use, the pooled unadjusted estimated annual percent change (EAPC) of HIV diagnoses was -4.7 percent. In the group of ten states with the lowest prevalence of Truvada for PrEP use, the EAPC of HIV diagnoses was +0.9 percent.

To evaluate the independence of the effect of Truvada for PrEP uptake from the effect of TasP, researchers analyzed data from a subset of 38 states and Washington, D.C., with viral suppression data (averaged for available years from 2012 to 2014) among people living with HIV. This analysis demonstrates that the rate of Truvada for PrEP uptake remained significantly associated with declines in new HIV diagnoses after controlling for state-level viral suppression.

“Since 2012, Truvada for PrEP has been an important component of HIV prevention strategies. We are pleased to share these additional data at AIDS 2018, correlating its uptake with declines in new diagnoses,” said Andrew Cheng, MD, PhD,

Chief Medical Officer, Gilead Sciences. “Gilead remains committed to partnering with organizations that serve people at risk for HIV, as well as those living with the disease, to increase awareness of the potential impact of both Truvada for PrEP and TasP on the HIV epidemic.”

Truvada for PrEP — in combination with safer sex practices — was approved in 2012 by the U.S. Food and Drug Administration (FDA) for HIV prevention in at-risk adults, and was approved in 2018 for use in at-risk adolescents weighing at least 35 kg.

Truvada does not prevent other sexually transmitted infections or cure HIV infection or AIDS.

IMPORTANT U.S. SAFETY INFORMATION AND INDICATION FOR TRUVADA for PrEP

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF TRUVADA FOR PrEP IN UNDIAGNOSED EARLY HIV-1 INFECTION and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Truvada for PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiation and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with use of Truvada for PrEP following undetected acute HIV-1 infection. Do not initiate if signs or symptoms of acute HIV-1 infection are present unless HIV-negative status is confirmed**
- **Severe acute exacerbations of hepatitis B have been reported in HBV-infected patients who discontinued Truvada. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients with HBV after discontinuing Truvada. If appropriate, initiation of anti-hepatitis B therapy may be warranted**

Contraindications

- Do not use Truvada for PrEP in individuals with unknown or positive HIV status

Warnings and precautions: Comprehensive risk reduction strategies

- **Reduce HIV-1 risk:** Truvada for PrEP is not always effective in preventing HIV-1. Use only as part of a comprehensive prevention strategy that includes safer sex practices, regular testing for HIV-1 and other STIs, and counseling on reducing sexual risk behaviors
- **Reduce potential for drug resistance:** Truvada for PrEP should only be used in individuals confirmed to be HIV-negative immediately prior to initiation, at least every 3 months while taking Truvada, and upon an STI diagnosis. HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only Truvada. Truvada alone is not a complete regimen for treating HIV-1
    - HIV antibody tests may not detect acute HIV infection. If recent exposures are suspected or symptoms of acute HIV infection are present (e.g., fever, fatigue, myalgia, skin rash), delay initiating (≥1 month) or discontinue use and confirm HIV-negative status with a test approved by the FDA for the diagnosis of acute HIV infection
    - If a screening test indicates possible HIV-1 infection, convert the HIV-1 PrEP regimen to an HIV treatment regimen until HIV-negative status is confirmed.
- **Counsel on adherence:** Counsel individuals to strictly adhere to their dosing schedule, as efficacy is strongly correlated with adherence. Some individuals, such as adolescents, may benefit from more frequent visits and counseling.

Warnings and precautions

- **New onset or worsening renal impairment:** Cases of acute renal impairment and Fanconi syndrome have been reported with the use of tenofovir disoproxil fumarate (TDF). Truvada is not recommended in individuals with estimated creatinine clearance (CrCl) <60 mL/min. Avoid concurrent or recent use with a nephrotoxic agent. Acute

renal failure has been reported after initiation of high dose or multiple NSAIDs in patients at risk for renal dysfunction; consider alternatives to NSAIDs in these patients. Monitor renal function in all patients – See Dosage and Administration

- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia associated with proximal renal tubulopathy, have been reported with the use of TDF Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for bone loss
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including Truvada. Discontinue use if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations
- **Drug interactions:** See Drug Interactions section. Consider the potential for drug interactions prior to and during use of Truvada and monitor for adverse reactions

Adverse reactions

- **Common adverse reactions** (>2% and more frequently than placebo) of Truvada for PrEP in clinical trials were headache, abdominal pain, and weight loss

Drug interactions

- **Prescribing information:** Consult the full Prescribing Information for Truvada for more information, warnings, and potentially significant drug interactions, including clinical comments
- **Hepatitis C antivirals:** Coadministration with ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir increases TDF exposure; monitor for adverse reactions
- **Drugs affecting renal function:** Coadministration of Truvada with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine and/or tenofovir

Pregnancy and lactation

- **Pregnancy:** An Antiretroviral Pregnancy Registry (APR) has been established. Available data from observational studies and the APR show no increase in the rate of major birth defects for Truvada compared with a US reference population. Consider HIV prevention methods, including Truvada for PrEP in at-risk women due to the potential increased risk of HIV-1 infection during pregnancy and mother to child transmission during acute HIV-1 infection
- **Lactation:** Emtricitabine and tenofovir have been detected in human milk. Evaluate the benefits and risks of Truvada for PrEP in breastfeeding women, including the risk of HIV-1 acquisition due to nonadherence, and subsequent mother to child transmission. Health benefits of breastfeeding should be considered along with potential adverse effects of Truvada on the child, which are unknown

Dosage and administration

- **Dosage:** One tablet once daily with or without food
- **HIV screening:** Test for HIV-1 infection prior to initiating and at least every 3 months during treatment
- **HBV screening:** Test for HBV infection prior to or when initiating treatment
- **Renal impairment and monitoring:** Not recommended in individuals with CrCl <60 mL/min. In all patients, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein on a clinically appropriate schedule. In patients with chronic kidney disease, also assess serum phosphorus

INDICATION

Truvada for PrEP (pre-exposure prophylaxis) is indicated to reduce the risk of sexually acquired HIV-1 in adults and adolescents (≥35 kg) who are at risk for HIV, when used in combination with safer sex practices. HIV-negative status must be confirmed immediately prior to initiation

- If clinical symptoms of acute HIV-1 infection are present and recent exposures (<1 month) are suspected, delay initiation for at least 1 month until HIV-negative status is reconfirmed. Alternatively, confirm HIV-negative status with a test cleared by the FDA to aid in the diagnosis of acute HIV-1 infection

Individuals at risk for sexually acquired HIV-1 may include those:

- With HIV-1 infected partner(s), or
- Who engage in sexual activity in a high prevalence area or social network and have additional risk factors, such as: inconsistent or no condom use, diagnosis of sexually transmitted infections (STIs), exchange of sex for commodities, use of illicit drugs or alcohol dependence, incarceration, or sexual partners of unknown HIV status with any of these risk factors

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

For nearly 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Today, it's estimated that more than 10 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

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 and the possibility of unfavorable results from additional studies involving 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 March 31, 2018, 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.

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

Truvada, Truvada for PrEP, and Gilead are trademarks 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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