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10.18.19

Treatment of Refractory Status Epilepticus Prevents Need for Induced Coma With Intravenous Anesthetics in Phase 2 Trial

Epilepsy & Seizures



KEYWORDS: Epilepsy • Seizures

In a phase 2 clinical trial, treatment with ganaxolone prevented all 17 participants from needing IV anesthetics for induced coma within 24 hours of treatment initiation. All participants had ganaxolone after status epilepticus continued despite treatment with benzodiazepines. A target dose of ganaxolone, supported by pharmacokinetic (PK) data, has been identified for advancement to phase 3 clinical trials.

The PK data show that the target dose of ganaxolone (713 mg/day) achieved plasma drug concentrations greater than 500 ng/mL for approximately 8 hours, the longest and highest duration of the 3 dosing groups. A dose-response relationship among the dose groups was apparent, with the target dose demonstrating the best and most durable efficacy for the period beginning with the commencement of the ganaxolone infusion through the 24-hour period that followed discontinuation of ganaxolone therapy. In addition, the targeted effective plasma concentrations were shown to be generally safe and well-tolerated for this ill patient population, at concentrations at least 5 times higher than a previously studied neurosteroid.

“We are grateful these data were selected for a platform presentation and recognized by the Neurocritical Care Society,” said Dr. Scott Braunstein, chief executive officer of Marinus. “The efficacy outcomes from our phase 2 study are particularly compelling, given that 14 of the 17 patients failed first-line benzodiazepine treatment, and then failed 2 or more second-line antiepileptic drugs prior to receiving ganaxolone. These data, particularly at the target dose, show promise to potentially improve patient outcomes by breaking RSE early and avoiding the morbidities and mortality associated with medically induced coma and prolonged hospitalization.”

Henrikas Vaitkevicius, MD, Neurologist at Brigham and Women’s Hospital, assistant professor at Harvard Medical School and study investigator, commented, “Status epilepticus is a medical emergency that requires

urgent diagnosis and treatment to prevent potentially devastating long-term effects. These data provide compelling evidence that IV ganaxolone has the potential to change the treatment paradigm for RSE with rapid onset of impressive activity paired with a manageable safety profile. Neurosteroids, as a group, are potentially safer and much easier to use than existing treatment options for refractory seizures, and these important results, including the pharmacokinetic data, provide valuable insight for understanding ganaxolone dosing for future studies. I look forward to seeing ganaxolone rapidly advance to phase 3 development as I believe this is an important new option for patients with limited safe and effective treatments.”

The results were presented at the neurocritical Care Society 17th Annual Meeting in Vancouver, BC.

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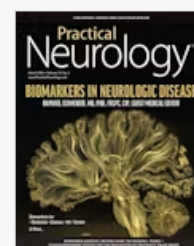
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