Plain Language Summary

Long-Term Safety and Efficacy of Esketamine Nasal Spray Among Hispanic and Latino Adults With Treatment-Resistant Depression in the SUSTAIN-3 Study

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What do these results mean for individuals with treatment-resistant depression (TRD)?

For Hispanic and Latino adults with TRD, long-term esketamine treatment may provide sustained symptom improvement and functional benefits, with no new safety concerns, supporting its use as a viable long-term treatment option in this population.

Purpose of the study

To evaluate the long-term safety and effectiveness of esketamine nasal spray, used with an oral antidepressant, specifically in Hispanic and Latino adults with TRD participating in the SUSTAIN-3 extension study.

- **Esketamine:** A nasal spray formulation approved for treatment-resistant depression in adults.
- **Treatment-resistant depression:** major depressive disorder that has not adequately responded to at least two antidepressants.

How was the study conducted?

This was a subgroup analysis of Hispanic and Latino adults enrolled in SUSTAIN-3, an open-label, multicenter extension study. Participants received flexible-dose esketamine plus an oral antidepressant during induction (4-weeks) and long-term maintenance phases, with ongoing efficacy and safety assessments.

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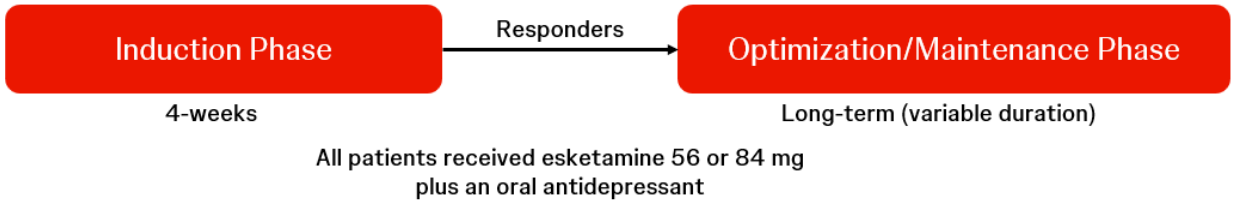
What is the design of the study?

SUSTAIN-3 was a multicenter, open-label, long-term extension study (up to 6.5 years). Participants entered from one of six prior esketamine studies and received flexible doses of esketamine nasal spray (56 or 84 mg) plus an oral antidepressant. The study included an induction phase and an optimization/maintenance phase. Depression severity, functioning, and safety were assessed repeatedly over time using validated clinician- and patient-reported scales. This analysis focused on Hispanic and Latino adults aged 18-64 years.

Study Design



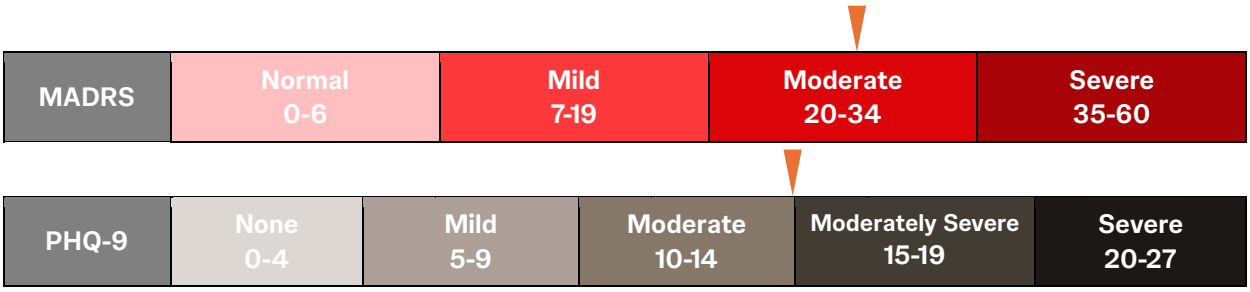
Efficacy was measured by:

- **Montgomery-Åsberg Depression Rating Scale (MADRS)**: Clinician-rated scale measuring depression severity, scores range 0-60.
- **Patient Health Questionnaire-9 item (PHQ-9)**: Patient-reported questionnaire assessing depressive symptoms, scores range 0-27.
- **Sheehan Disability Scale (SDS)**: Measure of functional impairment in work, social, and family domains, scores range 0-30.

What were the results of the study?

This analysis included 182 patients. Mean MADRS and PHQ-9 total scores entering induction phase were 28.9 and 14.8, respectively; 83.5% were female and mean age was 48.6. Patients showed clinically meaningful reductions in depressive symptoms and functional impairment during induction, with improvements maintained over long-term treatment.

Baseline Symptom Rating Scale Scores



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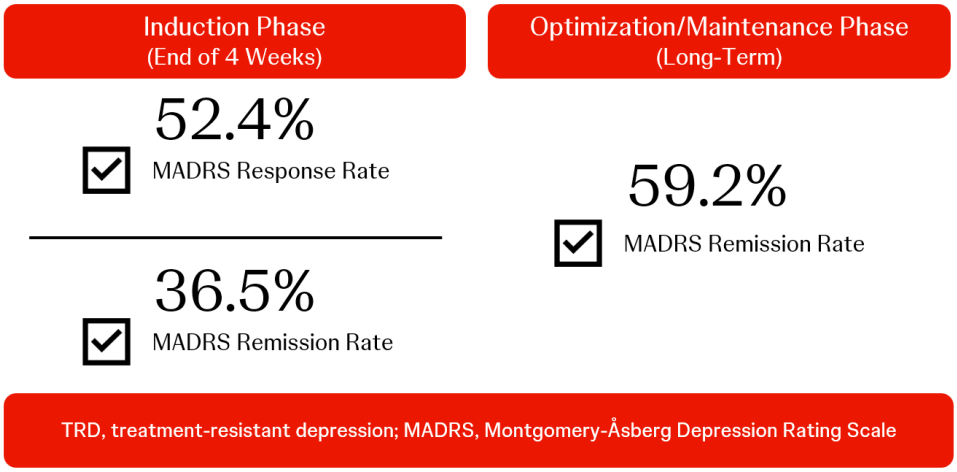
Mean (SD) Change in Symptom Rating Scales During the Induction Phase

Change in MADRS total score	Change in PHQ-9 total score	Change in SDS total score
13.6 (11.2) point improvement	5.5 (5.4) point improvement	7.2 (7.6) point improvement

SD, standard deviation

Rates of MADRS Response and Remission



TRD, treatment-resistant depression; MADRS, Montgomery-Åsberg Depression Rating Scale

- **Response rate:** ≥50% improvement in the MADRS total score
- **Remission rate:** MADRS total score ≤12

The safety profile was consistent with previously known esketamine effects. Most patients experienced ≥1 treatment-emergent adverse event (TEAE) during the study (95.6%), and most TEAEs were mild or moderate in severity and were resolved on the same day as dosing.

The most common TEAEs were:

- Dizziness
- Headache
- Somnolence – a state of **excessive sleepiness or drowsiness**, characterized by reduced alertness and a tendency to fall asleep during normal waking hours
- Dissociation – a mental state in which a person feels temporarily **detached from their thoughts, feelings, body, or surroundings**

What were the limitations of the study?

The study lacked a control group and was open-label, limiting causal inference. This was a subgroup analysis not powered for Hispanic/Latino-specific comparisons. Generalizability may be limited due to exclusion of patients with significant comorbidities or substance dependence and potential continuation bias.

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