Molnupiravir

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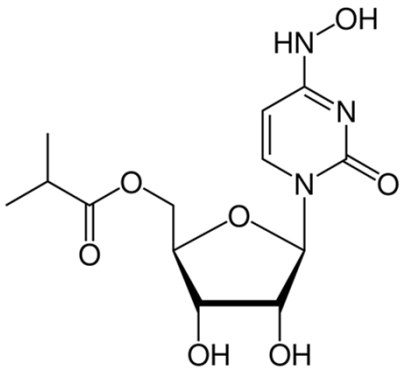
What is Molnupiravir?

- Molnupiravir is an orally administered investigational drug
- Potent ribonucleoside analog that inhibits the replication of SARS-CoV-2 through mutagenesis
- Manufactured by Merck and Ridgeback Biotherapeutics
- Developed in 2003 at Emory University's non-profit company Drug Innovation Ventures at Emory (DRIVE) in Atlanta, Georgia
- Originally developed as possible therapy for Venezuelan equine encephalitis virus and Influenza



https://www.merck.com/news/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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MOVe-OUT Trial Design

- Randomized, Phase III trial
- Conducted worldwide in over 170 sites
  - Argentina, Brazil, China, Germany, Israel, Italy, Mexico, Philippines, Poland, Russia, Japan, South Africa, Taiwan, Spain, the U.K. and the U.S.
- Participants (n=1433) had tested positive for COVID-19 and experienced mild to moderate symptoms for no more than five days
- Every participants had at least one risk factor for severe COVID-19 but had not been admitted to a hospital
  - Risk factors: obesity, >60 years of age, diabetes, cardiovascular disease
- Approximately 80% of the evaluable cases in the trial included the Delta, Gamma, and Mu variants

https://clinicaltrials.gov/ct2/show/NCT04575597

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MOVe-OUT Trial: Results

- 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
  - Absolute risk reduction of 3.0% (95% confidence interval [CI]: 0.1, 5.9; nominal p-value=0.0218)
  - Relative risk reduction (RRR) of 30% (relative risk 0.70; 95% CI: 0.49, 0.99)
    - RRR of 50% had been reported in interim analysis, n =775
- Nine deaths were reported in the placebo group and one in the molnupiravir group
- Adverse event profile remained consistent with the profile reported in the interim analysis
  - Not publicly released yet

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Concerns…

Safety profile not well-understood

- Low DNA mutagenic capability (long term effects)
- Pregnancy, lactation, and fetus effects

Effectiveness

- Lower than expected
- Omicron variant

Limited resource

- Maximizing benefit

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On the Positive Side

- Unmet medical need for an oral antiviral medication
- Lower cost than monoclonal infusions
- Less invasive administration than monoclonal treatment
- Potential to reduce prevalence of severe cases
  - Mild to moderate (81%), severe (14%), and critical (5%)

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Authorization for Use

- On November 30th, 2021, the FDA advisory committee, in a 13-to-10 vote, endorsed the medication approval
- Emergency Authorization Use is pending
- Treatment is to be authorized for patients with confirmed Covid-19 and at high risk of becoming severely ill
- The drug has already been approved for use in the U.K.
- The European Medicines Agency (EMA) is reviewing the application for marketing authorization

https://www.nytimes.com/2021/11/30/business/merck-covid-antiviral-pill-fda.html

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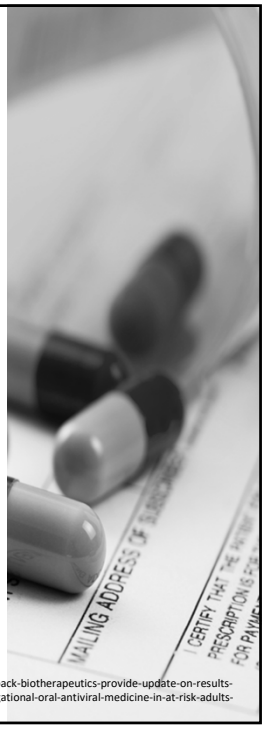
Prescribing Molnupiravir

- Dosing: Molnupiravir 200 mg: Take 4 capsules (800 mg total) by mouth every 12 hours for five days
- Pre-packaged in bottles containing 40 capsules (one patient treatment course)
- Treatment eligibility:
  - Adults (age to be determined)
  - A positive SARS-CoV-2 diagnostic test
  - Experiencing mild to moderate symptoms for ≤ 5 days
  - High risk for progression to severe COVID-19
    - obesity, > 60 years of age, diabetes, and cardiac disease included in trial



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Availability in the US

- 3.1 million treatment courses have been purchased by the U.S. government
  - Anticipated production amount by February 2022
- U.S. government has purchased at the price of $700 per course
- PREP Act Amendment 9 grants pharmacists prescribing privileges for FDA Approved COVID-19 therapeutics
- Interested providers for molnupiravir should complete this survey

https://www.nytimes.com/2021/11/30/business/merck-covid-antiviral-pill-fda.html

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COVID-19 Molnupiravir Pharmacy Interest Survey

Please use this survey to indicate your interest in prescribing and dispensing Molnupiravir

Purpose

Per the Health and Human Services (HHS) PREP Act Amendment 9, Pharmacists have prescribing privileges for FDA Approved COVID-19 therapeutics.The purpose of this survey is to gather information on interest and capacity to prescribe and dispense Molnupiravir.

Link for more information on PREP Act Amendment 9:

https://www.phe.gov/Preparedness/legal/prepact/Pages/PREPact-NinethAmendment.aspx

Pharmacy Name

Pharmacy Business License

Type of Pharmacy

Select Type

If other, please specify

We provide onsite COVID-19 testing:

- ◯ Yes
- ◯ No
- ◯ Not at this time

We have an onsite clinic:

- ◯ Yes
- ◯ No
- ◯ Not at this time

Would you be interested, per HHS guidance, in prescribing and dispensing Molnupiravir?

- ◯ Yes
- ◯ No
- ◯ Not at this time

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Thank You.

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