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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
March 16, 2023

DRAFT QUESTIONS

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1. **VOTE:** Is the overall benefit-risk assessment favorable for PAXLOVID when used for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death?

    a. If yes, please provide your rationale.
    b. If no, please provide your rationale and list what additional studies/trials are needed

2. **DISCUSSION**: Please comment on the strength of evidence for use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death, in the following populations:
    a. Individuals who are vaccinated against COVID-19 or had prior SARS-CoV-2 infection
    b. Individuals infected with Omicron subvariants
    c. Individuals who are immunocompromised

    Please comment if additional data are needed in these populations.

3. **DISCUSSION**: Please comment on the strength of evidence for an association between use of PAXLOVID in the treatment of mild-to-moderate COVID-19 and 'COVID-19 rebound'. Please comment if additional data are needed.