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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
June 4, 2024

DRAFT QUESTIONS

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1. **DISCUSSION**: Discuss the evidence of effectiveness for midomafetamine for the treatment of post-traumatic stress disorder (PTSD). Consider the following:
    - The potential impact of functional unblinding on interpretability of efficacy results
    - The durability of effect
    - The role of psychological intervention in the treatment paradigm

2. **DISCUSSION**: Discuss whether the available data are adequate to characterize the safety of midomafetamine for the treatment of PTSD.
    - Consider the limited data collected on events deemed positive, favorable, or neutral that would inform abuse potential for this program and the lack of data from some clinical laboratory tests.
    - Comment on whether you have concerns about other safety issues and what additional data would be useful to characterize the safety of midomafetamine.

3. **DISCUSSIO**N: Discuss the potential for patient impairment to occur with midomafetamine and the potential for serious harm that may result due to the impairment.

4. **DISCUSSION**: Discuss whether the proposed risk mitigation is sufficient to mitigate serious harm resulting from patient impairment. Include any additional safety monitoring conditions needed for the safe administration and monitoring of midomafetamine if approved for PTSD.

5. **VOTE**: Do the available data show that the drug is effective in patients with posttraumatic stress disorder?

6. **VOTE**: Do the benefits of midomafetamine with FDA's proposed risk evaluation and mitigation strategy (REMS) outweigh its risks for the treatment of patients with PTSD?