QUÉBEC PROVIDES ACCESS TO BIKTARVY® FOR THE TREATMENT OF HIV

– Gilead Canada recognizes Québec's Ministry of Health for providing access to new HIV treatment, listed under the "Régie de l'assurance maladie du Québec" List of Medications –

– According to the most recent Public Health Agency of Canada data, Québec accounts for 27.9 per cent of total reported new cases of HIV, and the second highest diagnosis rate of HIV[1] –

– In clinical trials, BIKTARVY demonstrated high efficacy and a high barrier to resistance –

MISSISSAUGA, ON, Aug. 15, 2019 – Gilead Sciences Canada, Inc. (Gilead Canada) today announced that effective today the Québec public drug insurance plan will provide eligible patients with access to Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg) tablets, a once-daily single tablet and complete regimen for the treatment of HIV-1 infection in adults. Health Canada granted a Notice of Compliance for BIKTARVY in July 2018.

"To support the long-term health of people living with HIV, it is ideal that treatment regimens deliver both durable viral suppression and a demonstrated tolerability profile," said Dr. Benoit Trottier, Physician and Director of Research at Clinique de médecine urbaine du Quartier latin, and a BIKTARVY clinical trial investigator. "In clinical trials through 96 weeks, BIKTARVY has shown high efficacy and no new resistance. Access to BIKTARVY is important for patients in Québec. With its convenient once-a-day dosing of a small single tablet this option simplifies treatment, requires minimal monitoring and is a new option for many patients on older antiretroviral regimens, including those with non-HIV comorbidities such as cardiac, renal, liver or bone disease."

Treatment for people living with HIV is evolving, with an increasing focus on dealing with longer-term age-related health matters, including non-HIV comorbidities (such as cardiac, renal, liver or bone disease), and drug-related issues that develop at younger ages and more often among people living with HIV than among those without HIV infection.[2]

Canada Strives to Achieve 90-90-90[3]

UNAIDS has set a goal of 90-90-90 by 2020 meaning: 90 per cent of all people living with HIV will know their HIV status; 90 per cent of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 90 per cent of all people receiving antiretroviral therapy will have viral suppression.[4] According to the most recent data from the Public Health Agency of Canada (2016), 63,110 people were living with HIV in Canada.

According to the Plan d'action commun de Montréal sans sida, in Québec, 86 per cent of people living with HIV know their status (2016). In Montreal, 97 per cent of people receiving care were on antiretroviral treatment and 92 per cent of people living with HIV on treatment had undetectable viral loads.[5]

In Canada in 2016, it was estimated that 86 per cent of people living with HIV are diagnosed, 81 per cent of patients diagnosed are on treatment, and 91 per cent of positive Canadians on treatment have achieved viral suppression.[6]

"Gilead Canada is pleased that Québec will provide access to new treatment options that help address the evolving needs of a range of people living with HIV," said Kennet Brysting, Vice President and General Manager, Gilead Canada. "Gilead is committed to improving care and simplifying therapy for people living with HIV, providing new treatments to support Canada to achieve its 90-90-90 goals, and continuing to invest in research in next-generation treatments, including the ultimate goal of therapies that could potentially cure HIV infection in patients."

BIKTARVY AND TAF

BIKTARVY is Gilead Canada's fourth tenofovir alafenamide (TAF)-based therapy. The TAF-based therapies include: Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/ emtricitabine 200 mg/tenofovir alafenamide 10 mg), Descovy® (emtricitabine 200 mg/tenofovir alafenamide 10 mg and 25 mg) tablets and Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg) tablets.

Process and analytical development of bictegravir, one of the components of BIKTARVY, took place in Canada, where Gilead Alberta ULC (Gilead Alberta) supports the development of new innovative therapies with its process development and manufacturing facilities. The facility produces active pharmaceutical ingredients (APIs) for the company's investigational compounds as well as for some commercial products including those APIs used in BIKTARVY for HIV.

The approval of BIKTARVY was supported by data from four Phase 3 studies: Studies 1489 and 1490 in treatment-naïve HIV-1 infected adults, and Studies 1844 and 1878 in virologically-suppressed adults. The trials were comprised of a diverse population of 2,414 participants, including a wide range of adult age groups and races/ethnicities. BIKTARVY met its primary objective of non-inferiority at 48 weeks across all four studies. Through 48 weeks, no participants in any of the four studies failed BIKTARVY with treatment-emergent virologic resistance, no patients discontinued BIKTARVY due to renal adverse events and there were no cases of proximal renal tubulopathy or Fanconi syndrome. The most common adverse reactions in patients taking BIKTARVY were diarrhea, nausea and headache.

BIKTARVY does not cure HIV infection or AIDS.

Important Safety Information

BIKTARVY has serious warnings and precautions box in its product label including the risk of post-treatment acute exacerbation of hepatitis B (HBV) in patients who are co-infected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF) and may occur with discontinuation of BIKTARVY. Prior to, or when initiating BIKTARVY, healthcare professionals should test for hepatitis B virus infection, and closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are co-infected with HIV-1 and HBV and discontinue BIKTARVY. Patients with chronic hepatitis B or C and treated with antiretroviral therapy are at increased risk for severe hepatic adverse events.

BIKTARVY should not be co-administered with any other antiretroviral products including those containing bictegravir, emtricitabine and tenofovir alafenamide, or those containing lamivudine or tenofovir disproxil fumarate. BIKTARVY should not be administered with adefovir dipivoxil.

BIKTARVY is contraindicated with the following drug products: dofetilide, rifampin. BIKTARVY is also contraindicated with the herbal product, St. John's wort.

For all important safety information, 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 biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. 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 11.5 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 BIKTARVY and the possibility of unfavourable results from additional clinical trials involving BIKTARVY. 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 June 30, 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.

The Canadian Product Monograph for BIKTARVY, including Boxed Warning, is available at www.gilead.ca.

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.

1 Public Health Agency of Canada, "HIV in Canada—Surveillance Report, 2017", N Haddad, JS Li, S Totten, M McGuire, December, 6, 2018.

2 "Managing HIV infection in patients older than 50" (Canadian Medical Association Journal)

3 Government of Canada: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/summary-measuring-canada-progress-90-90-90-hiv-targets.html

4 UNAIDS https://www.unaids.org/en/resources/909090

5 Plan d'action commun de Montréal sans sida: http://www.montrealsanssida.ca/wp-content/uploads/2018/11/Resume-Plan_d-Action-Commun_MSS_ANG.pdf

6 Public Health Agency of Canada, https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/hiv-vih/hiv-vih-eng.pdf