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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
December 13, 2022

QUESTIONS

The Applicant is seeking approval of omecamtiv mecarbil to reduce the risk of cardiovascular death and heart failure events in adults with symptomatic chronic heart failure with reduced ejection fraction.

1. **DISCUSSION:** Discuss the proposed benefits of omecamtiv mecarbil and whether there is adequate evidence for concluding these benefits. Include a discussion comparing the findings for the heart failure and cardiovascular mortality components of the primary efficacy endpoint in the GALACTIC-HF trial. What role does the phase 2 trial play in your assessment of the benefits?

2. **DISCUSSION:** If omecamtiv mecarbil were approved, what should the labeling say about use as a function of left ventricular ejection fraction?

3. **DISCUSSION:** If omecamtiv mecarbil were approved, what should the labeling say about use in patients with atrial fibrillation or atrial flutter?

4. **DISCUSSION:** Discuss whether omecamtiv mecarbil is safe enough to support its proposed use; consider safety with and without pharmacokinetic-based dosing.

5. **VOTE:** Do the benefits of omecamtiv mecarbil outweigh its risks for the treatment of heart failure with reduced ejection fraction?
    - Provide rationale for your vote.
    - If you voted yes, comment on whether pharmacokinetic-based dosing is essential for the safe and effective use.
    - If you voted no, provide recommendations for additional data or analyses that may support a positive benefit/risk assessment.