



GILEAD CANADA SUBMITS SUPPLEMENTAL NEW DRUG SUBMISSION TO HEALTH CANADA FOR DESCOVY® FOR HIV PRE-EXPOSURE PROPHYLAXIS

– Submission supported by data from the DISCOVER trial, which evaluated the safety and efficacy of Descovy® compared to Truvada® in people at risk for sexually acquired HIV-1 infection –

Mississauga, ON – April 9, 2020 – Gilead Sciences Canada, Inc. (Gilead Canada) announced today that the company has submitted a Supplemental New Drug Submission (SNDS) to Health Canada for Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets). DESCOVY is being evaluated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection among individuals who are HIV-negative and at risk for HIV.

The submission 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.ⁱ

"Data have shown that when used in combination with other agents for HIV treatment, DESCOVY offers similar efficacy and improved safety for renal and bone parameters compared with TRUVADA," said Dr. Jason Brunetta, a Canadian DISCOVER investigator. "Results from DISCOVER now show a similar safety profile for DESCOVY in HIV prevention. These are important considerations for the potential long-term use of PrEP. If approved, DESCOVY will provide health care professionals with an additional preventive option for their patients, thereby potentially expanding the beneficial impact of PrEP."

"Gilead Canada looks forward to working with Health Canada to help evaluate bringing this option to people at risk of acquiring HIV infection," said Melissa Koomey, Vice President and General Manager, Gilead Canada. "We believe that anyone living with HIV or at risk for HIV should have access to the latest treatment innovations. We remain committed to investing in the research and development required to bring these options to Canadians who need them," added Koomey.

DESCOVY received approval in Canada in 2016 for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg, in combination with other antiretroviral agents.ⁱⁱ

The use of DESCOVY for PrEP is investigational in Canada. Market authorization for this indication has not yet been obtained; safety and efficacy are still under review by Health Canada.

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

Important Safety Information for DESCOVY for HIV Treatmentⁱⁱⁱ

Serious Warnings and Precautions Box: Post-treatment Exacerbation of Hepatitis B Virus: DESCOVY is not approved for the treatment of chronic HBV infection and the safety and efficacy of DESCOVY have not been established in patients coinfecting with HIV-1 and HBV.



Discontinuation of DESCOPY therapy in patients coinfecting with HIV-1 and HBV may be associated with severe acute exacerbations of hepatitis due to the emtricitabine (FTC) or tenofovir alafenamide (TAF) components of DESCOPY. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfecting with HIV-1 and HBV and discontinue DESCOPY. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

DESCOPY should not be coadministered with products containing any of the same components; or with products containing lamivudine or tenofovir disoproxil fumarate; and DESCOPY should not be administered with adefovir dipivoxil.

For all important safety information for DESCOPY, 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, 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 risk that Health Canada may not approve Descovy for PrEP in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. As a result, Descovy for PrEP may never be successfully commercialized in Canada. There is also the possibility of unfavorable results from ongoing and additional studies 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 Annual Report on Form 10-K for the year ended December 31, 2019 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.

i Gilead Sciences, Inc., DESCOVY for PrEP FDA filing news release, April 5, 2019.

<https://www.gilead.com/news-and-press/press-room/press-releases/2019/4/gilead-submits-supplemental-new-drug-application-to-us-food-and-drug-administration-for-oncedaily-descovy-for-hiv-preexposure-prophylaxis>

ii DESCOVY Product Monograph (www.gilead.ca)