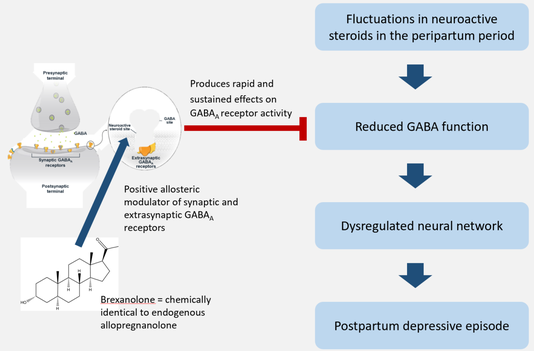
Efficacy of Brexanolone in the Treatment of Post-Partum Depression

Rachel E. Bent, Herman L. Hedriana, MD, Shannon Clark, MD

From the School of Medicine (Bent) and Department of Obstetrics and Gynecology (Dr. Hedriana and Dr. Clark), UC Davis Health, Sacramento, CA

Background

- Post-partum depression (PPD) affects 1 in 8 women
- PPD has consequences for both mother and child
  - Negatively impacts breastfeeding, sleep routines, well-child visits, vaccinations, and safety practices
- Until recently, the primary treatment for PPD has been psychotherapy and antidepressants
- Brexanolone (generic for Zulresso) was FDA approved March 2019 and is the first drug approved specifically for PPD
  - 60-hour IV infusion
  - Neurosteroid and analogue of allopregnanolone
  - This medication offers a novel approach to treatment of postpartum depression



- Brexanolone has been validated in three clinical trials prior to FDA approval
- These studies showed improvement in the Hamilton Depression Rating Scale (HAM-D) up to 30 days after infusion

Objective

Track symptoms of depression in women with post-partum depression every month for 6 months following brexanolone infusion

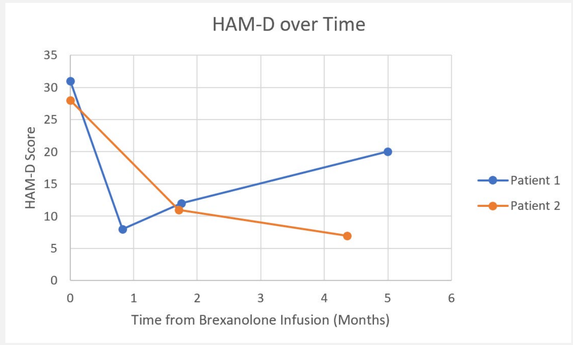
Materials and Methods

- UC Davis approved to enroll 6 patients for brexanolone infusion
  - 2 out of 6 patients have been administered the medication
- Patients recruited from Dr. Clark's OB/GYN clinic and/or CONNECTED group
- Patients admitted to Labor & Delivery for 60-hour IV brexanolone infusion. Patients were monitored using REMS for:
  - Sleepiness
  - Dry mouth
  - Loss of consciousness
  - Flushing of skin or face
- **Follow up:** Patients' symptoms of depression will be evaluated every month for 6 months
- **Outcome measure:** Hamilton Depression Rating Scale (HAM-D)
  - Scoring based on 17-item scale
  - 0-7: No Depression
  - 8-16: Mild Depression
  - 17-23: Moderate Depression
  - >24: Severe Depression
  - 52 = Max score

Results

Patient Demographics		
Age, years		
	Mean	31 years
Time from delivery to brexanolone infusion, weeks		
	Mean	15.9
	Range	14.7 – 17.0
Ethnicity, n (%)		
	Hispanic/Latino	0 (0)
	Not Hispanic/Latino	2 (100)
	Declined to state	0 (0)
Parity, n (%)		
	Nulliparous	1 (50)
	Parous	1 (50)

- Both patients received brexanolone for a diagnosis of post-partum depression with anxious distress
- Patients continued their home psychiatric medications
- Neither patient experienced medication side effects during the infusion period
- Both patients reported subjective improvement in symptoms during the infusion
  - Improvement in mood
  - Decreased anxiety



Conclusions

- Barriers to receiving brexanolone infusion:
  - Inpatient hospitalization
  - Insurance authorization
- HAM-D decreased for both patients and stayed below baseline for >30 days
- No significant side effects noted during infusion
- One patient who relapsed 5 months after the infusion had major life stressors at the time which may confound findings
- Limitations:
  - Small sample size
  - Limited follow-up period
- Brexanolone, the first medication of its kind, may open the door to many more treatment options in the future

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Acknowledgements

The project described was supported by Sage Therapeutics

Special thanks to Dr. Shannon Clark