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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
November 16, 2022

DRAFT QUESTIONS

The Applicant is seeking approval of tenapanor hydrochloride tablets for the control of serum phosphorus levels in adults with chronic kidney disease (CKD) on dialysis.

1. **DISCUSSION:** Discuss the magnitude and clinical meaningfulness of tenapanor's treatment effect on serum phosphorus when administered as monotherapy.

2. **DISCUSSION:** Discuss the magnitude and clinical meaningfulness of tenapanor's treatment effect on serum phosphorus when administered in combination with phosphate binder treatment.

3. **DISCUSSION:** Diarrhea was the most common adverse reaction in clinical trials of tenapanor in adults with CKD on dialysis. Discuss this risk from a safety and tolerability perspective.

4. **VOTE:** Do tenapanor's benefits outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered as monotherapy?

    a. Provide your rationale.
    b. If you voted no, provide recommendations for additional data and/or analyses that may support a positive benefit/risk assessment for tenapanor as monotherapy.

5. **VOTE:** Do tenapanor's benefits outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered in combination with phosphate binder treatment?

    a. Provide your rationale.
    b. If you voted no, provide recommendations for additional data and/or analyses that may support a positive benefit/risk assessment for tenapanor in combination with phosphate binder treatment.