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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
July 18, 2025

QUESTIONS

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1. **DISCUSSION**: Discuss the strength of evidence provided by the two phase 3 studies 00071 and 00072, in particular discuss the impact of the discordant results on your overall assessment of efficacy.

2. **DISCUSSION**: Discuss your view on the contribution of Study 00061 on the overall evidence of effectiveness.

3. **DISCUSSIO**N: Based on available data, and with consideration of the known risks of brexpiprazole and sertraline individually, discuss the acceptability of the proposed concurrent initiation treatment paradigm.

4. **VOTE**: Based on the available data presented, has the efficacy of brexpiprazole, when initiated concurrently with sertraline, been established for the treatment of PTSD?

   Please provide your rationale and indicate the specific information (e.g., statistical analyses, other data) on which you base your vote.