China National Medical Products Administration Approves Truvada® for HIV Pre-Exposure Prophylaxis (PrEP)

- Truvada is the First HIV PrEP Medicine Approved in China -

FOSTER CITY, Calif. -- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the China National Medical Products Administration (NMPA) has approved a pre-exposure prophylaxis indication for Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg,FTC/TDF). In China, Truvada for PrEP® is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg. Truvada for PrEP should be taken once daily and used together with safer sex practices. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for PrEP.

Truvada is the first medicine approved for HIV prevention in China. Previously, Truvada was approved in combination with other antiretroviral medicines as a treatment for HIV-1 infection in adults and pediatric patients 12 years of age and older.

According to data published by the China National Health Commission (NHC) in November 2019, 131,000 new HIV infections were reported between January and October 2019 in China. Among the newly reported cases, sexual transmission was the main mode of transmission. In addition to safer sex practices and using condoms correctly, the World Health Organization (WHO) recommends offering PrEP to all groups at substantial risk of HIV infection as part of a comprehensive HIV prevention plan. "The approval of Truvada for PrEP addresses an area of significant unmet need in the field of HIV prevention medicine in China. It provides a new prevention option with a demonstrated safety and efficacy profile," said Professor Zhang Fujie, Director of Clinical and Research Center of Infectious Diseases, Beijing Ditan Hospital, Capital Medical University. "Truvada for PrEP could play an important role in our response to the HIV epidemic and may help reduce the number of new HIV infections in China."

The approval of Truvada for PrEP was supported by data from two randomized, double-blind, placebo-controlled trials known as the Pre-Exposure Prophylaxis Initiative (iPrEx) and Partners PrEP. The iPrEx trial included 2,499 HIV-seronegative men and transgender women who have sex with men and the Partners PrEP trial included 4,758 HIV-1 serodiscordant heterosexual couples. In total, 2,834 HIV-1 uninfected adults received Truvada. The number of new HIV-1 seroconversions was significantly lower among those who received Truvada compared to those in the placebo group.
The efficacy of Truvada for PrEP was strongly associated with adherence. The most commonly reported adverse events among the individuals taking Truvada were headache, abdominal pain and weight decrease.

"Gilead is committed to delivering innovative therapeutics to help address unmet medical needs in China. Since launching our operations in China in 2017, we have introduced a number of HIV treatments for people living with HIV. With the inclusion of our HIV medicines in the 2019 National Reimbursement Drug List (NRDL), we are hopeful that access to treatments among people in need will be increased significantly," said Rogers Luo, Vice President & China General Manager, Gilead Sciences. "With the approval of Truvada for PrEP, Gilead is now able offer options for PrEP and treatment – as we strive to help people living with and at risk of acquiring HIV and to partner with the government and healthcare community to improve public health in China."

In the United States, Truvada for PrEP is indicated to reduce the risk of sexually acquired HIV-1 in adults and adolescents (≥35 kg) who are at risk for HIV. HIV-negative status must be confirmed immediately prior to initiation.

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, 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.

About PrEP

PrEP is an HIV prevention strategy in which medicine is taken daily before an HIV-negative person may be exposed to the virus through sex to help reduce the risk of infection. PrEP is highly effective at reducing the risk of HIV infection in at-risk populations.

Prevention methods, including PrEP, and safer sex practices are essential tools in the effort to end the HIV epidemic. PrEP use received an "A" rating from the U.S. Preventive Services Task Force (USPSTF), signifying that PrEP has a high certainty of substantial preventive benefits for reducing the risk of HIV. In addition, PrEP is recommended by the U.S. Centers for Disease Control and Prevention, the WHO and other national healthcare organizations as part of a comprehensive prevention strategy for individuals at risk for HIV.