

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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
June 9, 2023

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss the results from Study 301 (CLARITY AD) and whether they provide evidence of clinical benefit of lecanemab for the treatment of Alzheimer’s disease (AD).
2. **VOTE:** Do the results of Study 301 (CLARITY AD) verify the clinical benefit of lecanemab for the treatment of AD?
3. **DISCUSSION:** Discuss the overall benefit/risk assessment of lecanemab for the treatment of AD. Additionally, consider the following subgroups in your assessment:
 - Apolipoprotein E (ApoE) ε4 homozygotes
 - Patients requiring concomitant treatment with anticoagulant agents
 - Patients with cerebral amyloid angiopathy