NEWS RELEASE

Merck and Ridgeback Announce Publication of Phase 3 Study of Molnupiravir, an Investigational Oral Antiviral COVID-19 Treatment, in the New England Journal of Medicine

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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 announced the**New England Journal of Medicine** has published findings from the Phase 3 MOVe-OUT trial evaluating molnupiravir, an investigational oral antiviral medicine, in non-hospitalized high risk adults with mild to moderate COVID-19. Data from MOVe-OUT demonstrated that early treatment with molnupiravir significantly reduced the risk of hospitalization or death in high risk, unvaccinated adults with COVID-19. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20211216006079/en/

Molnupiravir is **authorized** in the United Kingdom as the first oral antiviral 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. The European Medicines Agency (EMA) issued a positive scientific opinion for molnupiravir under Article 5.3 Regulation 726/2004, which is intended to support national decision-making on the possible use of molnupiravir prior to marketing authorization. Regulatory applications are under review or are in the process of being submitted, including applications for Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) and Japan's Ministry of Health, Labor and Welfare.

"In MOVe-OUT, molnupiravir significantly reduced the risk of hospitalization and death among a diverse population

of patients at risk for more severe COVID-19. The increases in COVID-19 cases, hospitalizations and deaths being reported globally are a stark reminder that new tools are urgently needed, which is why we are moving with speed and rigor to obtain authorizations and to accelerate broad global access to this investigational medicine for appropriate patients," said Dr. Dean Y. Li, president, Merck Research Laboratories. "Importantly, we observed consistent efficacy among patients with more common variants at the time, and more recent preclinical evidence indicates that molnupiravir has antiviral activity against Omicron, which is encouraging considering the uncertain future of a rapidly evolving virus such as SARS-CoV-2."

"The publication of these positive results in the New England Journal of Medicine demonstrates that molnupiravir, which was studied as a single medicine that can be taken at home – regardless of food intake, with no known drug-drug interactions and without required dose modifications for those with kidney or liver impairment – has the potential to be a valuable addition to the therapeutic options available to fight COVID-19," said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics. "We are grateful for the efforts of the clinical trial participants and investigators and will continue to study molnupiravir for the treatment and prevention of COVID-19."

"One of the hallmarks of the MOVe-OUT study is the diverse patient population, which included adults from 20 countries, with one or more risk factors such as obesity, advanced age, diabetes and serious heart conditions. Based on this study, molnupiravir has the potential to have a meaningful impact for patients, healthcare systems and public health," said Dr. Monica Gomes, Universidade Federal do Paraná, Brazil.

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. 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 patients who are hospitalized and/or die through Day 29.

Patients enrolled in the study had at least one risk factor associated with poor disease outcomes (age >60 years; active cancer; chronic kidney disease; chronic obstructive pulmonary disease; obesity; serious heart conditions; or diabetes mellitus), and symptom onset within five days prior to study enrollment. Key exclusion criteria were an anticipated need for hospitalization for COVID-19 within the next 48 hours, dialysis or estimated glomerular filtration rate less than 30 ml per minute per 1.73 m2, unwillingness to use contraception during the intervention period and for at least 4 days after completion of the regimen, severe neutropenia (absolute neutrophil count of <500 per milliliter), platelet count below 100,000 per microliter, any prior SARS-CoV-2 vaccination and pregnancy. The potential impact of molnupiravir on fetal development if taken during pregnancy is unknown. Standard-of-care treatment with antipyretic agents, anti-inflammatory agents, glucocorticoids, or a combination was permitted; use

of therapies intended as COVID-19 treatments (including any monoclonal antibodies and remdesivir) was prohibited through Day 29.

In the all randomized analysis, 47.7% of patients had onset of signs or symptoms three days or less before randomization and 44.5% had moderate COVID-19. The most common risk factors were obesity (73.7%), age over 60 years (17.2%) and diabetes mellitus (15.9%). Presence of baseline SARS-CoV-2 nucleocapsid antibodies was assessed centrally using the Elecsys® assay. Positive baseline SARS-CoV-2 antibodies, indicating recent/prior infection (not vaccination), were reported for 19.8% of patients. Due to the ongoing nature of testing, the viral variant type at baseline was not available for 25.9% of randomized patients in the interim analysis sample and 44.7% of randomized patients in the all randomized sample at the time of the publication. Among the all randomized population with sequence data available (55.3%), the three most common SARS-CoV-2 variants were Delta (58.1%), Mu (20.5%) and Gamma (10.7%).

Positive top-line results from the interim analysis were previously announced on Oct. 1, and recruitment into the study was stopped early at the recommendation of an independent Data Monitoring Committee and in consultation with the FDA. At the interim analysis, which was the primary analysis timepoint of the study, superiority was demonstrated as treatment with molnupiravir reduced hospitalizations and death: 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 through Day 29, compared to eight patients who received placebo. The absolute risk reduction was 6.8 percentage points (95% CI: 2.4, 11.3; p=0.001, one-sided), which is approximately a 50% relative reduction in the risk of hospitalization or death through Day 29 for molnupiravir compared with placebo. In the all randomized analysis (n=1433), molnupiravir had a lower risk of hospitalization or death through Day 29: 9.7% (68/699) of patients in the placebo group compared to 6.8% (48/709) of patients in the molnupiravir group, for an absolute risk reduction of 3.0% (95% CI: 0.1, 5.9) and a relative risk reduction of 30%. The efficacy benefit with molnupiravir treatment was generally consistent across important patient subgroups, including patients infected with SARS-CoV-2 variants of concern, Delta, Gamma and Mu. Nine deaths were reported in the placebo group (29-day all-cause mortality rate of 1.3%) and one in the molnupiravir group (29-day all-cause mortality rate of 0.1%), representing a relative reduction in the risk of death of 89% (95% CI: 14, 99).

As in previous trials, no safety concerns with molnupiravir were identified, and there was no evidence of a pattern of clinically meaningful abnormalities in laboratory test results. The incidence of any adverse event (AE) was comparable in the molnupiravir and placebo groups (30.4% and 33.0%, respectively). The incidence of drug-related AEs was also comparable (8.0% and 8.4%, respectively), and a lower percentage of patients in the molnupiravir group discontinued therapy due to an AE compared to the placebo group (1.4% and 2.9%, respectively). Serious AEs, none of which were deemed drug-related by the investigator, were less frequently reported among patients

treated with molnupiravir. Through Day 29, one death was reported in patients who received molnupiravir, as compared to nine deaths in the placebo arm. After Day 29, three additional deaths resulting from adverse events occurred in the placebo group compared with one additional death reported in the molnupiravir group.

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 Emergency Use Authorization or approval from the U.S. Food and Drug Administration. Merck has entered into advance purchase and supply agreements for molnupiravir with governments and announced agreements for over 20 **countries** worldwide, including Australia, Canada, Korea, Japan, Thailand, 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 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 (i.e., without the need for concomitant antiviral medicines). Based on available data, no food intake restrictions or dose modifications based on renal or hepatic impairment are necessary, and no known drug interactions with molnupiravir have been identified.

Molnupiravir was invented at Emory University. Drug Innovation Ventures at Emory (DRIVE), LLC, which was formed by Emory to develop early-stage drug candidates for viral diseases of global concern, advanced molnupiravir through IND submission. 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 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 was evaluated in MOVe-OUT, a global Phase 3, randomized, placebo-controlled, double-blind, multi-site study of non-hospitalized adult patients with symptomatic, laboratory-confirmed mild to moderate COVID-19 and at least one risk factor associated with poor disease outcomes. The Phase 3 portion of the MOVe-OUT trial was conducted globally in more than 170 sites in locations including Argentina, Brazil, Canada, Chile, Colombia, Egypt, France, Germany, Guatemala, Israel, Italy, 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**. Molnupiravir is also being **evaluated** for post-exposure prophylaxis in MOVe-AHEAD, a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 study 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 Ridgeback Biotherapeutics

Headquartered in Miami, Florida, Ridgeback Biotherapeutics LP is a biotechnology company focused on emerging infectious diseases. Ridgeback markets EbangaTM 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. 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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