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
November 2, 2018

QUESTIONS

1. **VOTE:** Has substantial evidence been presented by the Applicant to support a claim of effectiveness for brexanolone for the treatment of postpartum depression?

2. **VOTE:** Has the Applicant adequately characterized the safety profile of brexanolone for the treatment of postpartum depression? Do you believe the loss-of-consciousness events have been characterized sufficiently to enable safe use of brexanolone?

3. **DISCUSSION:** There is evidence that both a 60 μg/kg/h and a 90 μg/kg/h dose (after 24 hours) are effective. Please discuss, if approved, which dose should be the recommended dose.
    - Start at 90 μg/kg/h with the option to decrease the dose to 60 μg/kg/h based on tolerability
    - Start at 60 μg/kg/h with the option to increase the dose to 90 μg/kg/h based on response

4. **DISCUSSION:** Discuss whether the FDA's proposed REMS would ensure safe use of brexanolone. If no, please discuss what additional safeguards would be needed

5. **VOTE:** Given the efficacy as presented, and when used in a certified facility by qualified staff and as outlined in the FDA's proposed REMS, do the benefits outweigh the risks of brexanolone for the treatment of postpartum depression?

6. **DISCUSSION:** If approved, what additional data will be needed to support safe use of brexanolone at home and address outstanding issues?