

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the
Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)***

April 14, 2023

QUESTIONS

1. **DISCUSSION:** Discuss the overall benefit/risk assessment of brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. In your discussion, take into consideration the following:
 - The increased risk of death among elderly patients with dementia receiving antipsychotic treatment
 - The risks of medications that are often used off-label for the treatment of agitation in dementia (e.g., antiepileptics, benzodiazepines) without established evidence of efficacy.

2. **DISCUSSION:** Discuss whether there is a population of patients with Alzheimer's dementia for whom the benefit/risk of brexpiprazole appears acceptable. Is there a population for whom the benefit/risk does not appear to be favorable?

3. **VOTE:** Has the Applicant provided sufficient data to allow identification of a population in whom the benefits of treating agitation associated with Alzheimer's dementia with brexpiprazole outweigh its risks?
 - If you do not believe the Applicant has provided sufficient data, what additional data is needed to support the use of brexpiprazole for the treatment of agitation associated with Alzheimer's dementia?