

For Your PHYSICIAN

What is the STATUS Trial?

The STATUS Trial evaluates the efficacy and safety of SAGE-547 Injection in the treatment of patients with super-refractory status epilepticus (SRSE). SAGE Therapeutics is sponsoring the STATUS Trial.

About SAGE-547

SAGE-547 is an allosteric modulator of both synaptic and extra-synaptic GABAA receptors under investigation as an adjunctive agent in the treatment of SRSE. SAGE-547 was granted orphan drug and fast-track designations by the FDA to expedite clinical development and review for SRSE.

Eligibility

Key Inclusion Criteria

Patients 2 years of age or older who present with status epilepticus and meet ALL of the following criteria:

First-line agent

- Failure to respond to at least one first-line agent, such as a benzodiazepine or other initial anti-epileptic drug (AED)

Second-line agent

- Failure to respond to at least one second-line agent (e.g., phenytoin, fosphenytoin, valproate, phenobarbital, levetiracetam, or other continuous IV [cIV] AED)

Third-line agent (one of the following)

- No previous administration of a third-line agent, but patient is admitted to the ICU with the intent of administering at least one third-line agent for at least 24 hours
- Previous failure of one or more wean attempts from third-line agent, and patient is now on cIV infusions of one or more third-line agents and is in an EEG burst suppression pattern
- Previous failure of one or more wean attempts from third-line agents and patient is not in an EEG burst suppression pattern with or without a cIV infusion of at least one third-line agent

Key Exclusion Criteria

- SRSE due to anoxic/hypoxic encephalopathy
- Encephalopathy due to a rapidly progressing neurological disorder in children under the age of 17
- A GFR low enough to warrant dialysis but continuous dialysis is not planned
- Fulminant hepatic failure
- Severe cardiogenic or vasodilatory shock not related to third-line agent use and requiring two or more pressors
- Administration of more than three third-line agents concomitantly
- Life expectancy less than 30 days
- Do not resuscitate (DNR) order or a living will that does not allow heroic measure

If you have a patient who may qualify or you would like additional information, please visit

www.statustrial.com