

**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

**QUESTIONS**

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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