

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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
October 26, 2022

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss the benefits of daprodustat in adults with non-dialysis dependent (NDD) chronic kidney disease (CKD).
2. **DISCUSSION:** Discuss the benefits of daprodustat in adults with dialysis-dependent (DD) CKD.
3. **DISCUSSION:** Discuss the risks of daprodustat in adults with NDD CKD, including cardiovascular harm, gastric erosions/hemorrhage, and acute kidney injury.
4. **DISCUSSION:** Discuss the risks of daprodustat in the DD population, including the risks of heart failure and gastric erosions/hemorrhage.
5. **VOTE:** Do the benefits of daprodustat outweigh its risks for the treatment of anemia due to CKD in adults not on dialysis?
 - Provide rationale for your vote.
 - If you voted No, provide recommendations for additional data and/or analyses that may support a positive benefit/risk assessment.
6. **VOTE:** Do the benefits of daprodustat outweigh its risks for the treatment of anemia due to CKD in adults on dialysis?
 - Provide rationale for your vote.
 - If you voted No, provide recommendations for additional data and/or analyses that may support a positive benefit/risk assessment.