



NEWS RELEASE

Merck and Ridgeback Biotherapeutics Provide Update on Results from MOVE-OUT Study of Molnupiravir, an Investigational Oral Antiviral Medicine, in At Risk Adults With Mild-to-Moderate COVID-19

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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 provided an update on the MOVE-OUT study of molnupiravir (MK-4482, EIDD-2801), an investigational oral antiviral medicine for COVID-19. Data are now available from all enrolled participants (n=1433). In this study population, molnupiravir reduced the risk of hospitalization or death from 9.7% in the placebo group (68/699) to 6.8% (48/709) in the molnupiravir group, for an absolute risk reduction of 3.0% (95% confidence interval [CI]: 0.1, 5.9; nominal p-value=0.0218) and a relative risk reduction of 30% (relative risk 0.70; 95% CI: 0.49, 0.99). Nine deaths were reported in the placebo group, and one in the molnupiravir group. The adverse event profile for molnupiravir remained consistent with the profile reported at the planned interim analysis.

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Based on the study design, the definitive evaluation of efficacy was considered complete at the planned interim analysis, when the statistical criterion for success was met and enrollment in the study was discontinued at the recommendation of the external Data Monitoring Committee and agreed to by the U.S. Food and Drug Administration (FDA). As previously reported, at the planned interim analysis, molnupiravir significantly reduced the

risk of hospitalization or death from 14.1% (53/377) in the placebo group to 7.3% (28/385) in the molnupiravir group (absolute risk reduction 6.8%; 95% CI: 2.4, 11.3; $p=0.0012$), for a relative risk reduction of 48% (relative risk 0.52; 95% CI: 0.33, 0.80).

The interim analysis and the additional analyses support the efficacy and overall favorable benefit-risk assessment of molnupiravir for the treatment of mild to moderate COVID-19 in adults at high risk for disease progression. Merck has shared these additional analyses with the FDA and they will be presented to the FDA's Antimicrobial Drugs Advisory Committee on Nov. 30th.

Molnupiravir is being developed by Merck and Ridgeback for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-CoV-2 diagnostic test and who are at high risk for progression to severe COVID-19, including hospitalization or death. Molnupiravir has been authorized for use in the U.K. The FDA is reviewing Merck's application for Emergency Use Authorization. The European Medicines Agency (EMA) is reviewing Merck's application for marketing authorization following a positive scientific opinion under Article 5.3 regulation 726/2004, which is intended to support national decision-making on the possible use of molnupiravir prior to marketing authorization. These regulatory applications for molnupiravir are based on the pre-specified interim analysis based on data from 762 patients, which is the primary analysis of the study.

Merck and Ridgeback Biotherapeutics have conducted a rigorous development program for molnupiravir, and believe that molnupiravir has the potential to address a significant unmet medical need for an oral medicine for adults with COVID-19 who are at risk for progressing to severe COVID-19 and/or hospitalization. We look forward to working with the FDA and other agencies as they review our applications.

About Molnupiravir

Molnupiravir (MK-4482, EIDD-2801) 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 is being studied as a single medicine, without the use of concomitant medicines and without food intake restrictions or dose modifications based on renal or hepatic impairment. Based on available data, no known drug interactions with molnupiravir have been identified.

Molnupiravir was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University; Emory/DRIVE received some research funding from the U.S. Department of Defense and the National Institutes of Health. Molnupiravir is being developed by Merck & Co., Inc. 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.

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 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).

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