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Merck Canada Media Contact: 1-800-463-7251
mediacanada@merck.com

Ridgeback Media Contact: Chrissy Carvalho
(646) 660-8641

Merck and Ridgeback Biotherapeutics Announce Initiation of Pivotal Phase 3 MOVe-AHEAD Study Evaluating Molnupiravir for Post-Exposure Prophylaxis of COVID-19 Infection

Study Now Enrolling Participants Who Live in the Same Household as Someone With Symptomatic, Laboratory-Confirmed COVID-19

KIRKLAND (Quebec), Sept. 1, 2021 – Merck (NYSE: MRK), known as MSD outside of Canada and the United States, and Ridgeback Biotherapeutics announced today the initiation of the Phase 3 MOVe-AHEAD clinical trial to evaluate molnupiravir, an investigational oral antiviral therapeutic, for the prevention of COVID-19 infection. The global study is enrolling individuals who are at least 18 years of age and reside in the same household as someone with laboratory-confirmed SARS-CoV-2 infection with symptoms. For more information on the molnupiravir MOVe-AHEAD clinical trial, visit www.clinicaltrials.gov.

“As the pandemic continues to evolve and surges are being reported in many places around the world, it is important that we investigate new ways to help protect individuals exposed to the virus from becoming infected with symptomatic disease,” said Dr. Nick Kartsonis, senior vice president, vaccines and infectious diseases, clinical research, Merck Research Laboratories.

The safety and efficacy of molnupiravir is also currently being evaluated in Part 2 of the ongoing MOVe-OUT trial, which is a global Phase 3, randomized, placebo-controlled, double-blind, multi-site study of non-hospitalized adult patients with laboratory-confirmed mild to moderate COVID-19 and at least one risk factor associated with poor disease outcomes. Data from the study is expected in the second half of 2021.
MOVe-AHEAD Study

MOVe-AHEAD (MK-4482-013) [NCT04939428] is a Phase 3 multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered molnupiravir compared to placebo in preventing the spread of SARS-CoV-2, the virus that causes COVID-19, within households. The trial will enroll approximately 1,332 participants who will be randomized to receive either molnupiravir (800 mg) or placebo orally every 12 hours for five days. The study will enroll participants who are at least 18 years of age and currently residing in the same household with someone who received a positive test for SARS-CoV-2, has at least one sign or symptom of COVID-19 and has not had those signs and symptoms for more than five days. Participants are not eligible for the trial if they have received the first dose of a COVID-19 vaccine seven days or more prior to enrollment, have previously had COVID-19 or are showing any signs or symptoms of COVID-19.

The primary endpoints of the trial include percentage of participants with COVID-19 (laboratory-confirmed SARS-CoV-2 infection with symptoms) through Day 14, percentage of participants with an adverse event and percentage of participants who discontinued study intervention due to an adverse event.

The trial is being conducted globally in countries including Argentina, Brazil, Colombia, France, Guatemala, Hungary, Japan, Mexico, Peru, Philippines, Romania, Russia, South Africa, Spain, Turkey, Ukraine, and the United States.

About Molnupiravir

Molnupiravir (MK-4482/EIDD-2801) is an investigational, orally administered form of a potent ribonucleoside analog that inhibits the replication of multiple RNA viruses including 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 and is being developed by Merck in collaboration with Ridgeback Biotherapeutics. Since licensed by Ridgeback, all funds used for the development of molnupiravir have been provided by Wayne and Wendy Holman and Merck.
About Ridgeback Biotherapeutics

Headquartered in Miami, Florida, Ridgeback Biotherapeutics LP is a biotechnology company focused on emerging infectious diseases. Ridgeback markets Ebanga™ for the treatment of Ebola (not available in Canada) and has a late-stage development pipeline which includes molnupiravir for the treatment of COVID-19. Development of molnupiravir is entirely funded by Ridgeback Biotherapeutics and Merck. All equity capital in Ridgeback Biotherapeutics, LP originated from Wayne and Wendy Holman, who are committed to investing in and supporting medical technologies that will save lives. The team at Ridgeback is dedicated to working toward finding life-saving and life-changing solutions for patients and diseases that need champions.

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, 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. 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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