

Media Contacts: Merck Canada Media Relations
1-833-906-3725

Merck Canada Initiates Rolling Submission to Health Canada for Molnupiravir, an Investigational Oral Therapeutic Agent for the Treatment of COVID-19

KIRKLAND, QC – August 13, 2021 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the initiation of a rolling submission to Health Canada for molnupiravir, an investigational twice daily oral antiviral agent currently in trials as a potential treatment for COVID-19. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics.

The rolling submission process was accepted under the Minister of Health's [Interim Order](#), which allows for the review of early safety, quality and efficacy data while later-stage clinical trials take place. Further findings from the ongoing molnupiravir development program will be shared with Health Canada as they become available. Health Canada will make a decision only when all necessary evidence has been submitted and reviewed.

Phase 2 interim results from the Phase 2/3 MOVE-OUT clinical trials were presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in July. [Phase 3](#) of the trial, evaluating molnupiravir twice daily for five days in non-hospitalized adults with confirmed SARS-CoV-2, five days or less following symptom onset and at least one risk factor associated with poor disease outcomes, is underway and includes sites in Canada.

About the MOVE-OUT study

MOVE-OUT (MK-4482-002) is a Phase 2/3, randomized, placebo-controlled, double-blind, multi-site study evaluating orally administered molnupiravir in non-hospitalized participants at least 18 years of age with laboratory confirmed COVID-19 and symptom onset within five days prior to randomization. The trial plans to enroll a total of 1,850 participants with mild or moderate COVID-19. A total of 1,550 patients in the Phase 3 portion of the trial will be randomized 1:1 to receive either molnupiravir (800 mg) or placebo twice daily for five days. The primary efficacy objective is to evaluate efficacy of molnupiravir compared to placebo as assessed by the

percentage of participants who are hospitalized and/or die during the period from randomization through Day 29. For further information regarding the trial please visit clinicaltrials.gov (NCT04575597).

About Molnupiravir

Molnupiravir (EIDD-2801/MK-4482) is an investigational, orally administered form of a potent ribonucleoside analog with antiviral activity against SARS-CoV-2, the causative agent of COVID-19. Molnupiravir has been shown to be active in several preclinical models of SARS-CoV-2, including for prophylaxis, treatment, and prevention of transmission, as well as SARS-CoV-1 and MERS. Molnupiravir was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University.

About Merck

For more than 130 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world.

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 \$93.58 million in 2020 and more than \$1.3 billion since 2000. Based in Kirkland, Québec, Merck employs approximately 592 people across the country. For more information about our operations in Canada, visit www.merck.ca and connect with us on [YouTube](#) and [Twitter @MerckCanada](#).

Forward-Looking Statement of Merck & Co. Inc., Kenilworth, NJ, 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. 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).

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