

Merck and Ridgeback's Investigational Oral Antiviral Molnupiravir Reduced the Risk of Hospitalization or Death by Approximately 50 Percent Compared to Placebo for Patients with Mild or Moderate COVID-19 in Positive Interim Analysis of Phase 3 Study - Merck.com

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Merck and Ridgeback's Investigational Oral Antiviral Molnupiravir Reduced the Risk of Hospitalization or Death by Approximately 50 Percent Compared to Placebo for Patients with Mild or Moderate COVID-19 in Positive Interim Analysis of Phase 3 Study

October 1, 2021 6:00 am ET

At the Interim Analysis, 7.3 Percent of Patients Who Received Molnupiravir Were Hospitalized Through Day 29, Compared With 14.1 Percent of Placebo-Treated Patients Who were Hospitalized or Died

Merck Plans to Seek Emergency Use Authorization in the U.S. as Soon as Possible and to Submit Applications to Regulatory Agencies Worldwide

If Authorized, Molnupiravir Could be the First Oral Antiviral Medicine for COVID-19

KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that molnupiravir (MK-4482, EIDD-2801), an investigational oral antiviral medicine, significantly reduced the risk of hospitalization or death at a planned interim analysis of the Phase 3 MOVE-OUT trial in at risk, non-hospitalized adult patients with mild-to-moderate COVID-19. 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. At the recommendation of an independent Data Monitoring Committee and in consultation with the U.S. Food and Drug Administration (FDA), recruitment into the study is being stopped early due to these positive results. Merck plans to submit an application for Emergency Use Authorization (EUA) to the U.S. FDA as soon

as possible based on these findings and plans to submit marketing applications to other regulatory bodies worldwide.

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

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“More tools and treatments are urgently needed to fight the COVID-19 pandemic, which has become a leading cause of death and continues to profoundly affect patients, families, and societies and strain health care systems all around the world. With these compelling results, we are optimistic that molnupiravir can become an important medicine as part of the global effort to fight the pandemic and will add to Merck’s unique legacy of bringing forward breakthroughs in infectious diseases when they are needed most. Consistent with Merck’s unwavering commitment to save and improve lives, we will continue to work with regulatory agencies on our applications and do everything we can to bring molnupiravir to patients as quickly as possible,” said Robert M. Davis, chief executive officer and president, Merck. “On behalf of all of us at Merck, I thank our network of clinical investigators and patients for their essential contributions to the development of molnupiravir.”

“With the virus continuing to circulate widely, and because therapeutic options currently available are infused and/or require access to a healthcare facility, antiviral treatments that can be taken at home to keep people with COVID-19 out of the hospital are critically needed,” said Wendy Holman, chief executive officer of Ridgeback Biotherapeutics. “We are very encouraged by the results from the interim analysis and hope molnupiravir, if authorized for use, can make a profound impact in controlling the pandemic. Our partnership with Merck is critical to ensuring rapid global access if this medicine is approved, and we appreciate the collaborative effort to reach this important stage of development.”

About the Results of the Planned Interim Analysis

The planned interim analysis evaluated data from 775 patients who were initially enrolled in the Phase 3 MOVE-OUT trial on or prior to Aug. 5, 2021. At the time of the decision to stop recruitment based on the compelling interim efficacy results, the trial was approaching full recruitment of the Phase 3 sample size of 1,550 patients, with more than 90% of the intended sample size already enrolled.

Eligibility criteria required that all patients had laboratory-confirmed mild-to-moderate COVID-19, with symptom onset within 5 days of study randomization. All patients were required to have at least one risk factor associated with poor disease outcome at study entry. Molnupiravir reduced the risk of hospitalization and/or death across all key subgroups; efficacy was not affected by timing of symptom onset or underlying risk factor. Additionally, based on the participants with available viral sequencing data (approximately 40% of participants), molnupiravir demonstrated consistent efficacy across viral variants Gamma, Delta, and Mu.

The incidence of any adverse event was comparable in the molnupiravir and placebo groups (35% and 40%, respectively). Similarly, the incidence of drug-related adverse events was also comparable (12% and 11%, respectively). Fewer subjects discontinued study therapy due to an adverse event in the molnupiravir group (1.3%) compared to the placebo group (3.4%).

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

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

Earlier this year, Merck [entered](#) into a procurement agreement with the U.S. Government under which Merck 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 purchase agreements for molnupiravir with other governments worldwide, pending regulatory authorization, and is currently in discussions with other 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 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.

More About the MOVE-OUT Study

The MOVE-OUT trial (MK-4482-002) ([NCT04575597](#)) was 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, 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. To date, the Delta, Gamma, and Mu variants have accounted for nearly 80% of the evaluable cases in the trial. Recruitment in Latin America, Europe, and Africa accounted for 55%, 23% and 15% of the study population, respectively.

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, and 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 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](#).

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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.

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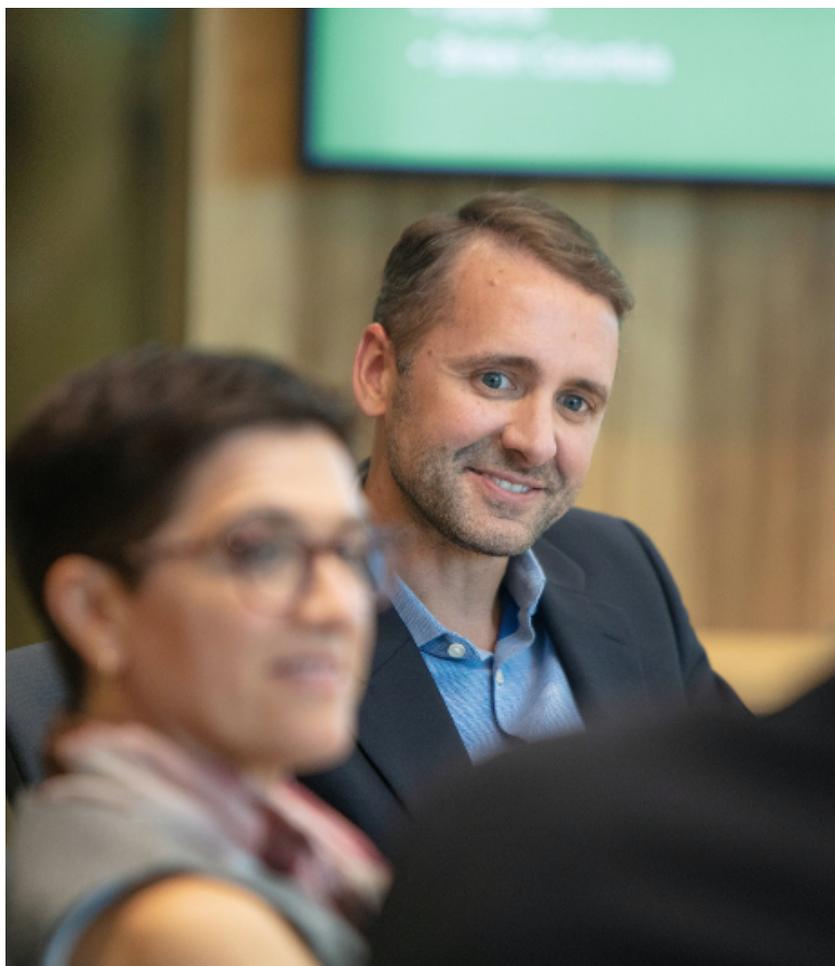
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