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

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 12, 2019

QUESTIONS

1. **VOTE:** Has the Applicant provided substantial evidence of the effectiveness of esketamine for the treatment of treatment-resistant depression?

2. **VOTE:** Has the Applicant adequately characterized the safety profile of esketamine for the treatment of treatment-resistant depression?

3. **VOTE:** Given the effectiveness and safety of esketamine and the FDA's proposed risk evaluation and mitigation strategy (REMS), do the benefits outweigh the risks of esketamine for the treatment of treatment-resistant depression?

4. **DISCUSSION:** Discuss whether the FDA's proposed REMS would assure safe use of esketamine and what additional safeguards would be needed, if any.

5. **DISCUSSION:** Are additional data needed pre- or post-approval to address outstanding issues? Discuss whether such data should be required prior to approval.