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Short Communication

Molnupiravir, A Promising Novel Drug Candidate Fighting against COVID-19 and its Variants

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Updated Molnupiravir (MK-4482/EIDD-2801, an orally investigational antiviral drug) clinical development program was provided by Merck (MSD, NYSE: MRK) and Ridgeback Biotherapeutics, as of April 15, 2021 (available at: https://merckcovidresearch.com/). Data from a previously completed Phase IIa dose-ranging study in outpatients and the two ongoing placebo-controlled Phase II/III trials were analyzed to evaluate molnupiravir administered twice daily for five days. They decided to continue MOVe-OUT, Phase III (Part II) in COVID-19 outpatients and not to proceed to Phase III of MOVe-IN due to general having a longer duration of symptoms prior to study entry that contributed to molnupiravir being unlikely to demonstrate a clinical benefit in COVID-19 inpatients in MOVe-IN by evaluation of the 800 mg dose of molnupiravir twice a day. During the period from participant randomization through the day 29, 302 mild-to-moderate-COVID-19-symptom participants with 18 years of age or older and all sexes, including individuals with high risk for poor COVID-19 outcomes (individuals with symptom duration of 5 days or less, aging, obese, or diabetic individuals) had been enrolled in Phase II portion of the MOVe-OUT study. Merck plans to initiate enrolling participants in Phase III portion (Part II) of MOVe-OUT by late April 2021 or early May 2021 and the final data is estimated to be available in September 2021 or October 2021. In the second half of 2021, starting an evaluation of molnupiravir clinical program for COVID-19-post-exposure prophylaxis and submission of pending favorable results from molnupiravir-MOVe-OUT for an Emergency Use Authorization will be occur. Molnupiravir is not genotoxic or mutagenic, demonstrated in data from several *in vivo* mammalian system studies [1]. This trial has been registered in the US patent system, entitled "The safety of molnupiravir (EIDD-2801) and its effect on viral shedding of SARS-CoV-2 (END-COVID)" with the ClinicalTrials.gov Identifier of NCT04405739. The actual study start date of trial, estimated primary completion date of trial, and estimated study completion date of trial are June 16, 2020, May 28, 2021 and May 28, 2021, respectively. Department of Drug Innovations at Emory (DRIVE), LLC, a non-profit biotechnology company wholly owned by Emory University, USA invented molnupiravir [2].

In conclusion, based on the preliminary results of this study, Merck and Ridgeback Biotherapeutics are advancing a Phase III program in outpatients with COVID-19 to achieve their large global network of clinical sites.

Bibliography

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