

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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
September 21, 2023

QUESTIONS

1. **DISCUSSION:** Discuss your assessment of the safety profile of ITCA 650 and whether the safety profile of the ITCA 650 drug-device combination product has been adequately characterized based on available data:
 - a. with respect to acute kidney injury
 - b. with respect to cardiovascular safety
 - c. with respect to overall safety

2. **DISCUSSION:** Discuss your assessment of the benefit risk balance of ITCA 650 for the indication to improve glycemic control in patients with type 2 diabetes mellitus (T2DM).

3. **VOTE:** Based on the available data has the Applicant demonstrated that the benefits of the ITCA 650 drug-device combination product outweigh its risks for the treatment of T2DM?
 - a. If yes, explain your rationale.
 - b. If no, explain your rationale and comment on additional data that could be provided to demonstrate the benefits outweigh the risks.