

# Health Canada Approves New Indication for Merck's PREVYMIS® (letermovir) for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Adult Kidney Transplant Recipients

**KIRKLAND, QC, April 19, 2024** – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced that Health Canada has approved a new indication for PREVYMIS® (letermovir) for the prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV-seropositive/Recipient CMV-seronegative [D+/R-]).

“We are pleased that PREVYMIS® has received Health Canada approval to help prevent CMV disease in high-risk adult kidney transplant patients.” said Philippe Houle, Executive Director of Infectious Diseases and Specialty Medicines at Merck Canada. “Our focus remains solely on providing innovative medicines to address the unmet needs of all Canadians.”

## **Phase 3 study for PREVYMIS in high-risk adult kidney transplant recipients [CMV D+/R-]**

Health Canada's approval of PREVYMIS® for CMV disease prophylaxis in adult kidney transplant recipients was supported by a Phase 3, randomized, multicenter, double-blind, active comparator-controlled non-inferiority trial (P002, NCT03443869) in 589 adult kidney transplant recipients at high risk (CMV D+/R-). Participants were randomized (1:1) to receive either PREVYMIS® concomitantly with acyclovir (n=292), or valganciclovir concomitantly with a placebo to acyclovir (n=297). Study drug was initiated between Day 0 and Day 7 post-kidney transplant and continued through Week 28 (~200 days) post-transplant. Study drug was administered either orally or IV; the dose of PREVYMIS® was the same regardless of the route of administration.

## **About Merck**

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca) and connect with us on [YouTube](#) and [X \(formerly known as Twitter\)](#) @MerckCanada.

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

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbour 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. **There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful.** 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 the global outbreak of novel coronavirus disease (COVID-19); 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 2020 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 PREVYMIS® (Ietermovir) at: [PREVYMIS-PM\\_E.pdf \(merck.ca\)](#)**

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