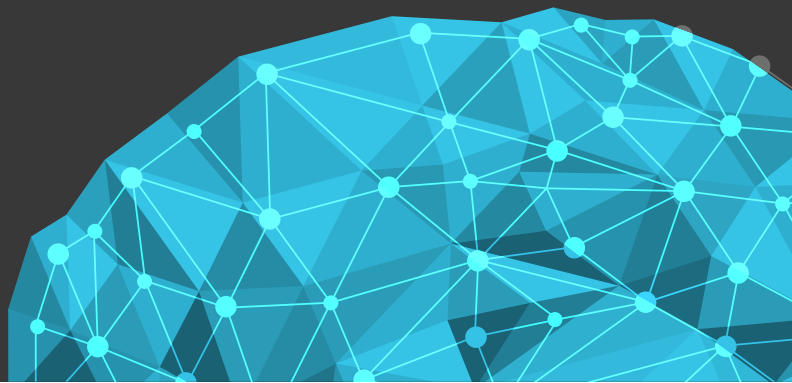


## NOW ENROLLING

A Clinical Research Study evaluating an investigational medication in **moderate to severe**

# POSTPARTUM DEPRESSION



## THE HUMMINGBIRD STUDY

The Hummingbird Study is a Phase 3, randomized, double-blind trial evaluating the efficacy and safety of SAGE-547 (brexanolone [USAN]), an investigational medication, in the treatment of moderate and severe postpartum depression compared to placebo, as assessed by the Hamilton Rating Scale for Depression (HAM-D).

### KEY **INCLUSION CRITERIA:**

- Women ages 18-45 years and  $\leq 6$  months postpartum
- Had a major depressive episode (MDE) that began no earlier than the third trimester and no later than the first 4 weeks following delivery\*
- Must be amenable to IV therapy and a 3-day, in-patient treatment period
- Willing to temporarily cease breastfeeding for 7 days, starting immediately before the in-patient period

### KEY **EXCLUSION CRITERIA:**

- Active psychosis
- Attempted suicide associated with index case of postpartum depression. Suicidal ideation is not an exclusion.
- Medical history of bipolar disorder

*\*As diagnosed by Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).*

*Note: Other protocol-defined inclusion/exclusion criteria may apply.*

## PATIENT INVOLVEMENT

**STUDY DURATION:** approximately 37 days

**SCREENING PERIOD:** ( $\leq 7$  days) to determine eligibility

**TREATMENT PERIOD:** (3 days)

- 2.5-day (60-hour), in-patient infusion of SAGE-547 (brexanolone [USAN]) or placebo
- 12 hours of post-treatment assessments
- Patients who are breastfeeding must temporarily cease for 7 days, starting immediately before the in-patient period

### **FOLLOW-UP PERIOD:**

- Four **follow-up visits** after the start of the treatment period

All study-related procedures will be provided at no cost. Transportation may be provided for those who require assistance.

FOR ADDITIONAL INFORMATION, OR TO LEARN MORE ABOUT PARTICIPATING IN THE **HUMMINGBIRD STUDY**, PLEASE CONTACT:

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