NEWS RELEASE

Merck and Ridgeback Announce New Data For Investigational LAGEVRIO™ (molnupiravir) From Phase 3 MOVe-OUT Study

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Based on Prespecified Exploratory Endpoints, a Lower Proportion of Participants Treated With LAGEVRIO Had an Acute Care Visit Compared to Those Who Received Placebo

Based on a Post Hoc Analysis, Fewer Required Respiratory Interventions (Including Invasive Mechanical Ventilation)

RAHWAY, N.J. & MIAMI--(BUSINESS WIRE)-- Merck, known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced the **Annals of Internal Medicine** has published additional data from the Phase 3 MOVe-OUT trial evaluating LAGEVRIO™ (molnupiravir), an investigational oral antiviral medicine, in non-hospitalized adults with mild to moderate COVID-19 who were at high risk for progressing to severe disease.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20220607005398/en/

Analyses of pre-specified exploratory endpoints indicate that a lower proportion of LAGEVRIO-treated participants in the modified intent-to-treat (MITT) population had an acute care visit or a COVID-19-related acute care visit versus placebo-treated participants in the MITT population: 7.2% of participants who received LAGEVRIO reported an acute care visit through Day 29, versus 10.6% of placebo participants, with a relative risk reduction [RRR] of 32.1% [CI, 4.4% to 51.7%]; 6.6% of participants who received LAGEVRIO reported a COVID-19-related acute care visit, versus 10.0% of placebo participants, with a RRR of 33.8% [CI, 5.6% to 53.6%]. The MITT population included all

participants who were randomly assigned, received at least one dose of study drug, and were not hospitalized before the first dose of study drug. Based on a post hoc analysis, fewer LAGEVRIO-treated participants in the MITT population required respiratory interventions (including conventional oxygen therapy, a high-flow heated and humidified device, noninvasive mechanical ventilation, or invasive mechanical ventilation) versus placebo-treated participants, with a RRR of 34.3% [95% CI, 4.3% to 54.9%] for all respiratory interventions. Based on additional post hoc analyses, participants in the safety population who received LAGEVRIO showed earlier and larger reductions in mean C-reactive protein (CRP) values, and earlier and larger improvements in mean change from baseline oxygen saturation (SpO2) values, compared with participants who received placebo. The safety population consisted of all participants who had undergone randomization and had received at least one dose of LAGEVRIO.

Post hoc analyses also suggest that among the subgroup of participants who were hospitalized after randomization in MOVe-OUT, the median time to hospital discharge was nine days [CI, 7 to 12 days] for participants who received LAGEVRIO, versus 12 days [CI, 9 to 14 days] in the placebo group. Consistent with the full MITT population data, post hoc analyses also suggest that fewer LAGEVRIO-treated participants who were hospitalized after randomization required respiratory interventions versus placebo-treated participants, with a RRR of 21.3% [95% CI, 0.2% to 38.0%] for all respiratory interventions.

“The analyses add to our understanding of the clinical profile of LAGEVRIO and help to reinforce the importance of LAGEVRIO as part of the response to the COVID-19 pandemic,” said Dr. Dean Y. Li, president, Merck Research Laboratories.

“The primary data from MOVe-OUT demonstrated a significant reduction in the risk for progression to severe COVID-19, including hospitalization and death, when compared to placebo among non-hospitalized, at-risk patients. In light of the continued burden of COVID-19, we are encouraged by these new data,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics. “We look forward to continuing to study LAGEVRIO with the goal of helping high-risk patients and overburdened healthcare systems globally continue to combat the COVID-19 pandemic.”

In addition to the MOVe-OUT trial, LAGEVRIO is 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 LAGEVRIO in preventing the spread of COVID-19 within households.

About the MOVe-OUT Study

The Phase 3 MOVe-OUT clinical trial (**NCT04575597**) evaluated LAGEVRIO (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). The primary efficacy objective of MOVe-OUT was to evaluate the efficacy of LAGEVRIO 800 mg twice-daily for five days compared to placebo as assessed by the percentage of participants who were hospitalized and/or died through Day 29. These findings were published in the **New England Journal of Medicine**.

In **analyses** from all randomized patients (n=1433) in the MITT population, LAGEVRIO reduced the risk of hospitalization or death: 9.7% (68/699) of patients in the placebo group were hospitalized or died through Day 29 compared to 6.8% (48/709) of patients who received LAGEVRIO, for an absolute risk reduction of 3.0% (95% confidence interval [CI]: 0.1, 5.9). Nine deaths were reported in the placebo group, and one in the LAGEVRIO group.

The determination of primary efficacy was based on a planned **interim analysis** of 762 participants. At the interim analysis, treatment with LAGEVRIO significantly reduced the risk for 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 LAGEVRIO. The absolute risk reduction between the LAGEVRIO and the placebo arm was 6.8 percentage points (95% CI: 2.4, 11.3; p=0.0024).

The safety of LAGEVRIO was evaluated based on an analysis of MOVe-OUT in which 1,411 non-hospitalized subjects with COVID-19 were randomized and treated with LAGEVRIO (N=710) or placebo (N=701) for up to 5 days. Adverse events were those reported while subjects were on study intervention or within 14 days of study intervention completion/discontinuation. The most common adverse reactions for LAGEVRIO (incidence ≥1%) were diarrhea (2% for LAGEVRIO, 2% for placebo), nausea (1% for LAGEVRIO, 1% for placebo) and dizziness (1% for LAGEVRIO, 1% for placebo). Discontinuation of study intervention due to an adverse event (AE) occurred in 1% of subjects receiving LAGEVRIO and 3% of subjects receiving placebo. Serious AEs occurred in 7% of subjects receiving LAGEVRIO and 10% receiving placebo; most serious AEs were COVID-19 related.

About Merck's Global Efforts to Accelerate Access to LAGEVRIO (molnupiravir) Following Regulatory Authorizations or Approvals

Global access has been a priority for Merck and Ridgeback since the inception of their LAGEVRIO collaboration. The companies are committed to providing timely access to LAGEVRIO globally through our comprehensive supply and access approach, which includes:

Supply: As of May 31, 2022, Merck has supplied more than 8 million courses of treatment to governments in more than 30 markets worldwide.

Voluntary licenses: As part of its commitment to widespread global access, Merck granted voluntary licenses (VLs) to generics manufacturers and to the Medicines Patent Pool to make generic molnupiravir available in more than 100 low- and middle-income countries following approvals or emergency authorization by local regulatory

agencies. Through our VL agreements with generics manufacturers, more than 3 million courses of generic molnupiravir have been delivered to approximately 15 markets through March 2022.

UNICEF: To supplement the supply from licensed generic manufacturers, Merck has entered into an agreement with UNICEF to allocate up to 3 million courses of LAGEVRIO to low- and middle-income countries through the first half of 2022. Merck has also committed 2 million patient courses of LAGEVRIO, available to USAID at Merck's best access price to increase access in lower-income countries.

Product donation: Merck has donated 100,000 courses of therapy to Direct Relief, a global humanitarian aid organization, for distribution to refugees in low- and middle-income countries, including 50,000 courses of therapy for people affected by the invasion of Ukraine.

Purchase and supply agreements: Merck **entered** into a procurement agreement with the U.S. government under which the company supplied approximately 3.1 million courses of LAGEVRIO to the U.S. government, upon Emergency Use Authorization from the U.S. Food and Drug Administration. The U.S. Department of Health and Human Services (HHS) has created a public **website** to identify locations that have received shipments of government-procured COVID-19 therapeutics, including LAGEVRIO, available under Emergency Use Authorization. HHS has also created a **Test-to-Treat locator** to help identify pharmacies and community health centers across the nation where people can get tested for COVID-19 and receive appropriate treatments, as needed.

Merck has also entered into additional advance purchase and supply agreements for LAGEVRIO with governments of more than 30 markets worldwide, and is currently in discussions with additional governments. Merck is implementing a tiered pricing approach based on World Bank country income criteria to reflect countries' relative ability to finance their health response to the pandemic.

Merck continues to discuss additional measures and collaborations to accelerate broad, global access to LAGEVRIO.

Authorized Use of LAGEVRIO in the U.S.

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved product LAGEVRIO, a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate. LAGEVRIO is not FDA-approved for any use including for use for the treatment of COVID-19.

The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist

justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1) unless the declaration is terminated or authorization revoked sooner.

LAGEVRIO is not authorized for use in patients less than 18 years of age or for initiation of treatment in patients hospitalized due to COVID-19. Benefit of treatment with LAGEVRIO has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19. LAGEVRIO is not authorized for use for longer than five consecutive days. LAGEVRIO is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19. LAGEVRIO may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which LAGEVRIO belongs (i.e., anti-infectives).

Selected Safety Information for LAGEVRIO

Contraindications

No contraindications have been identified based on the limited available data on the emergency use of LAGEVRIO authorized under this EUA.

Warnings and Precautions

There are limited clinical data available for LAGEVRIO. Serious and unexpected adverse events may occur that have not been previously reported with LAGEVRIO use.

LAGEVRIO is not recommended for use during pregnancy. Based on findings from animal reproduction studies, LAGEVRIO may cause fetal harm when administered to pregnant individuals. There are no available human data on the use of LAGEVRIO in pregnant individuals to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

LAGEVRIO is authorized to be prescribed to a pregnant individual only after the healthcare provider has determined that the benefits would outweigh the risks for that individual patient. If the decision is made to use LAGEVRIO during pregnancy, the prescribing healthcare provider must document that the known and potential benefits and the potential risks of using LAGEVRIO during pregnancy were communicated to the pregnant individual.

There is a pregnancy surveillance program that monitors pregnancy outcomes in individuals exposed to LAGEVRIO during pregnancy. The prescribing healthcare provider must document that a pregnant individual was made aware of Merck's pregnancy surveillance program at 1-877-888-4231 or **pregnancyreporting.msd.com**. If the pregnant

individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient's name and contact information to Merck. Pregnant individuals exposed to LAGEVRIO can also report the exposure by contacting Merck at 1-877-888-4231 or **pregnancyreporting.msd.com**.

Advise individuals of childbearing potential of the potential risk to a fetus and to use an effective method of contraception correctly and consistently during treatment with LAGEVRIO and for 4 days after the final dose.

Prior to initiating treatment with LAGEVRIO, assess whether an individual of childbearing potential is pregnant or not, if clinically indicated.

Hypersensitivity reactions, including anaphylaxis, have been reported with LAGEVRIO. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue LAGEVRIO and initiate appropriate medications and/or supportive care.

LAGEVRIO is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth. The safety and efficacy of LAGEVRIO have not been established in pediatric patients.

Adverse Reactions

The most common adverse reactions occurring in ≥1% of subjects in the LAGEVRIO treatment group in the Phase 3 double-blind MOVe-OUT study were diarrhea (2% versus placebo at 2%), nausea (1% versus placebo at 1%), and dizziness (1% versus placebo at 1%) all of which were Grade 1 (mild) or Grade 2 (moderate).

Serious adverse events occurred in 7% of subjects receiving LAGEVRIO and 10% receiving placebo; most serious adverse events were COVID-19 related. Adverse events leading to death occurred in 2 (<1%) of the subjects receiving LAGEVRIO and 12 (2%) of subjects receiving placebo.

Drug Interactions

No drug interactions have been identified based on the limited available data on the emergency use of LAGEVRIO. No clinical drug-drug interaction trials of LAGEVRIO with concomitant medications, including other treatments for mild to moderate COVID-19, have been conducted.

Pregnancy/Breastfeeding

There are no data on the presence of molnupiravir or its metabolites in human milk. It is unknown whether molnupiravir has an effect on the breastfed infant or effects on milk production. Based on the potential for adverse

reactions in the infant from LAGEVRIO, breastfeeding is not recommended during treatment with LAGEVRIO and for 4 days after the final dose. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of LAGEVRIO.

Males of Reproductive Potential

Nonclinical studies to fully assess the potential for LAGEVRIO to affect offspring of treated males have not been completed. Advise sexually active individuals with partners of childbearing potential to use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose of LAGEVRIO. The risk beyond three months after the last dose of LAGEVRIO is unknown.

Required Reporting for Serious Adverse Events and Medication Errors

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events and medication errors potentially related to LAGEVRIO within 7 calendar days from the healthcare provider's awareness of the event.

Submit adverse event and medication error reports, using FDA Form 3500, to FDA MedWatch using one of the following methods:

- Complete and submit the report online: **www.fda.gov/medwatch/report.htm**
- Complete and submit a postage-paid FDA Form 3500 (**https://www.fda.gov/media/76299/download**) and return by:
    - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
    - Fax to 1-800-FDA-0178
- Call 1-800-FDA-1088 to request a reporting form
  In addition, please provide a copy of all FDA MedWatch forms to:
  Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA by:
  Fax: 215-616-5677
  E-mail: **dpoc.usa@merck.com**

About LAGEVRIO (molnupiravir)

LAGEVRIO(molnupiravir) (MK-4482) is an investigational, orally administered nucleoside analog that inhibits the replication of SARS-CoV-2, the causative agent of COVID-19.

Merck and Ridgeback's "orange COVID-19 pill" is a Swedish Orange opaque capsule with the Merck corporate logo

and “82” printed in white ink, available in certain markets as LAGEVRIO.

Results from the Phase 3 MOVe-OUT study demonstrated the efficacy benefit of LAGEVRIO treatment was generally consistent across patients infected with SARS-CoV-2 variants of concern, Delta, Gamma and Mu. Preclinical data has shown that LAGEVRIO has antiviral activity against the variant, Omicron (B1.1.529). LAGEVRIO has yet to be evaluated against Omicron in clinical studies.

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. LAGEVRIO 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 LAGEVRIO have been provided by Merck and Ridgeback.

LAGEVRIO 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

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. 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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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 Annual Report on Form 10-K for the year ended December 31, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Please see the Molnupiravir FDA Letter of Authorization at **https://www.merck.com/eua/Merck-EUA-letter.pdf** , Fact Sheet for Healthcare Providers, including Mandatory Requirements for Administration of Molnupiravir under Emergency Use Authorization, at **https://www.merck.com/eua/molnupiravir-hcp-fact-sheet.pdf** and Fact Sheet for Patients and Caregivers at **https://www.merck.com/eua/molnupiravir-patient-fact-sheet-english.pdf** .

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