## Zulresso® (brexanolone) – Expanded indication

- On June 16, 2022, the FDA approved Sage Therapeutics' Zulresso (brexanolone), for the treatment of postpartum depression (PPD) in patients 15 years and older.
    - Zulresso was previously approved for this indication in adults only.
    - Zulresso is a Schedule IV controlled substance.
- The approval of Zulresso for the expanded indication is supported by evidence from adequate and well-controlled studies in adults with PPD, pharmacokinetic data in adults and patients 15 to 17 years, and safety data in patients 15 to 17 years.
- Zulresso carries a boxed warning for excessive sedation and sudden loss of consciousness.
    - Because of these risks, Zulresso is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso REMS.
- Zulresso is administered for the treatment of PPD as a continuous intravenous infusion over a total of 60 hours (2.5 days). Refer to the drug label for complete dosing information.
- A healthcare provider must be available on site to continuously monitor the patient, and intervene as necessary, for the duration of the Zulresso infusion.