

First Patient Enrolled in Cavion Multi-Center Phase 2 Clinical Trial in Epilepsy

Study to investigate new therapeutic approach for generalized epilepsy with absence seizures

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CHARLOTTESVILLE, Va.--(BUSINESS WIRE)--Cavion, Inc. announced today that the first patient has been enrolled in its innovative T-WAVE Phase 2a proof-of-concept clinical trial ([NCT03406702](#)). T-WAVE will assess the safety, tolerability and efficacy of the T-type calcium channel modulator CX-8998 in drug-resistant absence seizures in adolescents and young adults with generalized epileptic syndromes.

Cavion enrolled the first patient in T-WAVE, an innovative Phase 2a clinical trial of its first-in-class Cav3 modulator CX-8998 in adolescents and young adults with drug-resistant absence seizures.

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Generalized epileptic syndromes are associated with abnormal activity of selected neural networks. T-type calcium channels, called Cav3, control neuronal firing and signaling. Cav3 is a strong genetic target as gain-of-function Cav3 mutations have been identified in patients with generalized

seizures. CX-8998 is a first-in-class oral therapeutic drug that was designed to selectively and potently inhibit Cav3 channels, repairing aberrant neuronal activity. Data from genetic preclinical models of generalized epilepsy suggest that CX-8998 suppresses epileptiform discharges and prevents the development of seizures, including absence seizures.

“Cavion has deep expertise advancing the science of Cav3 modulation in white-space central nervous system indications with high unmet need. T-WAVE leverages Cavion’s unique clinical development engine that delivers insightful data using cutting edge digital biomarkers and artificial intelligence while collaborating with advocacy groups to put patients and their families at the forefront,” said Spyros Papapetropoulos, Cavion’s Executive Vice President, Head of Research & Development and Chief Medical Officer.

“New treatment options to control generalized seizures and maintain quality of life for patients and their families are particularly needed, as there are limited options currently available. New treatments for generalized epilepsy would provide a significant opportunity to help adolescents and young adults,” said Dr. Jacqueline French, Chief Scientific Officer at the Epilepsy Foundation and Professor of Neurology at NYU School of Medicine.

Cavion is also currently enrolling subjects in its T-CALM Study (Tremor Cav3 Modulation Study), a Phase 2 clinical trial using CX-8998 for patients with Essential Tremor.

About the T-WAVE Study

T-WAVE is a proof-of-concept, multi-center, randomized, double-blind, placebo-controlled, parallel-group study assessing the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of CX-8998 in adolescents and young adults with generalized epilepsy with absence seizures. Efficacy and pharmacodynamics will be evaluated using digital diaries and quantitative ambulatory EEG readings. The study will enroll patients at seven medical research centers across the United States.

About Generalized Epilepsy with Absence Seizures

Generalized epilepsies constitute nearly one third of all epilepsies. Idiopathic generalized epilepsies manifest with absence seizures, myoclonic jerks, and generalized tonic-clonic seizures, alone or in varying combinations and severity. Absence seizures are the hallmark seizure type in absence epilepsy (a form of generalized epilepsy) but can also be a predominant seizure type in other generalized epileptic syndromes. Absence seizures are characterized by a transient impairment in consciousness generally not followed by a notable post-ictal state.

While a proportion of generalized epileptic syndrome patients with absence seizures respond to first line antiepileptic drugs and have a generally good prognosis, a significant proportion fail to achieve adequate seizure control with existing therapeutics or experience intolerable side effects limiting therapy. For these patients, the goal is to achieve seizure control while limiting side effects and negative impacts, especially on cognitive outcomes.

About Cavion, Inc.

Cavion, Inc. is a privately held clinical stage biotechnology company creating therapies modulating the T-type calcium channel (Cav3) for the treatment of white-space neurological diseases. Cavion's platform of Cav3 modulators restore the brain's natural rhythms in a variety of chronic neurological diseases such as essential tremor, Parkinson's disease, neuropathic pain, and epilepsy as well as orphan and rare neuro-developmental and genetic disorders.

Forward-Looking Statement

This press release contains forward-looking statements that are subject to risks and uncertainties and includes statements that are not historical facts. Actual results could differ significantly from results discussed. Cavion, Inc. disclaims any intent or obligation to update forward-looking statements, except as required by law.

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