

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

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

QUESTIONS

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.