



NEWS RELEASE

# Merck and Ridgeback's Molnupiravir, an Oral COVID-19 Antiviral Medicine, Receives First Authorization in the World

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U.K.'s Medicines and Healthcare Products Regulatory Agency Authorizes Molnupiravir for the Treatment of Mild-to-Moderate COVID-19 in Adults With a Positive SARS-CoV-2 Diagnostic Test and Who Have at Least One Risk Factor for Developing Severe Illness

Applications Remain Under Review by Other Regulatory Authorities, Including U.S. Food and Drug Administration and the European Medicines Agency

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 United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has granted authorization in the United Kingdom (U.K.) for molnupiravir (MK-4482, EIDD-2801), the first oral antiviral medicine authorized for the treatment of mild-to-moderate COVID-19 in adults with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness. In the U.K., LAGEVRIO® (lah-GEV-ree-oh) is the planned trademark for molnupiravir; the trademark for molnupiravir in other countries has not been approved. Merck **announced** its application with the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of molnupiravir is under review and recently **announced** the European Medicines Agency has initiated a rolling review of the company's Marketing Authorization Application. Merck is actively working to submit applications to other regulatory agencies around the world.

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

<https://www.businesswire.com/news/home/20211104005560/en/>

“The first global authorization of molnupiravir is a major achievement in Merck’s singular legacy of bringing forward breakthrough medicines and vaccines to address the world’s greatest health challenges. In pursuit of Merck’s unwavering mission to save and improve lives, we will continue to move with both rigor and urgency to bring molnupiravir to patients around the world as quickly as possible,” said Robert M. Davis, chief executive officer and president, Merck.

“As an oral therapeutic, molnupiravir offers an important addition to the vaccines and medicines deployed so far to counter the COVID-19 pandemic,” said Dr. Dean Y. Li, executive vice president and president, Merck Research Laboratories. “We are very grateful to the investigators, patients and their families for their critical contributions to the MOVE-OUT study that made this authorization possible.”

The authorization is based on **positive results from a planned interim analysis** from the Phase 3 MOVE-OUT clinical trial, which evaluated molnupiravir 800 mg twice-daily in non-hospitalized, unvaccinated adult patients with laboratory-confirmed mild-to-moderate COVID-19, symptom onset within five days of study randomization and at least one risk factor associated with poor disease outcomes (e.g., heart disease, diabetes).

“When we embarked on the journey to take molnupiravir from a hope to a reality, we believed we had a responsibility to move as quickly and safely as possible. We believed each day saved could save lives and limit severe disease and the global hardships of this pandemic,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics. “It is gratifying to reach this milestone and show that the extraordinary effort of our collaborators, patients, physicians and team and the personal sacrifices made have now achieved that important goal. It is also gratifying to see the first global authorization occur in the U.K., the very place where we administered molnupiravir to the first brave human volunteer.”

## About Merck’s Global Efforts to Accelerate Access to Molnupiravir Following Regulatory Authorizations or Approvals

Merck is committed to providing timely access to molnupiravir globally through our comprehensive supply and access approach, which includes investing at risk to produce millions of courses of therapy; tiered pricing based on the ability of governments to finance health care; entering into supply agreements with governments; and granting voluntary licenses to generic manufacturers and to the Medicines Patent Pool to make generic molnupiravir available in low- and middle-income countries following local regulatory authorizations or approvals.

**Supply:** 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 at least 20 million courses to be produced in 2022.

**Supply agreements:** 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 governments worldwide, including the U.K. Government for 480,000 courses of therapy, pending regulatory authorization, and is currently in discussions with additional governments. Merck 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.

**Voluntary licenses:** As part of its commitment to widespread global access, Merck previously **announced** that it has entered into a licensing agreement with the Medicines Patent Pool to increase broad access for molnupiravir in low- and middle-income countries. Additionally, 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 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, 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 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>. Please visit the Merck **media library** for molnupiravir images and b-roll.

## 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 in countries including Brazil, Canada, Chile, Colombia, France, Germany, Guatemala, Mexico, Philippines, Russia, South Africa, Spain, Taiwan, Ukraine, the United Kingdom and the United States. For further information about the MOVE-OUT trial, please visit **[clinicaltrials.gov](https://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](http://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](http://www.sec.gov)).

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