



Engage Therapeutics Announces Data from Phase 2a, Proof-of-concept Study of *Staccato* Alprazolam to Suppress Seizures in Patients with Epilepsy Published in *Epilepsia*

- *Staccato alprazolam shown to rapidly suppress seizure activity at two minutes in five patients with epilepsy –*
- *Staccato alprazolam generally well tolerated; no serious or severe adverse events reported –*
- *Enrollment in Phase 2b, double-blind, placebo-controlled study ongoing –*

SUMMIT, N.J., July 8, 2019 /PRNewswire/ — [Engage Therapeutics, Inc.](#), a clinical-stage biopharmaceutical company developing a Rapid Epileptic Seizure Termination (REST) therapy for people with epilepsy who experience a predictable pattern of seizures, today announced that data from a phase 2a study of *Staccato*[®] alprazolam to suppress seizures in patients with epilepsy were published in the peer-review journal [Epilepsia](#).

This proof-of-concept study demonstrated that *Staccato* alprazolam delivered the drug deep into the lung and rapidly suppressed seizure or epileptiform activity in five photosensitive patients with epilepsy. The paper, which is titled, “Inhaled Alprazolam Rapidly Suppresses Epileptic Activity in Photosensitive Participants,” was published online ahead of print on July 7 in *Epilepsia*, the journal of the [International League Against Epilepsy](#).

“The greater epilepsy community of patients, families and health care providers knows full well that there is an urgent need for acute rescue options to reduce or even halt seizure activity,” said lead author Jaqueline French, MD, the study’s principal investigator and professor in the Department of Neurology at [NYU Langone Health’s Comprehensive Epilepsy Center](#), and founder/director of the [Epilepsy Study Consortium](#). “The encouraging data from this phase 2a study served as the foundation for advancing *Staccato* alprazolam in the clinic as a potential rescue medication for the acute treatment of seizures.”

Engage Therapeutics is now enrolling up to 123 patients in the multi-center StATES Study (***Staccato* Alprazolam Terminates Epileptic Seizures** - [NCT03478982](#)), a phase 2b trial designed to evaluate the safety, efficacy and usability of *Staccato* alprazolam in subjects with epilepsy who have a predictable seizure pattern. The StATES study is being conducted at approximately 50 trial sites in the United States, Australia and Jamaica. Please visit [www.epilepsyhealthstudy.com](#) for more information about the StATES study and [www.engagetherapeutics.com/study-locations/](#) for a list of study locations.

This proof-of-concept study referenced in the *Epilepsia* paper demonstrated that three doses of *Staccato* alprazolam (0.5 mg, 1.0 mg, and 2.0 mg) rapidly suppressed epileptic activity in photosensitive participants with epilepsy. The primary endpoint of the study was the change in standardized photosensitivity range (SPR) in participants receiving each dose of *Staccato* alprazolam. Highlights from the phase 2a study as reported this week in *Epilepsia* include:

- *Staccato* alprazolam reduced epileptiform activity as measured by SPR at two minutes; the effect was sustained through four hours for the 0.5 mg dose and six hours for the 1.0 and 2.0 mg doses;
- Magnitude and duration of sedation and sleepiness were dose related and more prominent with higher doses;
- Peak plasma concentrations following administration were achieved following inhalation within minutes, and rapid onset of pharmacodynamic effects of somnolence and sedation were observed.

Staccato alprazolam was generally well tolerated with a safety profile similar to what has been reported for oral alprazolam or *Staccato* alprazolam for other indications. No participants in this study experienced any severe or serious adverse events. Four of five participants experienced at least one adverse event during the study, but all were mild or moderate in intensity.

Staccato alprazolam is a single-use, investigational epileptic seizure rescue therapy that combines *Staccato* delivery technology with alprazolam, both of which have been approved separately for unrelated indications by the U.S. Food and Drug Administration (FDA). Alprazolam is a well-known and highly characterized benzodiazepine for the treatment of anxiety disorders. The *Staccato*[®] system aerosolizes a drug and, via inhalation, delivers it deep into the lung for rapid systemic exposure.

Engage Therapeutics, Inc.

Engage Therapeutics is developing *Staccato* alprazolam for the immediate cessation of active and acute epileptic seizures. The investigational product is in the Rapid Epileptic Seizure Termination (REST) category of products. Engage Therapeutics is based in Summit, N.J. For additional information please see www.engagetherapeutics.com.

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