NEWS RELEASE

Merck and Ridgeback Biotherapeutics Provide Update on Progress of Clinical Development Program for Molnupiravir, an Investigational Oral Therapeutic for the Treatment of Mild-to-Moderate COVID-19

4/15/2021

Phase 3 MOVe-OUT Study of Molnupiravir in Outpatients to Proceed, Phase 2/3 MOVe-IN Study in Hospitalized Patients Will Not Proceed

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 clinical development program for molnupiravir (MK-4482/ EIDD-2801), an investigational orally available antiviral therapeutic. Based on a planned interim analysis of data from the Phase 2, dose-finding portion (Part 1) of two ongoing placebo-controlled Phase 2/3 trials evaluating molnupiravir administered twice a day for five days in outpatients (MOVe-OUT) and hospitalized patients (MOVe-IN) with COVID-19, and from a previously completed Phase 2a dose-ranging study in outpatients, the decision has been made to proceed with the Phase 3 portion (Part 2) of MOVe-OUT in outpatients with COVID-19, evaluating the 800 mg dose of molnupiravir twice daily. Data from MOVe-IN indicate that molnupiravir is unlikely to demonstrate a clinical benefit in hospitalized patients, who generally had a longer duration of symptoms prior to study entry; therefore, the decision has been made not to proceed to Phase 3.

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“We continue to make progress in the clinical development of our antiviral candidate molnupiravir. Data from the dose-finding portion of these studies are consistent with the mechanism of action and provide meaningful evidence

for the antiviral potential of the 800 mg dose," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "Based on the findings of this study we are advancing a Phase 3 trial program in non-hospitalized patients that strategically leverages our large network of clinical sites to enroll appropriate patients globally."

"We are pleased that molnupiravir continues to show promise as a potential treatment for non-hospitalized patients with COVID-19," said Wendy Holman, Chief Executive Officer, Ridgeback Biotherapeutics. "Data from Ridgeback Bio's EIDD-2801-2003 study (MK-4482-006) coupled with Merck's MK-4482-002 study provide compelling evidence for the antiviral activity of molnupiravir. We look forward to the initiation and completion of the Phase 3 portion of the MOVe-OUT study."

Update on MOVe-OUT (MK-4482-002) and MOVe-IN (MK-4482-001)

MOVe-OUT is an ongoing Phase 2/3, randomized, placebo-controlled, double-blind, multi-site study evaluating the efficacy, safety and pharmacokinetics of orally administered molnupiravir in non-hospitalized participants with COVID-19 confirmed using polymerase chain reaction. The primary efficacy objective of MOVe-OUT is to evaluate the efficacy of molnupiravir compared to placebo as assessed by the percentage of patients who are hospitalized and/or die from the time of randomization through Day 29. Part 1 of MOVe-OUT enrolled a total of 302 participants, with symptom onset within seven days prior to randomization, who were assigned to receive molnupiravir 200 mg (75), 400 mg (77), or 800 mg (76), or placebo (74).

The percentage of patients who were hospitalized and/or died in Part 1 of the MOVe-OUT study was lower in the combined molnupiravir-treated groups versus the placebo arm; the number of events reported are not sufficient to provide a meaningful measure of clinical effect. Analysis of SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs from patients in both MOVe-OUT and MOVe-IN using quantitative and qualitative polymerase chain reaction, an exploratory endpoint, indicated that molnupiravir inhibits replication of the virus, as demonstrated by a greater decrease from baseline in viral RNA compared to placebo at Day 5 and Day 10, and by a larger proportion of participants with undetectable viral RNA at Day 10 and Day 15 following the end of treatment. The largest overall magnitude of antiviral effect was observed in the 800 mg dose compared with the 200 mg and 400 mg doses. These differences in virology endpoints were more pronounced in participants enrolled $\leq$ 5 days following symptom onset.

Among 299 patients who received at least one dose of study intervention in MOVe-OUT, 6.2% (14/225) of those receiving molnupiravir and 6.8% (5/74) of those receiving placebo reported drug-related adverse events. In MOVe-IN, of 293 patients who received at least one dose of study intervention, 11.0% (24/218) of those treated with molnupiravir and 21.3% (16/75) of those receiving placebo reported drug-related adverse events. To date, safety

and laboratory data from MOVe-IN and MOVe-OUT provide no evidence for unexpected findings or trends observed at any of the doses studied. In both trials, no deaths were considered drug-related by the investigators, and there were no drug-related adverse events that led to discontinuation in participants who received molnupiravir. Interim results from both MOVe-IN and MOVe-OUT, including virology findings and pharmacokinetic analyses, have been shared with regulatory authorities and will be presented at an upcoming medical meeting.

The external Data Monitoring Committee noted that the subgroup analyses support potential benefit of treatment and suggested amendments to the MOVe-OUT protocol to focus enrollment on patients early in the course of disease and those considered high risk for poor COVID-19 outcomes (e.g., older patients, those with obesity and diabetes). Based upon these recommendations, Merck will amend the inclusion criteria for MOVe-OUT by reducing the allowable symptom duration for enrollment to $\leq$ 5 days and by enrolling participants with at least one risk factor for progression to severe disease. Merck plans to start enrolling patients in Phase 3 portion (Part 2) of MOVe-OUT by late April/early May.

Final data from the Phase 3 portion (Part 2) of the MOVe-OUT study is estimated to be available in September/ October 2021. 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.

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

About the MOVe-OUT study design

MOVe-OUT (MK-4482-002) is a Phase 2/3, randomized, placebo-controlled, double-blind, multi-site study evaluating the efficacy, safety and pharmacokinetics of orally administered molnupiravir in non-hospitalized participants at least 18 years of age with laboratory confirmed COVID-19 and symptom onset within seven days prior to randomization. The trial plans to enroll a total of 1850 participants with mild or moderate COVID-19. The Phase 2 portion of the trial enrolled 302 participants randomized 1:1:1:1 to receive molnupiravir 200 mg, 400mg, 800mg or placebo twice daily for 5 days. The primary efficacy objective is to evaluate efficacy of molnupiravir compared to placebo as assessed by the percentage of participants who are hospitalized and/or die during the period from randomization through Day 29. Exploratory endpoints supporting dose selection for Phase 3 portion (Part 2) include change from baseline in SARS-CoV-2 RNA plasma levels and percentage of participants with undetectable SARS-CoV-2 RNA various time points, viral RNA mutation rate as assessed by comparison of baseline and post-baseline virus sequencing and pharmacokinetic data (eg, Ctrough, Cmax, tmax, t1/2, AUC0-12). Following the completion of Part 1 the inclusion criteria for MOVe-OUT were amended reducing the allowable symptom duration

for enrollment to ≤ 5 days and increasing enrollment for those considered high risk for poor COVID-19 outcomes (e.g., older patients and those with obesity and diabetes). For further information regarding the trial please visit **clinicaltrials.gov**.

About the MOVe-IN study design

MOVe-IN (MK-4482-001) was a Phase 2/3, randomized, placebo-controlled, double-blind, multi-site trial evaluating the efficacy, safety, and pharmacokinetics of orally administered molnupiravir in hospitalized participants at least 18 years of age with laboratory confirmed COVID-19 and symptom onset within 10 days prior to randomization. The Phase 2 portion of the trial enrolled 304 participants randomized 1:1:1:1 to who received molnupiravir 200 mg, 400 mg, 800 mg or placebo twice daily for 5 days. The primary efficacy endpoint was to evaluate the efficacy of molnupiravir compared to placebo as assessed by the rate of sustained recovery from randomization through Day 29. Exploratory endpoints supporting dose selection for the Phase 3 portion (Part 2) of the trial included change from baseline in SARS-CoV-2 RNA levels and percentage of participants with undetectable SARS-CoV-2 RNA at various time points, viral RNA mutation rate as assessed by comparison of baseline and post-baseline virus sequencing and pharmacokinetic data (eg, Ctrough, Cmax, tmax, t1/2, AUC0-12). Following an interim analysis of data, it was concluded that the study was unlikely to demonstrate a clinical benefit in hospitalized patients. The decision was made to discontinue the study.

About Molnupiravir Protocol MK-4482-006 (also known as EIDD-2801-2003)

Protocol 6 (MK-4482-006) is a Phase 2a, double-blind, placebo-controlled, randomized trial designed to compare the safety, tolerability, and antiviral activity of molnupiravir versus placebo as measured by viral RNA detection in symptomatic, outpatient (at baseline) adults at least 18 years old with SARS-CoV-2 infection as confirmed by viral RNA detection within seven days of symptom onset. Of 202 treated participants, molnupiravir was considered generally well tolerated and of the 4 serious adverse events reported, none were considered study drug related. Preliminary data from this study was previously presented at CROI 2021.

About Molnupiravir Nonclinical studies

Merck has conducted a comprehensive nonclinical program to characterize the safety profile of molnupiravir. This program included assays such as Big Blue and PIG-a which are designed to provide a robust measure of a drug or chemical's ability to induce mutations in vivo. Animals were administered molnupiravir for longer and at higher doses (mg/Kg) than those employed in human studies. The totality of the data from these studies indicates that molnupiravir is not mutagenic or genotoxic in in vivo mammalian systems.

About Molnupiravir

Molnupiravir (EIDD-2801/MK-4482) is an investigational, orally administered 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 preclinical models of SARS-CoV-2, including for prophylaxis, treatment, and prevention of transmission, as well as SARS-CoV-1 and MERS. Molnupiravir was invented at Drug Innovations at Emory (DRIVE), LLC, a not-for-profit biotechnology company wholly owned by Emory University. For more information on molnupiravir clinical trials please visit **https://merckcovidresearch.com/**

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. Development of molnupiravir is entirely funded by Ridgeback Biotherapeutics and Merck & Co., Inc. All equity capital in Ridgeback Biotherapeutics, LP originated from Wayne and Wendy Holman, who are committed to investing in and supporting medical technologies that will save lives. The team at Ridgeback is dedicated to working toward finding life-saving and life-changing solutions for patients and diseases that need champions.

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** 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**).

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