NEWS RELEASE

Merck and Ridgeback Provide Update on EU Marketing Authorization Application for LAGEVRIO™ (Molnupiravir)

2/24/2023

RAHWAY, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the refusal of the marketing authorization for LAGEVRIO™ (molnupiravir) for the treatment of certain adults who have been diagnosed with COVID-19 in the European Union (EU). Merck and Ridgeback will appeal the decision and request a re-examination of the CHMP's opinion.

"We believe the CHMP's recommendation does not reflect the compelling data generated from the Phase 3 MOVe-OUT trial and from real-world studies demonstrating the positive impact that LAGEVRIO can provide for patients by reducing the risk of hospitalization and death among adults at increased risk for severe disease," said Dr. Dean Y. Li, president, Merck Research Laboratories. "More than 4 million patients worldwide have been treated with LAGEVRIO. We remain confident that LAGEVRIO has an important role to play in the COVID-19 treatment landscape and will appeal this opinion."

"LAGEVRIO is prescribed globally as an important medicine for appropriate adult patients at risk for severe disease, and there is a critical need for multiple approaches to treat COVID-19," said Wendy Holman, chief executive officer, Ridgeback Biotherapeutics.

The EMA scientific opinion under Article 5(3) of Regulation (EC) 726/2004, which has supported the decision by 16 EU national authorities to make LAGEVRIO available, remains in effect.

LAGEVRIO is approved or authorized for use in more than 25 countries, including Australia, Japan, the United States, the United Kingdom, and China for the treatment of certain adults who have been diagnosed with COVID-19. LAGEVRIO has been used in more than 4 million patients worldwide, and recent real-world studies – conducted across different geographies during the Omicron variant surge and as availability of effective vaccines has increased – support the clinical profile of LAGEVRIO as a treatment option for certain adults with mild to moderate COVID-19 who are at high risk for severe disease.

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 collaboration. The companies are committed to providing timely access to LAGEVRIO globally through our comprehensive supply and access approach, which included 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. To supplement the supply from licensed generic manufacturers and bridge to the availability of WHO prequalified generic supply, Merck entered into agreements with UNICEF and USAID to allocate up to a total of 5 million courses of LAGEVRIO to low- and middle-income countries.

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 adults with a current diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19) 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 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 registry 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 the pregnancy registry at **https://covid-pr.pregistry.com** or 1-800-616-3791. Pregnant individuals exposed to LAGEVRIO or their healthcare providers can also report the exposure by contacting Merck Sharp & Dohme LLC, Rahway, NJ USA at 1-877-888-4231.

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**.

LAGEVRIO is being studied in other diseases beyond coronaviruses. Early work on additional programs has begun, and a study evaluating LAGEVRIO for RSV (**NCT05559905**) is recruiting participants.

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., US

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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