NEWS RELEASE

Merck and Ridgeback to Present Data Demonstrating That Treatment With LAGEVRIO™ (molnupiravir) Was Associated With More Rapid Elimination of Infectious SARS-CoV-2 Than Placebo

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Additional Exploratory Patient Subgroup and Virology Data from MOVe-OUT Presented at ECCMID

Among Patients With Infectious Virus at Baseline, No Patients Who Received LAGEVRIO Had Infectious Virus at Days 3, 5 or 10

KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that data evaluating LAGEVRIO™(molnupiravir), an investigational oral antiviral COVID-19 medicine, will be presented at the 2022 European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) (Abstract #4514).

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20220401005097/en/

The presentation includes final analyses evaluating virologic outcomes throughout and following a five-day course of LAGEVRIO as part of the Phase 3 MOVe-OUT trial, which studied LAGEVRIO versus placebo for the treatment of COVID-19 in non-hospitalized adults with mild to moderate COVID-19 who were at high risk for progressing to severe disease. Among study participants for whom samples were available, viral infectivity was assessed via a plaque-forming assay in Vero cells. Prespecified exploratory virologic outcomes included changes from baseline in

SARS-CoV-2 RNA levels, and the percentage of study participants with viral clearance (i.e., undetectable SARS-CoV-2 RNA) and undetectable infectious SARS-CoV-2 through Day 29 in the modified intent-to-treat (mITT) population (≥1 dose of study intervention and not hospitalized prior to first dose).

In participants with infectious virus isolated at baseline and for whom post-baseline infectivity data were available, molnupiravir was associated with more rapid elimination of infectious virus than placebo. At Day 3 of treatment, among patients with infectious virus at baseline, infectious SARS-CoV-2 was detected in 0.0% (n=0/92) of patients who received LAGEVRIO, compared with 21.8% (n=20/96) of patients who received placebo. At Day 5, infectious virus was detected in 0.0% (n=0/91) of patients in the LAGEVRIO arm compared with 2.2% (n=2/89) in the placebo arm. At Day 10, no infectious virus was detected in either arm for patients with infectious virus at baseline. Molnupiravir was also associated with greater mean reductions from baseline in SARS-CoV-2 RNA than placebo from Days 3 through 10, though molnupiravir and placebo were associated with comparable rates of viral RNA clearance through Day 29.

“In these exploratory analyses from our Phase 3 study in patients with mild to moderate COVID-19, LAGEVRIO, an investigational oral antiviral medicine, cleared infectious SARS-CoV-2 faster than placebo among patients who had infectious virus at baseline, resulting in no infectious virus detected at Day 3, 5 or 10,” said Dr. Jay Grobler, associate vice president, infectious diseases and vaccines, Merck Research Laboratories. “These data reinforce our confidence in the potential of LAGEVRIO as a part of the solution to the COVID-19 pandemic.”

“We are encouraged by these data, which are consistent with findings from the Ridgeback Bio sponsored Phase 2 trial. These additional data will help to strengthen the base of scientific knowledge around LAGEVRIO as a treatment option for mild to moderate COVID-19 in appropriate patients,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics. “We look forward to continuing to study LAGEVRIO to build our understanding with the goal of helping high-risk patients around the world.”

Additional molnupiravir data to be presented at ECCMID include:

- Abstract #4865: Effects of Molnupiravir on the SARS-CoV-2 Genome: Next-Generation Sequencing Data from the MOVe-OUT Phase 3 Trial. J. Strizki.

- Abstract #4545: Molnupiravir for the Treatment of COVID-19 in Immunocompromised Patients: Efficacy, Safety, and Virology Results from the Phase 3 MOVe-OUT Trial. M. Johnson.

- Abstract #4548: Impact of Molnupiravir Treatment on Patient-Reported COVID-19 Symptoms in the MOVe-OUT Study. Y. Guan.

- Abstract #5113: Cost-effectiveness analysis of molnupiravir versus best supportive care for the outpatient treatment of adults with COVID-19. H. Goswami.

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

In the U.S. and select markets outside the U.S., LAGEVRIO is the approved trademark for molnupiravir.

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 LAGEVRIO800 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**.

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: Merck manufactured 10 million courses of treatment by the end of 2021, and at least 20 million courses are expected to be produced in 2022. To date, Merck has shipped LAGEVRIO to over 30 markets.

Voluntary licenses: As part of its commitment to widespread global access, Merck granted 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 approvals or emergency authorization by local regulatory agencies.

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.

Product donation: Merck has committed to donating 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 conflict in 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 or approval from the U.S. Food and Drug Administration. The U.S. Department of Health and Human Services (HHS) has created a public **website** to help providers locate public locations that have received shipments of government-procured COVID-19 therapeutics available under Emergency Use Authorization.

Merck has also entered into additional advance purchase and supply agreements for molnupiravir with governments for over 30 markets worldwide, including Australia, Canada, Korea, Japan, Thailand and United Kingdom, pending regulatory authorizations, 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 molnupiravir 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

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 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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