



NEWS RELEASE

# Merck Announces Supply Agreement with U.S. Government for Molnupiravir, an Investigational Oral Antiviral Candidate for Treatment of Mild to Moderate COVID-19

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U.S. government commits to purchase approximately 1.7 million courses of Molnupiravir upon issuance of Emergency Use Authorization or approval by the U.S. Food and Drug Administration

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced it has entered into a procurement agreement with the United States government for molnupiravir (MK-4482). Molnupiravir is currently being evaluated in a Phase 3 clinical trial, the MOVE-OUT study, for the treatment of non-hospitalized patients with laboratory-confirmed COVID-19 and at least one risk factor associated with poor disease outcomes. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics.

"Merck is pleased to collaborate with the U.S. government on this new agreement that will provide Americans with COVID-19 access to molnupiravir – an investigational oral therapy being studied for outpatient use early in the course of disease – if it is authorized or approved," said Rob Davis, president, Merck. "In addition to this agreement with the U.S. government, we are actively engaged in numerous efforts to make molnupiravir available globally to fulfill Merck's commitment to widespread access."

Through the agreement, if molnupiravir receives Emergency Use Authorization (EUA) or approval by the U.S. Food and Drug Administration (FDA), Merck will receive approximately \$1.2 billion to supply approximately 1.7 million

courses of molnupiravir to the United States government. Merck has been investing at risk to support development and scale-up production of molnupiravir and expects to have more than 10 million courses of therapy available by the end of 2021.

Merck also plans to submit applications for emergency use or approval to regulatory bodies outside of the U.S. and is currently in discussions with other countries interested in advance purchase agreements for molnupiravir. Merck is committed to providing timely access to molnupiravir globally and intends to implement a tiered pricing approach based on World Bank data that recognizes countries' relative ability to finance their public health response to the pandemic.

As part of its access strategy, Merck has also entered into non-exclusive voluntary licensing agreements for molnupiravir with established generic manufacturers to accelerate availability of molnupiravir in 104 low- and middle-income countries (LMICs) following approvals or emergency authorization by local regulatory agencies.

In addition to developing molnupiravir, Merck is contributing to the pandemic response by collaborating with Johnson & Johnson to support the manufacture of its COVID-19 vaccine.

This procurement of molnupiravir will be supported in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, in collaboration with the DOD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) under contract number W911QY21C0031.

## About Molnupiravir

Molnupiravir (EIDD-2801/MK-4482) is an investigational, orally bioavailable form of a potent ribonucleoside analog that inhibits the replication of multiple RNA viruses including SARS-CoV-2, the causative agent of COVID-19. Molnupiravir has been shown to be active in several models of SARS-CoV-2, including for prophylaxis, treatment and prevention of transmission, as well as SARS-CoV-1 and MERS. EIDD-2801 was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University, and with partial funding support from the U.S. government. Since licensed by Ridgeback, all funds used for the development of EIDD-2801 by Ridgeback have been provided by Wayne and Wendy Holman and Merck.

The Phase 3 portion (Part 2) of the MOVE-OUT study, evaluating the potential of molnupiravir to reduce the risk of hospitalization or death, is ongoing. Merck currently anticipates that, pending favorable results from MOVE-OUT, the earliest possible submission for an Emergency Use Authorization for molnupiravir will be in the second half of 2021. Merck and Ridgeback Biotherapeutics plan to share further findings from the ongoing molnupiravir development program with regulatory agencies as they become available. For more information on the

molnupiravir clinical trial please visit <https://merckcovidresearch.com/>.

In addition, Merck plans to initiate a clinical program to evaluate molnupiravir for post-exposure prophylaxis in the second half of 2021.

## About Merck

For 130 years, Merck, known as MSD outside of 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 products that the products 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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Media Contacts:

Melissa Moody  
(215) 407-3536

Investor Contacts:

Peter Dannenbaum  
(908) 740-1037

Raychel Kruper  
(908) 740-2107

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