molnupiravir – An oral treatment for COVID-19 filed for EUA

- On October 11, 2021, Merck announced the submission of an application for emergency use authorization (EUA) to the FDA for molnupiravir, an oral treatment for COVID-19.

- Molnupiravir is a ribonucleoside analog that inhibits the replication of SARS-CoV-2, the virus responsible for COVID-19.

- Molnupiravir is intended for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.

- The EUA submission is based on a planned interim analysis from the phase 3, randomized, double-blind, placebo-controlled MOVe-OUT clinical trial, which evaluated **775 non-hospitalized, unvaccinated adult patients with mild-to-moderate COVID-19** who were at risk for progressing to severe COVID-19 and/or hospitalization.

    — At the interim analysis, molnupiravir reduced the risk of hospitalization or death by approximately 50%; 7.3% (28/385) of patients who received molnupiravir were either hospitalized or died through day 29 following randomization vs. 14.1% (53/377) of placebo-treated patients (p = 0.0012).
    — Through day 29, no deaths were reported in patients who received molnupiravir vs. 8 deaths in patients who received placebo.
    — The incidence of any adverse event was comparable in the molnupiravir and placebo groups (35% and 40%, respectively).

- A second clinical trial is underway: The MOVe-AHEAD trial will evaluate 1,332 individuals for preventing the spread of COVID-19 within households (e.g., post-exposure prophylaxis). The test dose will be molnupiravir 800 mg every 12 hours for 5 days. Data is expected in the first half of 2022.

- The U.S. government has paid $1.2 billion for 1.7 million courses (an oral dose twice daily for 5 days) of treatment if authorized or approved by the FDA.

    — Merck expects to produce 10 million courses of treatment by the end of 2021, and more in 2022.

- Before molnupiravir can be used commercially, the FDA must authorize its use.
    — Since molnupiravir is an oral treatment for COVID-19, it would not be in scope for review by CDC's Advisory Committee on Immunization Practices (ACIP).

    — No FDA Advisory Committee has been scheduled. If a meeting is scheduled, OptumRx will monitor it for relevant information.