



NEWS RELEASE

Merck and Ridgeback Announce Submission of Emergency Use Authorization Application to the U.S. FDA for Molnupiravir, an Investigational Oral Antiviral Medicine, for the Treatment of Mild-to-Moderate COVID-19 in At Risk Adults

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If Authorized, Molnupiravir Could Be the First Oral Antiviral Medicine for the Treatment of COVID-19

Submissions to Regulatory Agencies Worldwide Underway

KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that Merck has submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for molnupiravir, an investigational oral antiviral medicine, for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization. The companies are actively working with regulatory agencies worldwide to submit applications for emergency use or marketing authorization in the coming months.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20211011005110/en/>

The submission is based on **positive results from a planned interim analysis** from the Phase 3 MOVE-OUT clinical trial, which evaluated molnupiravir in non-hospitalized adult patients with mild-to-moderate COVID-19 who were at

risk for progressing to severe COVID-19 and/or hospitalization. At the interim analysis, molnupiravir reduced the risk of hospitalization or death by approximately 50%; 7.3% of patients who received molnupiravir were either hospitalized or died through Day 29 following randomization (28/385), compared with 14.1% of placebo-treated patients (53/377); $p=0.0012$. Through Day 29, no deaths were reported in patients who received molnupiravir, as compared to 8 deaths in patients who received placebo. The incidence of any adverse event was comparable in the molnupiravir and placebo groups (35% and 40%, respectively). The incidence of drug-related adverse events was also comparable (12% and 11%, respectively), and fewer subjects in the molnupiravir group discontinued therapy due to an adverse event compared to the placebo group (1.3% and 3.4%, respectively).

“The extraordinary impact of this pandemic demands that we move with unprecedented urgency, and that is what our teams have done by submitting this application for molnupiravir to the FDA within 10 days of receiving the data,” said Robert M. Davis, chief executive officer and president, Merck. “We are grateful to the patients and investigators in our study, and of course to our own colleagues who have exemplified Merck’s high standards of scientific excellence and our unwavering commitment to patients. I also want to take this moment to applaud our colleagues in the pharmaceutical industry and our collaborators in global health for rising to the challenge of bringing forward medicines and vaccines to fight COVID-19 — medicines and vaccines are both essential to our collective efforts. We look forward to working with the FDA on its review of our application, and to working with other regulatory agencies as we do everything we can to bring molnupiravir to patients around the world as quickly as possible.”

“We are grateful to the clinical investigators and patients who have helped bring us to this important milestone. Without their significant contributions, today’s achievement would not be possible. The submission to the FDA is a critical step towards making molnupiravir available to people who may benefit from an oral antiviral medicine that can be taken at home shortly after diagnosis with COVID-19,” said Wendy Holman, chief executive officer of Ridgeback Biotherapeutics. “We are pleased to partner with Merck and regulatory authorities to help provide molnupiravir to the people who need it here in the U.S. and around the world.”

About Merck’s Efforts to Enable Access to Molnupiravir, if it is Granted EUA or Approval

In anticipation of the results from MOVE-OUT and the potential for regulatory authorization or approval, Merck has been producing molnupiravir at risk and expects to produce 10 million courses of treatment by the end of 2021, with more courses expected to be produced in 2022.

Earlier this year, Merck **entered** into a procurement agreement with the U.S. Government under which the company will supply approximately 1.7 million courses of molnupiravir to the U.S. Government, upon EUA or approval from the U.S. FDA. Additionally, Merck has entered into supply and advance purchase agreements for molnupiravir with other governments worldwide, pending regulatory authorization, and is currently in discussions

with additional governments.

Merck is committed to providing timely access to molnupiravir globally, if it is authorized or approved, and plans to implement a tiered pricing approach based on World Bank country income criteria to reflect countries' relative ability to finance their health response to the pandemic.

As part of its commitment to widespread global access, Merck previously **announced** that the company has entered into non-exclusive voluntary licensing agreements for molnupiravir with established Indian generic manufacturers to accelerate availability of molnupiravir in more than 100 low- and middle-income countries (LMICs) following approvals or emergency authorization by local regulatory agencies.

About Molnupiravir

Molnupiravir (MK-4482/EIDD-2801) is an investigational, orally administered form of a potent ribonucleoside analog that inhibits the replication of 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. Additionally, pre-clinical and clinical data have shown molnupiravir to be active against the most common SARS-CoV-2 variants.

Molnupiravir was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University; Emory/DRIVE received some research funding from the U.S. Department of Defense and the National Institutes of Health. Molnupiravir is being developed by Merck & Co., Inc. in collaboration with Ridgeback Biotherapeutics. Ridgeback received an upfront payment from Merck and also is eligible to receive contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. Any profits from the collaboration will be split between the partners equally. Since licensed by Ridgeback, all funds used for the development of molnupiravir have been provided by Merck and by Wayne and Wendy Holman of Ridgeback.

Molnupiravir is also being evaluated for post-exposure prophylaxis in MOVE-AHEAD, a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 study, which is evaluating the efficacy and safety of molnupiravir in preventing the spread of COVID-19 within households. For more information, please visit <http://merckcovidresearch.com>.

About the MOVE-OUT Study

The MOVE-OUT trial (MK-4482-002) (**NCT04575597**) 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.

Patients enrolled in the study were unvaccinated against SARS-CoV-2, had at least one risk factor associated with poor disease outcomes, and symptom onset within five days prior to randomization. The primary efficacy objective of MOVE-OUT is to evaluate the efficacy of molnupiravir compared to placebo as assessed by the percentage of participants who are hospitalized and/or die from the time of randomization through Day 29.

The Phase 3 portion of the MOVE-OUT trial was conducted globally, including in more than 170 planned sites in countries including Argentina, Brazil, Canada, Chile, Colombia, Egypt, France, Germany, Guatemala, Israel, Italy, Japan, Mexico, Philippines, Poland, Russia, South Africa, Spain, Sweden, Taiwan, Ukraine, the United Kingdom and the United States. For further information about the MOVE-OUT trial, please visit clinicaltrials.gov.

The most common risk factors for poor disease outcome included obesity, older age (>60 years), diabetes mellitus and heart disease. Delta, Gamma and Mu variants accounted for nearly 80% of the baseline viral variants that had been sequenced at the time of the interim analysis. Recruitment in Latin America, Europe, and Africa accounted for 56%, 23% and 15% of the study population, respectively.

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 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 & Co., Inc. 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 over 130 years, Merck, known as MSD outside 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, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

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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