



NEWS RELEASE

# Merck and Ridgeback Announce U.K. Government to Purchase Additional 1.75 Million Courses of Molnupiravir

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KENILWORTH, N.J. & MIAMI--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics today announced that the United Kingdom Government will purchase an additional 1.75 million patient courses of molnupiravir (MK-4482), an investigational oral antiviral COVID-19 medicine. In the U.K., LAGEVRIO® is the planned trademark for molnupiravir; the trademark for molnupiravir in other countries has not been approved. With this additional procurement agreement, which follows a previously announced agreement for 480,000 courses of treatment, the U.K. Government has now committed to purchase a total of 2.23 million courses of molnupiravir.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20211222005164/en/>

In early November, molnupiravir 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. Molnupiravir is currently available in the U.K. and patients have started to receive treatment. An application for Emergency Use Authorization for molnupiravir is under review by the U.S. Food and Drug Administration.

Merck has entered into advance purchase and supply agreements for molnupiravir with governments of more than 30 countries worldwide, including 21 agreements with countries in Europe.

## About Merck's Global Efforts to Accelerate Access to Molnupiravir Following Regulatory Authorizations or Approvals

Global access has been a priority for Merck and Ridgeback since the inception of their molnupiravir collaboration. The companies are committed to providing timely access to molnupiravir globally through our comprehensive supply and access approach, which includes investing at risk to produce millions of courses of therapy; tiered pricing based on the ability of governments to finance health care; entering into supply agreements with governments; and granting voluntary licenses to generic manufacturers and to the Medicines Patent Pool to make generic molnupiravir available in more than 100 low- and middle-income countries following local regulatory authorizations or approvals.

**Supply:** In anticipation of the results from MOVE-OUT and the potential for regulatory authorization or approval, Merck has been producing molnupiravir at risk and expects to produce 10 million courses of treatment by the end of 2021, with at least 20 million courses to be produced in 2022. To date, Merck has shipped molnupiravir to 12 countries; in countries where it is approved or authorized, patients have begun to receive the drug.

**Supply agreements:** Merck **entered** into a procurement agreement with the U.S. Government under which the company will supply approximately **3.1 million** courses of molnupiravir to the U.S. Government, upon Emergency Use Authorization or approval from the U.S. Food and Drug Administration. Merck has entered into advance purchase and supply agreements for molnupiravir with governments for over 30 countries worldwide, including Australia, Canada, Korea, Japan, Thailand, United Kingdom and United States, pending regulatory authorizations, and is currently in discussions with additional governments. Merck plans to implement a tiered pricing approach based on World Bank country income criteria to reflect countries' relative ability to finance their health response to the pandemic.

**Voluntary licenses:** As part of its commitment to widespread global access, Merck previously **announced** that it has entered into a licensing agreement with the Medicines Patent Pool to increase broad access for molnupiravir in low- and middle-income countries. Additionally, Merck previously **announced** that the company has entered into non-exclusive voluntary licensing agreements for molnupiravir with established generic manufacturers to accelerate availability of molnupiravir in more than 100 low- and middle-income countries following approvals or emergency authorization by local regulatory agencies.

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

## About Molnupiravir

Molnupiravir (MK-4482) is an investigational, orally administered form of a potent ribonucleoside analog that inhibits the replication of SARS-CoV-2, the causative agent of COVID-19. Molnupiravir has been shown to be active in several preclinical models of SARS-CoV-2, including for prophylaxis, treatment, and prevention of transmission. Pre-clinical data suggest that molnupiravir has a high barrier to the development of resistance.

Molnupiravir was studied as a single medicine (i.e., without the need for co-administered medicines to achieve therapeutic effect). Based on available data, no food intake restrictions or dose modifications based on renal or hepatic impairment are necessary, and no known drug interactions with molnupiravir have been identified.

Results from the Phase 3 MOVE-OUT study demonstrated the efficacy benefit of molnupiravir treatment was generally consistent across patients infected with SARS-CoV-2 variants of concern, Delta, Gamma and Mu. Preliminary preclinical data has shown that molnupiravir has antiviral activity against the newly identified variant, Omicron (B.1.1.529). Molnupiravir 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. Molnupiravir is being developed by Merck in collaboration with Ridgeback Biotherapeutics. Ridgeback received an upfront payment from Merck and also is eligible to receive contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. Any profits from the collaboration will be split between the partners equally. Since licensed by Ridgeback, all funds used for the development of molnupiravir have been provided by Merck and Ridgeback.

Molnupiravir was evaluated in MOVE-OUT, a global Phase 3, randomized, placebo-controlled, double-blind, multi-site study of non-hospitalized adult patients with symptomatic, laboratory-confirmed mild to moderate COVID-19 and at least one risk factor associated with poor disease outcomes. 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 Ebanga™ 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](http://www.merck.com) and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

## Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA.

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2020 Annual Report on Form 10-

K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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