Merck and Ridgeback Statement on Positive FDA Advisory Committee Vote for Investigational Oral Antiviral Molnupiravir for Treatment of Mild to Moderate COVID-19 in High Risk Adults

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KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today provided the following statement at the conclusion of the U.S. Food and Drug Administration’s (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) regarding the Emergency Use Authorization (EUA) application for molnupiravir (MK-4482, EIDD-2801), an investigational oral antiviral medicine, for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization. The Advisory Committee voted 13-10 that the known and potential benefits of molnupiravir outweigh its known and potential risks for the treatment of mild to moderate COVID-19 in high risk adult patients who are within five days of symptom onset. The FDA is not bound by the committee's guidance but takes its advice into consideration.

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

“The positive outcome of today’s FDA Advisory Committee meeting, following a comprehensive review of molnupiravir, including the compelling data from the MOVe-OUT study demonstrating a significant reduction in hospitalizations and deaths, is a critical step toward bringing this promising oral medicine for COVID-19 to appropriate patients in the U.S. With the continued spread of the virus and the emergence of variants, additional treatments for COVID-19 are urgently needed. That is why we are moving with speed and rigor to pursue
authorizations and to accelerate broad global access to this investigational medicine,” said Dr. Dean Y. Li, executive vice president and president, Merck Research Laboratories. “We are grateful to the members of the Advisory Committee who reviewed our application, as well as to the patients and investigators who participated in our clinical trials, and we will continue to work with the FDA as the agency completes its review.”

“We are one step closer to being able to add molnupiravir to the tools that we have – in addition to vaccines – that can be available and accessible to help fight COVID-19. Importantly, our data show activity against the most prevalent variants today, and molnupiravir was studied as a monotherapy with no drug-drug interactions observed to date. We will continue to work with urgency to bring this investigational medicine forward to appropriate patients,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics.

Under an EUA, to help strengthen the nation’s protection against public health threats, such as SARS-CoV-2, the FDA may authorize unapproved medical products or unapproved uses of approved medical products in a public health emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain criteria are met, including when there are no adequate, approved, and available alternatives. The AMDAC provides the FDA with independent, expert advice and recommendations for consideration in making final decisions, including decisions related to authorization.

Merck’s submission to the FDA for EUA, as discussed by the AMDAC, is based on the positive results from a planned interim analysis of the Phase 3 MOVe-OUT clinical trial and the recent study update, including data from all randomized patients. MOVe-OUT evaluated molnupiravir in non-hospitalized adult patients with mild to moderate COVID-19 with symptom onset within five days prior to randomization who were at high risk for progressing to severe COVID-19 and/or hospitalization. At the planned interim analysis, which based on the study design was the primary efficacy analysis of the study, treatment with molnupiravir significantly reduced hospitalizations and death through Day 29 following randomization: 14.1% (53/377) of patients in the placebo group were hospitalized or died, compared to 7.3% (28/385) of patients who received molnupiravir who were hospitalized; at the interim analysis, no patients who took molnupiravir died, compared to eight patients who received placebo. The absolute risk reduction between the molnupiravir and the placebo arm was 6.8 percentage points (95% confidence interval [CI]: 2.4, 11.3; p=0.0012), which is approximately a 50% reduction in the risk of hospitalization or death through Day 29 compared with placebo. The efficacy benefit with molnupiravir treatment was consistent across important patient subgroups, including patients infected with SARS-CoV-2 variants of concern, Delta, Gamma and Mu.

On Nov. 26, Merck announced additional analyses from all enrolled participants (n=1433). In this population, molnupiravir reduced the risk of hospitalization or death from 9.7% in the placebo group (68/699) to 6.8% (48/709) in the molnupiravir group, for an absolute risk reduction of 3.0% (95% CI: 0.1, 5.9; nominal p-value=0.0218) and a relative risk reduction of 30% (relative risk 0.70; 95% CI: 0.49, 0.99). Nine deaths were reported in the placebo
group, and one in the molnupiravir group.

At the planned interim analysis, the incidence of any adverse event (AE) was comparable in the molnupiravir and placebo groups (35.0% and 39.6%, respectively). The incidence of drug-related AEs was also comparable (12.4% and 11.1%, respectively). Fewer subjects discontinued study therapy due to an AE in the molnupiravir group (1.3%) compared to the placebo group (3.4%). In the supportive analysis of all randomized patients, the AE profile for molnupiravir remained consistent with the profile reported at the planned interim analysis.

**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. Pre-clinical data suggest that molnupiravir has a high barrier to the development of resistance.

Molnupiravir is being studied as a single medicine, without the use of concomitant medicines and without food intake restrictions or dose modifications based on renal or hepatic impairment. Based on available data, no known drug interactions with molnupiravir have been identified.

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 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](http://merckcovidresearch.com).

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

Global access has been a priority for Merck and Ridgeback since the inception of their molnupiravir collaboration. The companies are 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 more than 100 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:** Merck entered into a procurement agreement with the U.S. Government under which the company will supply approximately 3.1 million courses of molnupiravir to the U.S. Government, upon EUA or approval from the U.S. FDA. Merck has entered into advance purchase and supply agreements for molnupiravir with the governments of multiple countries worldwide, including Thailand, Korea, Japan, United Kingdom and United States, pending regulatory authorizations, 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 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 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. 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 the vast majority of the baseline viral variants that had been sequenced at the time of the interim analysis.

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. The team at Ridgeback is dedicated to developing life-saving and life-changing solutions for patients and diseases that need champions as well as providing global access to these medicines. In line with Ridgeback's mission for equitable global access, all Ridgeback services and treatment for Ebola patients in Africa are delivered free of charge.

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 candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful.
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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