



NEWS RELEASE

Merck and Ridgeback Announce Initiation of a Rolling Review by the European Medicines Agency for Molnupiravir, an Investigational Oral Antiviral Medicine, for the Treatment of COVID-19 in Adults

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If Granted Marketing Authorization by the European Commission, Molnupiravir Could Be the First Oral Antiviral Medicine for the Treatment of COVID-19 in the European Union

KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that the European Medicines Agency (EMA) has initiated a rolling review for molnupiravir, an investigational oral antiviral medicine, for the treatment of COVID-19 in adults. Merck plans to work with the EMA's Committee for Medicinal Products for Human Use (CHMP) to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application. As previously **announced**, Merck has submitted an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA), and is actively working to submit applications to other regulatory agencies worldwide.

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

<https://www.businesswire.com/news/home/20211025005204/en/>

"This application to the EMA is another step in our efforts to bring molnupiravir forward to patients globally," said Dr. Dean Y. Li, executive vice president and president, Merck Research Laboratories. "We believe that molnupiravir will be an important addition to the range of public health tools to fight COVID-19 – including the vaccines developed by the research-based pharmaceutical industry, which remain essential and are the first-line of defense

against this pandemic.”

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 increased risk for progressing to severe COVID-19 and/or hospitalization. At the interim analysis, molnupiravir 800 mg twice-daily reduced the risk of hospitalization or death by approximately 50%; 7.3% of patients who received molnupiravir were hospitalized through Day 29 following randomization (28/385), compared with 14.1% of placebo-treated patients (53/377) that were either hospitalized or died; $p=0.0012$. 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 patients in the molnupiravir group discontinued therapy due to an adverse event compared to the placebo group (1.3% and 3.4%, respectively).

“In the nearly two years since COVID-19 emerged, the global scientific community has made extraordinary strides in developing several critical vaccines and treatments, but we still have a need for an oral antiviral medicine that can be taken at home,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics. “We believe that molnupiravir, with the exciting finding of reduction in hospitalization and death in the MOVE-OUT study, may help fill that need and look forward to working with the EMA on its review.”

About Merck’s Efforts to Enable Global Access to Molnupiravir, if it is Granted Authorization 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 even more courses expected to be produced in 2022.

On October 11, Merck and Ridgeback **announced** that Merck had submitted an application for EUA to the U.S. FDA for molnupiravir for the treatment of at-risk adults with mild-to-moderate COVID-19. Additional submissions to global regulatory agencies are underway.

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 following 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 that 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. Merck continues to discuss additional measures and collaborations to accelerate broad, global access to molnupiravir.

About Molnupiravir

Molnupiravir (MK-4482 and 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 U.S. 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 800 mg twice daily for five days 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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