FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
November 30, 2021

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss the potential use of molnupiravir during pregnancy – both in terms of risk and benefit.

    a. Comment if you think molnupiravir should be accessible for use in pregnancy in certain scenarios, and if so, please describe what those scenarios might be.

    b. Do the concerns regarding the use of molnupiravir during pregnancy extend to the use of molnupiravir in individuals of childbearing potential? If so, are there mitigation strategies that should be considered?

2. **DISCUSSION:** Please discuss the concern regarding the observed increased rate of viral mutations involving the spike protein among participants receiving molnupiravir. In your discussion, please comment on what, if any, additional risk mitigation strategies or limitations on the authorized population could be considered. What monitoring strategies should be considered to better understand and mitigate these concerns?

3. **VOTE:** Do the known and potential benefits of molnupiravir outweigh the known and potential risks of molnupiravir when used for the treatment of mild-moderate COVID-19 in adult patients who are within 5 days of symptom onset and are at high risk of severe COVID-19, including hospitalization or death?

    a. If yes, please describe the appropriate authorized population such as risk factors for disease progression and pregnant individuals. Please comment on the proposed risk mitigation strategies and if additional risk mitigation strategies are needed.

    b. If no, please describe your reasons for concluding that the overall benefit-risk for molnupiravir is not favorable for any population based on the data available at this time.