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**Ontario and Quebec provide reimbursement for HIV therapies PIFELTRO®  
(doravirine) and DELSTRIGO® (doravirine/lamivudine/tenofovir disoproxil  
fumarate)**

- Although treatment progress has been made, human immunodeficiency virus (HIV) is still one of the world's most serious public health challenges.<sup>i</sup> In 2018, approximately 37.9 million people were living with HIV worldwide.<sup>ii</sup> During that same year, an estimated 1.7 million people became newly infected globally.<sup>iii</sup>
- For more than 30 years, Merck has been committed to scientific research and discovery in HIV that addresses unmet medical needs and helps people living with HIV have a long and healthy life.

**KIRKLAND, QC – November 18, 2019** - Merck Canada Inc., an affiliate of Merck & Co., Inc., known as MSD outside the United States and Canada, announced today that reimbursement will be provided to PIFELTRO® and DELSTRIGO®, a once-daily NNRTI regimen for the treatment of HIV-1 infection, effective October 31<sup>st</sup> for the Ontario Drug Benefit Program and November 14<sup>th</sup> for la Régie de l'assurance maladie du Québec, RAMQ. Ontarians and Quebecers aged 18 years or older who are living with an HIV-1 infection will be eligible for reimbursement under the public program.

“While living well with HIV infection is now a reality for most people, HIV remains a major public health challenge and identifying individuals with infection and ensuring access to effective treatment and care is a priority”, says Dr. Fiona Smail, Infectious Diseases and Medical Microbiology, McMaster University. “These two new products, from the class of drugs known as NNRTIs, provide another simple, effective and well tolerated treatment choice for patients”.

Merck's PIFELTRO® and DELSTRIGO® were approved for the treatment of HIV-1 by Health Canada in 2018. Both treatments provide additional options to adults infected with HIV-1 to help manage their disease.

“We're pleased to see both products now reimbursed for patients living with HIV in Ontario and Quebec,” says Anna Van Acker, President, Merck Canada. “At Merck, we are committed to scientific research and discovery of new treatment options that address the unmet medical needs and bring hope and quality of life to patients living with the consequences of this devastating disease. This includes ensuring that effective therapies are accessible to many patients as quickly as possible.”

## **About HIV-1 Infection**

HIV is a virus which causes HIV infection, with acquired immunodeficiency virus (AIDS) being the most advanced stage of HIV infection.<sup>iv</sup> HIV attacks the body by targeting and dismantling the immune system's infection-fighting CD4 cells.<sup>v</sup> As the body loses CD4 cells, the immune system struggles to fight off infections and certain cancers.<sup>vi</sup> If left untreated, the immune system can be broken down further by HIV and result in AIDS.<sup>vii</sup>

HIV-1 is the most predominant type of HIV infection, accounting for approximately 95 per cent of all infections worldwide.<sup>viii</sup>

## **About PIFELTRO®**

PIFELTRO® is a new non-nucleoside reverse transcriptase inhibitor (NNRTI) of HIV-1 to be administered in combination with other antiretroviral medicines. The approval of this therapy is based on data from two randomized, international, multicenter, double-blind, and active-controlled pivotal Phase 3 trials entitled DRIVE-FORWARD and DRIVE-AHEAD. PIFELTRO® is indicated, in combination with other antiretroviral medicinal products for the treatment of adults infected with HIV-1 without past or present evidence of viral resistance to doravirine. In DRIVE-FORWARD, once-daily PIFELTRO, demonstrated non-inferior efficacy to darunavir + ritonavir (DRV+r), each in combination with two nucleoside reverse transcriptase inhibitors (NRTI) at 48 weeks (84% in the PIFELTRO group achieved viral suppression of HIV-1 RNA <50 copies/mL vs. 80% in the DRV+r group). The most frequently reported adverse reactions considered possibly or probably related to PIFELTRO were nausea (6%) and headache (5%).<sup>ix</sup>

## **About DELSTRIGO®**

DELSTRIGO® is a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate, designed as a complete regimen for the treatment of HIV-1 infection in appropriate patients. The approval of this therapy is based on data from two randomized, multicenter, double-blind and active controlled pivotal Phase 3 trials entitled DRIVE-AHEAD and DRIVE-SHIFT. DELSTRIGO® is indicated as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults without past or present evidence of viral resistance to doravirine, lamivudine or tenofovir. In DRIVE-AHEAD, once-daily DELSTRIGO demonstrated non-inferior efficacy to the combination of efavirenz/emtricitabine/tenofovir DF (EFV/FTC/TDF) at 48 weeks (84% in the DELSTRIGO group achieved viral suppression of HIV-1 RNA <50 copies/mL vs. 81% in the EFV/FTC/TDF group). The most frequently reported adverse reactions considered possibly or probably related to DELSTRIGO were dizziness (7%) and nausea (5%).<sup>x</sup>

## **About Merck**

For over a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also

demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships.

Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola.

In Canada, Merck markets a broad range of vaccines, pharmaceutical and animal health products and is one of the top R&D investors in Canada, with investments totaling \$69 million in 2018 and more than \$1 billion since 2000. Based in Kirkland, Québec, Merck employs approximately 765 people across the country. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca) and connect with us on YouTube and Twitter @MerckCanada.

### **Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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Please see the product monograph for PIFELTRO® (doravirine) at:

[https://www.merck.ca/static/pdf/PIFELTRO-PM\\_E.pdf](https://www.merck.ca/static/pdf/PIFELTRO-PM_E.pdf)

Please see the product monograph for DELSTRIGO<sup>®</sup> (doravirine/lamivudine/tenofovir disoproxil fumarate) at:

[https://www.merck.ca/static/pdf/DELSTRIGO-PM\\_E.pdf](https://www.merck.ca/static/pdf/DELSTRIGO-PM_E.pdf)

## References

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<sup>i</sup> U.S. Department of Health & Human Services. Global statistics. Available at <https://www.hiv.gov/hiv-basics/overview/data-and-trends/global-statistics>

<sup>ii</sup> UNAIDS. Global HIV & AIDS statistics – 2019 fact sheet. Available at <https://www.unaids.org/en/resources/fact-sheet>

<sup>iii</sup> UNAIDS. Global HIV & AIDS statistics – 2019 fact sheet. Available at <https://www.unaids.org/en/resources/fact-sheet>

<sup>iv</sup> Aids Info – U.S. National Library of Medicine. HIV/Aids: The Basics Available at <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/45/hiv-aids--the-basics>

<sup>v</sup> Aids Info – U.S. National Library of Medicine. HIV/Aids: The Basics Available at <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/45/hiv-aids--the-basics>

<sup>vi</sup> Aids Info – U.S. National Library of Medicine. HIV/Aids: The Basics Available at <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/45/hiv-aids--the-basics>

<sup>vii</sup> Aids Info – U.S. National Library of Medicine. HIV/Aids: The Basics Available at <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/45/hiv-aids--the-basics>

<sup>viii</sup> Avert. Global information and education on HIV and AIDS. HIV Strains and Types. Available at <https://www.avert.org/professionals/hiv-science/types-strains>

<sup>ix</sup> Product Monograph. PIFELTRO<sup>®</sup>. 2018.

<sup>x</sup> Product Monograph. DELSTRIGO<sup>®</sup>. 2018.