NEWS RELEASE

Merck and Ridgeback Biotherapeutics Provide Update on New Clinical and Non-Clinical Studies of LAGEVRIO™ (molnupiravir)

10/6/2022

- A preliminary analysis of the University of Oxford's open label, prospective real-world evidence study, PANORAMIC, conducted in the UK in highly-vaccinated adults mostly <65 years of age, showed no evidence of a difference between LAGEVRIO added to usual care compared to usual care alone for the reduction of hospitalizations and deaths through Day 28 (primary endpoint was not met); the incidence of hospitalizations and death through Day 28 was very low overall (0.8% in both groups).
- The main secondary endpoint (time to first self-reported recovery) in the PANORAMIC study was 6 days shorter with the LAGEVRIO group compared to the usual care group; in addition, the use of LAGEVRIO also was associated with earlier recovery across a wide range of other symptom measures, as compared to the usual care group.
- An analysis of real-world data from a separate observational, retrospective study conducted by investigators in Israel (known as the Clalit study) showed that in a cohort of non-hospitalized, high-risk patients, LAGEVRIO reduced hospitalizations and mortality due to COVID-19 in patients 65 years and above; no evidence of benefit was found in younger adults ages 40 to 64 years.
- Results from a separate, non-clinical 6-month carcinogenicity study in mice demonstrated that LAGEVRIO was not carcinogenic.

RAHWAY, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today issued the following announcement regarding data from two real-world evidence studies evaluating LAGEVRIO™ (molnupiravir), an investigational oral antiviral COVID-19 medicine.

The first study, PANORAMIC, was conducted by the University of Oxford in the UK in highly-vaccinated adults mostly less than age 65 during the period when the circulating SARS-CoV-2 variant was predominantly Omicron. The second study, Clalit, was conducted by investigators in Israel in mostly older adults with underlying chronic health conditions that make them vulnerable to severe COVID-19 disease, also when Omicron was the most dominant strain. The **PANORAMIC** pre-print was published today and the **Clalit** pre-print was published last week. Additionally, Merck is reporting results from a recent carcinogenicity study in transgenic mice, which demonstrated that LAGEVRIO was not carcinogenic at any dose tested.

Preliminary results from the PANORAMIC study

The PANORAMIC study, a UK-based clinical trial sponsored by the University of Oxford, included 25,783 participants who were randomized to open label treatment with LAGEVRIO plus usual care (n=12,821) or usual care alone (n=12,962); mean age of participants was

56.6 years. Primary outcome data were available in 25,000 (97%) participants. Nearly all (>98%) participants were vaccinated, with approximately 95% receiving three or more doses of a SARS-CoV-2 vaccine. In the preliminary analysis, the primary endpoint of reduction of hospitalizations and deaths within 28 days of randomization, compared to usual care, was not met; 0.8% of patients in both the LAGEVRIO group (n=103/12,516) and the usual care group (n=96/12,484) were hospitalized or died in the first 28 days.

On secondary objectives, LAGEVRIO was associated with improvement on a range of measures compared to usual care. The observed median time to first self-reported recovery (the main secondary endpoint) was 6 days shorter in the LAGEVRIO group; the median time to first recovery was 9 days on LAGEVRIO (range 5-23 days) vs. 15 days on usual care (range 7 to not reached). Following adjustment for age and baseline comorbidity, there was a substantial estimated improvement of 4 days in time-to-first recovery in the LAGEVRIO group vs. usual care group (10.4 days vs. 14.5 days; treatment benefit ratio 1.36 (95% Bayesian credible interval (BCI) 1.3-1.4). The finding on time-to-first recovery was consistent for LAGEVRIO across key subgroups. Secondary objectives were not adjusted for multiplicity.

Results from the Clalit study

In this observational, retrospective cohort study, LAGEVRIO was associated with a lower rate of hospitalizations and mortality due to COVID-19 in patients 65 years and above, but not in younger adults. In patients 65 years of age and above (n=13,569), hospitalizations related to COVID-19, the primary endpoint, occurred in 18 LAGEVRIO-treated patients (74.6 per 100,000 person-days) and in 513 untreated patients (127.6 per 100,000 person-days); adjusted hazard ratio (HR) for hospitalization was 0.55 (95% confidence interval (CI), 0.34 to 0.88). The secondary endpoint of death due to COVID-19 in this same age group occurred in 4 of 845 LAGEVRIO-treated and 137 of 12,724 untreated

patients; adjusted HR=0.26 (95% CI, 0.10 to 0.73).

In patients 40 to 64 years of age (n=6,229), hospitalizations related to COVID-19, the primary endpoint, occurred in 8 treated patients (125.8 per 100,000 person-days) and

97 untreated patients (49.1 per 100,000 person-days), and adjusted HR for hospitalization was 1.80 (95% CI, 0.86 to 3.77). The secondary endpoint of death due to COVID-19 in this same age group occurred in 4 of 224 LAGEVRIO-treated and 7 of 6,075 untreated patients; adjusted HR=12.82 (95% CI, 3.41 to 48.17). All four deaths in the LAGEVRIO-treated group occurred in patients 60-64 years of age.

“The totality of the data from both PANORAMIC and Clalit give us critical insights into the ways certain patients may benefit from treatment with LAGEVRIO. These data also emphasize the critical need and value for LAGEVRIO in the treatment of mild to moderate COVID-19 for appropriate high-risk patients. Most significantly, the Clalit study reinforces what the Phase 3 MOVe-OUT study demonstrated - a reduction in hospitalizations and mortality in an older population at high risk for progression to severe disease, where a clinically meaningful benefit was observed,” said Dr. Dean Y. Li, president, Merck Research Laboratories. “These findings, particularly with regard to symptomatic improvement seen in a secondary objective in PANORAMIC and the reduction in hospitalization and death rates seen in the older part of the patient population in Clalit, further support the urgent need for global access to LAGEVRIO for the treatment of COVID-19 in appropriate high-risk patients.”

“With the continuing uncertainty about potential severity of emerging variants, we are pleased that the real-world data from Israel showed that, in an older part of the study population that experienced more hospitalizations, rates of hospitalization and death were reduced in patients taking LAGEVRIO. Also notable is the substantial reduction in time to symptom resolution observed on a secondary endpoint in PANORAMIC even when background hospitalization rates were low. The observed six-day improvement symptom resolution in the PANORAMIC study is an important finding as we look for ways to further reduce the burden of this virus. As studies begin to assess how this medicine could potentially treat other significant illnesses with pandemic potential, we will remain steadfast in our commitment to ensuring global access to this important treatment,” said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics.

Additional results - PANORAMIC secondary and virology endpoints

On additional secondary objectives in the PANORAMIC study, compared to usual care, LAGEVRIO-treated participants reported:

- Reduced time to sustained recovery (21 days vs. 24 days);
- Reduced time to sustained alleviation of all symptoms (9 days vs. 12 days);

- Reduced time to reduction of symptom severity (8 days vs. 12 days);
- Higher self-rating of wellness on Days 7, 14, and 28;
- Fewer moderate or severe symptoms at Day 7, 14, and 28 for cough, shortness of breath, loss of taste/smell, and fatigue;
- Less health care seeking in primary care, including less contacts with a general practitioner or the UK National Health Service (NHS).

Additionally, a greater proportion of LAGEVRIO patients reported:

- Early sustained recovery, defined as recovered by Day 14 and remained recovered until Day 28 (32% receiving LAGEVRIO vs. 23% receiving usual care);
- Sustained recovery, defined as date participant first reported recovery and subsequently remained well until 28 days (69% vs. 60%);
- Sustained alleviation of all symptoms, defined as date symptoms first reported as minor or none and subsequently remained minor or none until 28 days (84% vs. 79%).

In a substudy in which a cohort of participants was sampled for virology outcomes:

- On Day 7, SARS-CoV-2 virus was below detection in 21% receiving LAGEVRIO vs. 3% receiving usual care;
- The mean viral load on Day 7 was lower on LAGEVRIO (3.82 log10 viral load) as compared to usual care (4.93 log10 viral load).

LAGEVRIO was generally well tolerated, with serious adverse events reported at a rate of 0.4% in both study groups and a low treatment withdrawal rate (1.1%).

About the PANORAMIC study

The PANORAMIC trial (Platform Adaptive trial of NOvel antiviRals for eArly treatMent of covid-19 In the Community), led by the University of Oxford and funded by UK Research and Innovation (UKRI) and National Institute for Health Research (NIHR), studied treatments approved by the UK Medicines and Health Care Products Regulatory Agency (MHRA), including LAGEVRIO, in patients with confirmed COVID-19 and ongoing symptoms. The study is a pragmatic-design trial intended to inform policy and public on treatments for COVID-19. The study began recruitment in December 2021 and completed enrollment in April 2022, all during the era of the Omicron variant.

The study was designed as an open-label, prospective, individually-randomized, controlled clinical trial evaluating the efficacy and safety for LAGEVRIO added to usual care compared to usual care alone in participants who have confirmed COVID-19 infection, in adults who were either ≥ 50 years of age or ≥ 18 years of age with comorbidities/known underlying chronic health conditions making them clinically vulnerable to COVID-19 infection.

Usual care was predominantly focused on managing symptoms with antipyretics; however, participants at highest risk (very impaired immunity or extremely clinically vulnerable) were eligible for additional therapies, including monoclonal antibodies (sotrovimab) and intravenous remdesivir.

Overall, 25,783 participants were randomized in the trial to LAGEVRIO (added to usual care) or usual care alone; the participant demographics, baseline characteristics, and other COVID-related characteristics at baseline were similar in the 2 groups. The trial sample size was intentionally expanded during the course of the trial from the initial goal of 10,600, due to a very low observed event rate for the primary endpoint of hospitalizations/deaths through Day 28 (observed <1% vs. initial estimate of 3%). Approximately 20% of participants were aged 50 to 65 years without additional risk factors.

Treatment with LAGEVRIO (standard dose 800 mg twice daily for 5 days; added to usual care) or usual care alone was initiated within 5 days of COVID-19 symptom onset in participants confirmed to have a positive PCR or rapid antigen test for SARS-CoV-2 in the past 7 days prior to treatment onset. The median duration of COVID-19 symptoms prior to treatment onset was 3 days. Overall, 87% of participants received treatment within 5 days of symptom onset. More than 95% of the participants reported taking LAGEVRIO for the full 5-day treatment course.

About the Clalit Health Services trial

The Clalit trial, an observational, retrospective cohort study, evaluated data obtained from the electronic medical records of members of Clalit Health Services (CHS), a large healthcare organization covering approximately 65% of the elderly Israeli population. The study assessed the real-world effectiveness of LAGEVRIO in preventing severe COVID-19 outcomes in patients 40 years of age and older estimated to be at high risk of progression to severe disease, who were infected by the Omicron variant and were not eligible for ritonavir-boosted nirmatrelvir therapy due to drug-drug interactions or impaired kidney function. High risk was defined according to a predictive risk score developed in CHS to evaluate the risk for severe COVID-19 in SARS-CoV-2 infected patients; patients with a score of 2 points or more were considered high risk. The most common coexisting conditions were obesity, hypertension, and diabetes. The study period started on January 16, 2022, the first day LAGEVRIO was administered to CHS patients, and ended on March 31, 2022, while the Omicron variant (BA.1) was the dominant SARS-CoV-2 strain in Israel.

A total of 1,166,404 CHS members were infected with SARS-CoV-2 during the study period. Of them, 19,868 patients were eligible for LAGEVRIO therapy; 1,069 (5%) patients received at least one dose of LAGEVRIO. The mean age of the study participants was 69 years, with 68% of the participants aged 65 years and older. Eighty-two percent of participants had previous COVID-19 immunity, either by vaccination, prior SARS-CoV-2 infection, or hybrid immunity. Patients residing in long-term care facilities, patients hospitalized before or on the same day of a positive SARS-CoV-2 test, and patients treated with ritonavir-boosted nirmatrelvir or monoclonal antibodies were all

excluded from the study.

Recent hospitalizations, active cancer, and diabetes were associated with high rates of hospitalizations due to COVID-19 across both age groups. Chronic heart failure, active cancer disease, prior CVA and COPD were prominent risk factors in patients aged 65 years or older. In the younger age group, immunosuppression and lack of prior immunity were strongly associated with the risk of hospitalizations related to COVID-19.

Update on results from recent carcinogenicity study

Results from a recent study (Tg RasH2) evaluating carcinogenicity in transgenic mice that received molnupiravir orally for six months at doses of 30, 100 or 300 mg/kg/day demonstrated that LAGEVRIO was not carcinogenic. These results further support the safety profile of LAGEVRIO.

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: Patients around the world have received more than 2 million courses of LAGEVRIO. Merck has supplied LAGEVRIO to more than 30 markets worldwide.

Voluntary licenses: As part of its commitment to widespread global access, Merck granted voluntary licenses (VLs) 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. Through our VL agreements with generic manufacturers, more than 3 million courses of molnupiravir have been delivered to nearly 20 markets through September 2022. Additionally, Hetero Labs, Ltd. has received WHO prequalification, an important step in enabling broader access for molnupiravir.

UNICEF: To supplement the supply from licensed generic manufacturers and bridge to the availability of WHO prequalified generic supply, Merck entered into an agreement with UNICEF to allocate up to 3 million courses of LAGEVRIO to facilitate timely supply to low- and middle-income countries from January 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 **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 40 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 (molnupiravir) 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 or
    - 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 LLC, Rahway, 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.

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**.

In November 2021, LAGEVRIO received **conditional marketing authorization** in the U.K. 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. In December 2021, it was **announced** that the U.K. government would purchase an additional 1.75 million patient courses of LAGEVRIO, which follows a previously announced agreement for 480,000 courses of treatment.

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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