

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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
June 17, 2022

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss whether the evidence supports the effectiveness of pimavanserin for the treatment of hallucinations and delusions in the Alzheimer's disease psychosis (ADP) population. In your discussion, comment on the strengths, limitations, and the extent to which each of the following potential sources of evidence contribute to your overall assessment of effectiveness:
 - Study 019
 - Study 045
 - The prior approval of pimavanserin for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis

2. **VOTE:** Does the available evidence support a conclusion that pimavanserin is effective for the treatment of hallucinations and delusions in the ADP population?
 - If yes, provide the rationale.
 - If no, provide your rationale and a recommendation for what further evidence should be generated.