



GILEAD CANADA ANNOUNCES NOTICE OF COMPLIANCE FOR DESCOVY® (EMTRICITABINE, TENOFOVIR ALAFENAMIDE) FOR HIV PRE-EXPOSURE PROPHYLAXIS (PREP)

– PrEP is part of the ongoing efforts by Gilead Canada to end the HIV epidemic –

Mississauga, ON – December 1, 2020 – Gilead Sciences Canada, Inc. (Gilead Canada) today announced that Health Canada has granted a Notice of Compliance (NOC) for DESCOVY® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets) for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection among individuals who are HIV-negative and at risk of HIV acquisition. Canada is now the third market globally to receive approval of DESCOVY for the PrEP indication following the approval by the U.S. Food and Drug Administration in October, 2019, and the Taiwan Food and Drug Administration in August, 2020.

DESCOVY is indicated for PrEP to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing ≥ 35 kg, excluding individuals at risk from receptive vaginal sex. DESCOVY is taken orally once daily with or without food. DESCOVY is also approved in Canada for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 25 kg, in combination with other antiretroviral agents.¹

PrEP – Reducing the Risk of Acquiring HIV

PrEP is an HIV prevention strategy to reduce the risk of acquiring HIV infection. It can be taken by HIV-negative individuals considered at high risk of infection. PrEP is taken daily, on an ongoing basis, in advance of high-risk activity. According to the Public Health Agency of Canada, when medication for PrEP is taken as prescribed, the medication reduces the risk of acquiring sexually transmitted HIV by more than 90 per cent.²

Before prescribing DESCOVY for PrEP™, healthcare providers must counsel all uninfected individuals to strictly adhere to the recommended DESCOVY dosing schedule and must screen all individuals for HIV-1 immediately prior to initiating DESCOVY for PrEP and at least once every three months while taking DESCOVY, and upon diagnosis of any other sexually transmitted infections.¹

Canadian Experts Involved in DESCOVY for PrEP Research

“Pre-exposure prophylaxis, or PrEP, is a highly effective strategy to reduce the risk of sexually acquired HIV infection. When taken daily, PrEP provides individuals at high and ongoing risk of infection with the confidence to live their lives,” said Dr. Jason Brunetta, a Canadian DISCOVER investigator, and with the Department of Family and Community Medicine, Maple Leaf Medical Clinic, Toronto. “With the approval of DESCOVY for PrEP, health care professionals now have an additional preventive option for their patients that demonstrates high efficacy and improved maintenance of kidney and bone health. We now need to identify individuals at risk of HIV infection, provide them with PrEP and link them to care in an effort to reduce new HIV infections in Canada.”



The PrEP indication is based on data from the DISCOVER trial, a multi-year global Phase 3 registrational clinical trial that evaluated the safety and efficacy of DESCovy for PrEP compared with that of Truvada® (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg tablets; F/TDF) for PrEP in reducing the risk of acquiring HIV-1 infection. Enrollment included more than 5,300 adult cisgender men who have sex with men or transgender women who have sex with men.

"DESCovy for PrEP provides a new HIV prevention option that has demonstrated high efficacy and statistically significant improvements in renal and bone safety," said Melissa Koomey, Vice President and General Manager, Gilead Canada. "As an important public health strategy, PrEP can help to reduce HIV infections. As such, Gilead Canada is committed to educating and raising awareness of HIV prevention in Canada and contributing to efforts to end the HIV epidemic."

HIV in Canada³

According to the most recent HIV data from the Public Health Agency of Canada (PHAC), "HIV in Canada – Surveillance Report 2018" (published in December 2019), there were more than 68,000 Canadians living with HIV, with 14 per cent unaware of their HIV status.⁴ A cumulative total of 88,881 HIV diagnoses have been reported to PHAC since HIV reporting began in Canada in 1985.

In 2018, a total of 2,561 HIV diagnoses (new cases) were reported in Canada, an increase of 8.2 per cent compared with 2017, and an increase of 25.3 per cent over the previous four years (2014 to 2018). The national HIV diagnosis rate increased to 6.9 per 100,000 population in 2018 from 6.5 per 100,000 population in 2017. Saskatchewan reported the highest provincial diagnosis rate at 14.9 per 100,000 population. Overall, the 2018 diagnosis rate for males continued to be higher than that of females (9.8 versus 4.0 per 100,000 population, respectively); however, females experienced a larger increase in reported cases and diagnosis rate.

Important Safety Information for DESCovy for HIV Treatment and PrEP¹

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

The DESCovy Product Monograph includes a Serious Warnings and Precautions Box:

Post-treatment Exacerbation of Hepatitis B Virus: DESCovy is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of DESCovy have not been established in individuals infected with HBV. Discontinuation of DESCovy therapy in individuals infected with HBV may be associated with severe acute exacerbations of hepatitis due to the emtricitabine (FTC) or tenofovir alafenamide (TAF) components of DESCovy. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in individuals infected with HBV who discontinue DESCovy. If appropriate, initiation of anti-hepatitis B therapy may be warranted.



Risk of Drug Resistance with Use of DESCovy for HIV-1 PrEP in Undiagnosed Early HIV-1 Infection: DESCovy used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with use of FTC/TDF for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate DESCovy for HIV-1 PrEP if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed.

The safety and efficacy of DESCovy for HIV-1 PrEP in individuals at risk from receptive vaginal sex have not been studied.

DESCovy should not be coadministered with products containing any of the same components, or with products containing lamivudine or tenofovir disoproxil fumarate. In addition, DESCovy should not be administered with adefovir dipivoxil.

For all important safety information for DESCovy, including contraindications, additional warnings and precautions, adverse reactions and drug interactions, please see the Canadian Product Monograph at www.gilead.ca.

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. Gilead Sciences Canada, Inc. is the Canadian affiliate of Gilead Sciences, Inc. and was established in Mississauga, Ontario, in 2006.

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.

For more information on Gilead Sciences, Inc., please visit the company's website at www.gilead.com.

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. 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 September 30, 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.



Canadian Product Monographs for DESCOVY and TRUVADA, including Serious Warnings and Precautions, are available at www.gilead.ca

DESCOVY, DESCOVY for PrEP, TRUVADA, TRUVADA for PrEP and Gilead are trademarks of Gilead Sciences, Inc. or its related companies.

For more information on Gilead Sciences, Inc., 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.

References:

DESCOVY Product Monograph.

Government of Canada, Public Health Agency of Canada. HIV factsheet: Biomedical prevention of HIV–PrEP and PEP. November 2019.

<https://www.canada.ca/en/public-health/services/publications/diseases-conditions/hiv-factsheet-biomedical-prevention-prep-pep.html>

Centre for Communicable Diseases and Infection Control, Public Health Agency of Canada. HIV in Canada – Surveillance Report 2018. December 5, 2019.

<https://www.canada.ca/content/dam/phac-aspc/documents/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2019-45/issue-12-december-5-2019/ccdrv45i12a01-eng.pdf>

Canadian AIDS Society. Canada sees its fourth consecutive year of increasing HIV rates. February 18, 2020. <https://www.cdn aids.ca/canada-sees-its-fourth-consecutive-year-of-increasing-hiv-rates/>