Gilead Sciences Presents Survey Findings on PrEP Access and Utilization in the U.S. During COVID-19 Shelter-in-Place Orders

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– Healthcare Providers Reported High Rates of Continued Care and Prescribing Behavior, Despite Practice-Site Restrictions Affecting >90% of the Survey Respondents –

– Separate Clinical Data Presented Suggest no Reported Increase in Sexual Health Risk Behavior From Baseline Among DISCOVER Trial Study Participants –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 8, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced data presented at the 23rd International AIDS Conference (AIDS 2020: Virtual) evaluating the impact of COVID-19 shelter-in-place orders (SIPOs) and PrEP utilization on HIV prevention strategies and associated risk behaviors. Findings presented included results from an online survey conducted by The American Academy of HIV Medicine (AAHIVM) to understand potential changes in behavior among pre-exposure prophylaxis (PrEP) users and prescribers in the United States during the height of COVID-19 SIPOs. There were 598 total respondents – 409 PrEP users and 189 PrEP prescribers. While most prescribers (90 percent) reported recommending no change in PrEP regimen, about one-third (33 percent) of PrEP users discontinued therapy voluntarily, mostly (85 percent) due to low perceived HIV risk associated with decreased sexual activity. Only 8 percent of those users who discontinued PrEP cited inability to access PrEP medications. Nearly all prescribers (95 percent) were able to successfully prescribe PrEP despite limitations caused by SIPOs.

PrEP users reported modified sexual behavior associated with HIV risk during SIPOs, with 90 percent reporting no or fewer sexual partners, and no or fewer sex events. From the providers who completed the survey, 68 percent implemented telemedicine practices; 59 percent indicated refilling PrEP medications while postponing routine HIV/sexually transmitted infection (STI) and laboratory tests, to be completed as soon as possible; and 15 percent opted to completely forgo testing and lab monitoring. Of the 20 percent of responding providers who encountered PrEP users with suspected STIs for which they could not obtain a test, 47 percent treated STIs empirically.

“Reducing the number of new HIV transmissions and ensuring access to critical HIV prevention services must remain a public health priority during this challenging time,” said Bruce Packett, Executive Director, The American Academy of HIV Medicine. “These data demonstrate the crucial role that technology-enabled care can play in helping facilitate the safe and timely delivery of critical public health services. My hope is that clinics and HIV prevention providers can continue to adapt to changing circumstances by offering expanded use of telehealth services and other innovative tools to help meet the evolving needs of people at risk for HIV.”

“Gilead is committed to supporting efforts to substantially expand access to HIV prevention medications in the communities most impacted. This includes, but is not limited to, the company’s ongoing efforts to address the social and structural barriers to care,” said Diana Brainard, MD, Senior Vice President and Virology Therapeutic Area Head, Gilead Sciences. “As we work collectively toward ending the epidemic, these survey findings can aid in our efforts to assess and address such barriers.”

PrEP is a guideline recommended HIV prevention strategy, but risk compensation could undermine potential benefits. Understanding sexual decision-making and how PrEP is incorporated into existing prevention strategies can help inform future PrEP implementation efforts. DISCOVER is an ongoing multi-center randomized controlled trial evaluating the safety and efficacy of Descovy (emtricitabine 200 mg/tenofovir alafenamide 25 mg) for PrEP® in men and transgender women who have sex with men and are at risk for sexually acquired HIV infection. Data presented on study participant behavior in the DISCOVER trial found no longitudinal changes in the mean number of participants’ sex partners; condomless, insertive anal sex partners; or condomless, receptive anal sex partners from baseline through 96 weeks of follow-up. These findings suggest that an increase in risk behavior due to a reduction in perceived risk did not occur in the DISCOVER trial.

In the United States, Descovy for PrEP® is indicated to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg, excluding individuals at risk of HIV-1 from receptive vaginal sex, as effectiveness in this population has not been evaluated.

Descovy has a Boxed Warning in its U.S. product label regarding the risk of drug resistance when used for PrEP in undiagnosed early HIV infection, and the risk of post-treatment acute exacerbation of hepatitis B. See below for Indication and Important Safety Information.

Key abstracts for HIV prevention data presented at AIDS 2020: Virtual include:

Late-Breaker Submission OADLB01: Impact of COVID-19 Related Shelter-in-Place Orders on PrEP Access, Usage

Details above.

Virtual Poster PEB0165: DISCOVER Study for HIV Pre-Exposure Prophylaxis (PrEP): No Evidence of Risk Compensation in Participants Taking F/TDF or F/TAF for Prep Through 96 Weeks

Baseline prevalence and longitudinal trends in HIV-associated sexual risk behaviors during the DISCOVER trial suggest that risk compensation, defined as an increase in risk behavior due to a reduction in perceived risk, did not occur among study participants. Over a 96-week follow-up period, sexual behavior was assessed by a computer-assisted self-interview questionnaire, including number of sex partners, condomless insertive anal sex (CIAS) partners, and condomless receptive anal sex partners. Study participants’ median age was 34 years; 9 percent (474) were black, 24 percent (1,318) were of Hispanic or Latinx ethnicity; 91 percent (4,854) self-identified as gay, 7 percent (385) as bisexual, 1 percent (41) as heterosexual, and 1 percent (71) as transgender women. Through 96 weeks, study participants reported a stable number of total and condomless sexual partners.

Poster Discussion PDB0303: Persistently High Rates of Sexually Transmitted Infections in the DISCOVER HIV PrEP Trial

Through the 96 weeks of follow-up as part of the DISCOVER trial, rates of STI acquisition remained consistent with baseline rates of STIs. At baseline,
16.1 percent of study participants (430) in the Descovy for PrEP® arm and 15.8 percent (421) in the Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) for PrEP® arm tested positive for gonorrhea or chlamydia at any anatomic site; 11.3 percent (299) and 10.5 percent (279) tested positive at the rectum. The overall incidence rate of gonorrhea or chlamydia at any anatomic site was 85.7 and 83.1 per 100 person-years for the Descovy for PrEP® and the Truvada for PrEP® arms respectively. In addition, the overall incidence rate of rectal gonorrhea and chlamydia was 47.5 and 46.9 per 100 person-years for the Descovy for PrEP® and the Truvada for PrEP® arms respectively. At 96 weeks, syphilis was found in 14.8 percent and 15.2 percent in the Descovy for PrEP® and Truvada for PrEP® arms, and the incidence rate was 9.9 and 9.3 per 100 person-years, respectively.

**Poster Discussion PDB0404: DISCOVER: Deep Sequencing with Unique Molecular Identifiers for Evaluation of HIV-1 Drug Resistance in the Pre-Exposure Prophylaxis Trial**

A study examining standard and ultrasensitive resistance testing from the subset of DISCOVER participants who acquired HIV infection found using standard Sanger sequencing that four of the 20 participants who acquired HIV had the M184V mutation, all in the Truvada for PrEP® arm. These four study participants all had suspected baseline infection, and two of the four also had the M184I mutation. Six study participants had additional mutations related to non-study drug resistance and were presumed to be transmitted.

Similar results were observed when using next generation sequencing (UMI-NGS), with the addition of one participant with M184V in the Descovy for PrEP® arm. Overall, drug resistance in the DISCOVER study was most commonly seen in participants with suspected baseline infections and in only one individual who became infected while on study.

Descovy and Truvada do not prevent other sexually transmitted infections or cure HIV or AIDS.

**About the DISCOVER Trial**

The DISCOVER trial is a multi-year global Phase 3 registrational clinical trial evaluating the safety and efficacy of once-daily Descovy for PrEP® compared with Truvada for PrEP® in men and transgender women who have sex with men and are at risk for sexually acquired HIV infection. The primary analysis of the study occurred when all participants had a minimum of 48 weeks of follow-up and 50 percent of participants reached 96 weeks of follow-up; the prespecified secondary analysis occurred when 100 percent of participants reached 96 weeks of follow-up. At both the primary and secondary endpoints, Descovy for PrEP® demonstrated non-inferior efficacy to Truvada for PrEP®.

**U.S. Important Safety Information for Descovy for PrEP®**

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

- DESCovy FOR PrEP must be prescribed only to patients 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 emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for HIV-1 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 exacerabtions of hepatitis B have been reported in patients infected with hepatitis B virus (HBV) who discontinued products containing FTC and/or TDF and may occur with discontinuation of DESCovy. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients with HBV who discontinue DESCovy. If appropriate, anti-hepatitis B therapy may be warranted.

**Contraindication**

- DESCovy FOR PrEP is contraindicated in patients with unknown or positive HIV status.

**Warnings and precautions**

- Comprehensive management to reduce risks:
  - Use DESCovy FOR PrEP to reduce the risk of HIV-1 infection as part of a comprehensive strategy that includes adherence to daily dosing and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs).
  - HIV-1 risk factors: Behavioral, biological, or epidemiologic HIV-1 risk factors may include, but are not limited to: condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high-prevalence area or network.
  - Reduce STI risk: Counsel on the use of STI prevention measures (e.g., consistent and correct condom use, knowledge of partner’s HIV-1 viremic status, regular testing for STIs).
  - Reduce potential for drug resistance: Only prescribe DESCovy FOR PrEP to patients confirmed to be HIV negative immediately prior to initiation, at least every 3 months while taking DESCovy, and upon an STI diagnosis. HIV-1 resistance substitutions may emerge in patients with undetected HIV-1 infection who are taking only DESCovy because DESCovy alone is not a complete regimen for treating HIV-1.
  - Some HIV tests may not detect acute HIV infection. Prior to initiating DESCovy FOR PrEP, ask patients about potential recent exposure events. If recent (<1 month) exposures are reported or suspected, or symptoms of acute HIV infection (e.g., fever, fatigue, myalgia, skin rash) are present, confirm HIV-negative status with a test approved by the FDA for use in the diagnosis of acute HIV infection.
Counsel patients to strictly adhere to daily dosing, as efficacy is strongly correlated with adherence. Some patients, such as adolescents, may benefit from more frequent visits and counseling.

New onset or worsening renal impairment: Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. Do not initiate DESCOVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue DESCOVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients (see Dosage and Administration section).

Lactic acidosis and severe hepatomegaly with steatosis: Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. 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.

Adverse reactions

- Most common adverse reactions (≥2%) in the DESCOVY FOR PrEP clinical trial were diarrhea, nausea, headache, fatigue, and abdominal pain.

Drug interactions

- Prescribing information: Consult the full Prescribing Information for DESCOVY for more information, warnings, and potentially significant drug interactions, including clinical comments.
- Metabolism: Drugs that inhibit P-gp can increase the concentrations of tenofovir alafenamide (TAF), a component of DESCOVY. Drugs that induce P-gp can decrease the concentrations of TAF, which may lead to loss of efficacy.
- Drugs affecting renal function: Coadministration of DESCOVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Dosage and administration

- Dosage: One tablet taken once daily with or without food.
- HIV screening: Test for HIV-1 infection immediately prior to initiating, at least every 3 months during use, and upon diagnosis of an STI (see Warnings and Precautions section).
- HBV screening: Test for HBV infection prior to or when initiating DESCOVY.
- Renal impairment and monitoring: Not recommended in patients with creatinine clearance (CrCl) <30 mL/min. Prior to or when initiating DESCOVY, and during use on a clinically appropriate schedule, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

U.S. Indication for Descovy for PrEP®

DESCOVY for PrEP is indicated in at-risk adults and adolescents (≥35 kg) to reduce the risk of sexually acquired HIV-1 infection, excluding individuals at risk from receptive vaginal sex. HIV-1-negative status must be confirmed immediately prior to initiation.

- Limitation of Use: DESCOVY FOR PrEP is not indicated in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

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 more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, it’s estimated that more than 12 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company’s manufacturing partners.

Gilead is committed to supporting the global health community to quickly and effectively respond to serious and life-threatening viral outbreaks worldwide. To that end, we are contributing our antiviral expertise and resources to help investigate potential treatments for patients with COVID-19.

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 possibility of unfavorable results from ongoing and additional clinical trials involving Descovy for PrEP® and Truvada for PrEP®, and the possibility that we are unable to complete one or more of such trials in the currently anticipated timelines or at all. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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, 2020, 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.