



News Release

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Merck Canada Announces Start of Enrollment for Phase 3 Clinical Trial of Molnupiravir, an Investigational Oral Therapeutic Agent for the Treatment of COVID-19

KIRKLAND, QC – May 10, 2021 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the initiation of the Phase 3 portion of the trial for molnupiravir, an investigational twice daily oral antiviral agent being evaluated for the treatment of COVID-19. The global MOVE-OUT clinical trial, evaluating the 800 mg dose of molnupiravir twice daily for five days in non-hospitalized patients with confirmed SARS-CoV-2 and early symptoms, has begun enrolling patients. Molnupiravir is being developed in collaboration with Ridgeback Biotherapeutics.

“We are excited to begin enrolling patients in the Phase 3 portion of the MOVE-Out study, based on the encouraging data to date. We very much look forward to completing this enrollment and to receiving the data in due time” said AnnA Van Acker, President, Merck Canada.

The decision to proceed with enrolment was based on an interim analysis of data from the Phase 2 portion of the study in non-hospitalized participants which showed that the percentage of patients who were hospitalized and/or died was lower in the combined molnupiravir-treated groups versus the placebo arm.

Final data from the Phase 3 portion (Part 2) of the MOVE-OUT study is anticipated in September/October 2021. Merck and Ridgeback Biotherapeutics plan to share further findings from the ongoing molnupiravir development program with regulatory agencies as they become available. The timing of the Canadian regulatory submission is currently being evaluated. To be eligible for the phase 3 portion of the study, patients must be 18 years or older, have tested positive for the virus causing COVID-19 and have symptom onset within five days prior to randomization. They must also have at least one risk factor for progressing to severe COVID-19, have at least one COVID-19 sign or symptom such as fever, cough, or loss of taste or smell, and not be hospitalized or expecting to be in the near future.

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 enrol 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 125 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. For more information about our operations in Canada, visit www.merck.ca and connect with us on [YouTube](https://www.youtube.com/merck) and [Twitter](https://twitter.com/merck).

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. 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).

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