



NEWS RELEASE

# Ridgeback Biotherapeutics and Merck Announce Preliminary Findings from a Phase 2a Trial of Investigational COVID-19 Therapeutic Molnupiravir

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The findings reported on a secondary objective to reduce time to negativity of infectious SARS-CoV-2 virus isolation from nasopharyngeal swabs from participants with symptomatic COVID-19

Primary and other secondary findings to be presented at an upcoming medical meeting

MIAMI & KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics, LP today announced preliminary results from Ridgeback's Phase 2a randomized, double-blind, placebo-controlled trial to evaluate the safety, tolerability, and efficacy to eliminate SARS-CoV-2 viral RNA of molnupiravir (EIDD-2801/MK-4482), an investigational oral antiviral agent. The companies today reported findings on one secondary objective from the Phase 2a study, showing a reduction in time (days) to negativity of infectious virus isolation in nasopharyngeal swabs from participants with symptomatic SARS-CoV-2 infection, as determined by isolation in Vero cell line culture. These preliminary findings were presented today during Science Spotlights™ at the 2021 Conference on Retroviruses and Opportunistic Infections (CROI 2021). Findings from the primary efficacy and safety endpoints and additional secondary objectives will be presented at an upcoming medical meeting.

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This multi-center U.S. Phase 2a study enrolled 202 non-hospitalized adults who had signs or symptoms of COVID-19 within 7 days and confirmed active SARS-CoV-2 infection. The primary efficacy objective was reduction in time to viral negativity measured by reverse transcriptase polymerase chain reaction (RT-PCR) analysis of nasopharyngeal swabs. Periodic samples were collected for virologic analysis. Of the 182 participants with an evaluable nasopharyngeal swab, 42% (78/182) showed detectable levels of cultured virus at baseline. The full study results remain blinded and will be shared at a later date, as they become available. Other Phase 2 and Phase 2/3 studies are underway.

Today's presentation described findings from the secondary endpoint of reduction in time (days) to negativity of infectious virus isolation in nasopharyngeal swabs from participants with symptomatic SARS-CoV-2 infection, as determined by isolation in Vero cell line culture. At day 5, there was a reduction (nominal  $p=0.001$ , not controlled for multiplicity) in positive viral culture in subjects who received molnupiravir (all doses) compared to placebo: 0% (0/47) for molnupiravir and 24% (6/25) for placebo.

Of 202 treated participants, no safety signals have been identified and of the 4 serious adverse events reported, none were considered to be study drug related. In addition to the ongoing clinical studies, Merck has conducted a comprehensive nonclinical program to characterize the safety profile of molnupiravir. This program included assays such as Big Blue and PIG-a designed to provide a robust measure of a drug or chemical's ability to induce mutations in vivo. Animals were administered molnupiravir for longer and at higher doses (mg/Kg) than those employed in human studies. The totality of the data from these studies indicates that molnupiravir is not mutagenic or genotoxic in in vivo mammalian systems.

"We are very pleased to share our initial Phase 2 infectivity data at this important conference, which remains at the forefront for critical clinical scientific information in infectious diseases," shared Dr. Wendy Painter, Chief Medical Officer of Ridgeback Biotherapeutics. "At a time where there is unmet need for antiviral treatments against SARS-CoV-2, we are encouraged by these preliminary data."

"The secondary objective findings in this study, of a quicker decrease in infectious virus among individuals with early COVID-19 treated with molnupiravir, are promising and if supported by additional studies, could have important public health implications, particularly as the SARS-CoV-2 virus continues to spread and evolve globally," noted Dr. William Fischer, lead investigator of the EIDD-2801 2003 study and Associate Professor of Medicine, Division of Pulmonary Diseases and Critical Care Medicine at the University of North Carolina School of Medicine.

"We continue to make progress in our Phase 2/3 clinical programs evaluating molnupiravir in both outpatient and hospital settings and plan to provide updates when appropriate," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories.

## About Molnupiravir

Molnupiravir (EIDD-2801/MK-4482) is an investigational, orally-bioavailable 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 models of SARS-CoV-2, including for prophylaxis, treatment, and prevention of transmission, as well as SARS-CoV-1 and MERS. EIDD-2801 was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University. Since licensed by Ridgeback all funds used for the development of EIDD-2801 by Ridgeback 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 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 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. 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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