

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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
May 24, 2024

QUESTIONS

1. **DISCUSSION:** Discuss the benefits of insulin icodec and the risk of hypoglycemia in adults with type 1 diabetes mellitus (T1D).
2. **DISCUSSION:** Discuss the role of continuous glucose monitoring (CGM) devices and measures of glycemic variability with respect to the risk of hypoglycemia in patients with T1D using insulin icodec.
3. **DISCUSSION:** Discuss the proposed dosing and titration regimen and the extent to which the modeling data support alternative dosing strategies.
4. **DISCUSSION:** Discuss the role of insulin icodec in the context of the available treatment armamentarium to improve glycemic control in patients with T1D.
5. **VOTE:** Based on the available data, has the Applicant demonstrated that the benefits of insulin icodec outweigh its risks for improving glycemic control in adults with T1D?

If yes, explain your rationale and comment on any risk mitigation measures you believe would be necessary to ensure that the benefits outweigh the risks.

If no, explain your rationale and comment on additional data that could be provided to demonstrate that the benefits outweigh the risks.