



Cassava Presents Promising Preclinical Simufilam Data at TSC Alliance Meeting

Jun 30, 2025

Data show that simufilam reduced seizure activity in a preclinical mouse model

Presentation also highlights favorable human safety data from 1,929 patient Phase 3 program

AUSTIN, Texas, June 30, 2025 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (NASDAQ: SAVA, "Cassava", the "Company"), a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system (CNS) disorders, today announced that the Company presented a poster at the [TSC International Research Conference](#) (TSC 2025) held June 26-28, 2025 in Bethesda, MD.

The poster, available on the Company website via [this link](#), detailed two important observations that support Cassava's plan to initiate human clinical studies in H1 2026 to evaluate simufilam as a treatment for Tuberous Sclerosis Complex (TSC)-related epilepsy:

- **Preclinical proof-of-concept:** Treatment with simufilam alleviated neuronal abnormalities and reduced seizure frequency by 60% compared to vehicle in a mouse model of focal onset seizures.
- **Clinical safety:** Data from two human Phase 3 studies in Alzheimer's disease demonstrated a favorable safety profile.

"My research and collaboration with the TSC Alliance demonstrate our commitment to address the high unmet need in people with TSC-related epilepsy. We are excited to share this research with the TSC community, including the preclinical data showing that simufilam significantly reduced seizure frequency. Additional pre-clinical studies are underway to further confirm these promising findings," said **Angélique Bordey, PhD, Senior Vice President, Neuroscience** of Cassava.

"TSC leads to lifelong epilepsy and severe neurological issues for the approximately 50,000 patients in the US living with this rare disease. The data we presented at TSC 2025 mark the Company's first presentation of simufilam's positive results in a preclinical model. These compelling preclinical data build on favorable safety findings from prior human clinical studies and support our plan to begin our first clinical study in TSC-related epilepsy in the first half of 2026," said **Rick Barry, President and Chief Executive Officer** of Cassava.

Poster Title and Highlights:

Title: Simufilam, a small molecule, reduced seizure activity in a mouse model of focal cortical malformations and has demonstrated a favorable clinical safety profile.

Brief Background: Tuberous sclerosis complex (TSC)-related epilepsy is a genetic disorder of the intracellular signaling pathway "mechanistic target of rapamycin" or mTOR, caused by mutations in the *TSC1* or *TSC2* gene. The presence of focal malformations in the brains of TSC patients is associated with lifelong epilepsy, leading to severe neurological issues. Recent evidence shows that expression of filamin A is increased in patients with TSC and in mouse models that recapitulate TSC and a related mTOR disorder, focal cortical dysplasia type II.

Simufilam is a proprietary, investigational oral small molecule that is hypothesized to modulate the function of the filamin A protein.

Preclinical Data:

Studies conducted in the lab of Angélique Bordey (the "Bordey lab"), at Yale School of Medicine, form the basis of the preclinical data. The Bordey lab showed that **treating mice with simufilam, before or after seizure onset, alleviated neuronal abnormalities and reduced seizure frequency by 60% compared to vehicle-treated mice:**

- Simufilam significantly reduced **seizure frequency** ($p < 0.0001$).
- Significantly more mice achieved **seizure freedom** with simufilam (3/29 vehicle (saline) treated mice v. 11/32 simufilam treated mice, $p = 0.0343$).

While the effective dose in mice was 20 mg/kg/day, chronic oral toxicology studies showed no adverse effects at doses up to 50 mg/kg/day in rats and 1250 mg/kg/day in mice.

Looking to the future, additional preclinical studies are underway with the TSC Alliance preclinical consortium and other collaborators to explore further simufilam's mechanism of action and its potential to treat TSC-related epilepsy.

Human Safety Data:

Data from two Phase 3 studies of simufilam in 1,929 patients with mild-to-moderate Alzheimer's disease were also presented in the poster:

- **Simufilam demonstrated a favorable safety profile.**

- Non-serious adverse events were typically mild and not considered simufilam-related.
- None of the serious adverse events in these studies, or any other study, were assessed to be study-drug related.

About Simufilam

Simufilam is a proprietary, investigational oral small molecule that is hypothesized to modulate the function of the filamin A protein.

About TSC

Tuberous sclerosis complex (TSC) and focal cortical dysplasia (FCD) type II are neurodevelopmental disorders caused by mutations in the mechanistic target of rapamycin (mTOR) pathway genes. These mutations lead to focal malformations of the developing cortex and seizures in 80% to 90% of patients.

Nearly two-thirds of TSC patients do not respond to antiepileptic drugs and experience lifelong seizures, leading to a spectrum of neurocognitive and psychological disabilities and poor quality of life. Current treatments, including antiepileptic drugs, mTOR analogs, and surgery, are not fully effective, are associated with serious adverse events, and/or are invasive.¹

Cassava is initially focused on developing simufilam as a potential treatment for TSC-related seizures. According to the TSC Alliance, the disorder affects an estimated 1 in 6,000 live births. Approximately 50,000 people in the United States and more than one million worldwide live with TSC².

Resources:

1. *Science Translational Medicine*. 2020 Feb 19: <https://pubmed.ncbi.nlm.nih.gov/32075941/>
2. <https://www.tscalliance.org/understanding-tsc/what-is-tsc/>

About Cassava Sciences, Inc.

Cassava Sciences, Inc. (NASDAQ: SAVA), is a clinical-stage biotechnology company focused on developing novel, investigational treatments, including simufilam, for central nervous system disorders, such as tuberous sclerosis complex (TSC)-related epilepsy, and potentially for additional pipeline indications. Simufilam is a proprietary, investigational oral small molecule that is hypothesized to modulate the function of the filamin A protein. The Company is based in Austin, Texas.

For more information, please visit: <https://www.CassavaSciences.com>

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Cautionary Note Regarding Forward-Looking Statements:

This news release contains forward-looking statements that may include but are not limited to statements regarding: our plans to conduct preclinical studies of simufilam relating to seizures/epilepsy in TSC, the potential for simufilam to continue to deliver preclinical efficacy and activity related to seizures and epilepsy in TSC, the expected timing of our plans to conduct clinical studies with simufilam in H1 2026, the potential for simufilam as a treatment for TSC-related epilepsy and other potential indications, the potential for simufilam to continue to deliver favorable safety results, and the timing of anticipated milestones. These statements may be identified by words such as “anticipate”, “before”, “believe”, “could”, “expect”, “forecast”, “intend”, “may”, “pending”, “plan”, “possible”, “potential”, “prepares for”, “will”, and other words and terms of similar meaning.

Such statements are based on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to advance preclinical studies related to TSC-related epilepsy and other potential indications, the ability to successfully carry out the Company's obligations under the Yale License Agreement, and other risks inherent in drug discovery and development or specific to Cassava Sciences, Inc., as described in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2024, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties, and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.

All of our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates is approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials or preclinical studies may not be indicative of future results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

We are in the business of new drug discovery and development. Our research and development activities are long, complex, and costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, you are cautioned not to invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.



Source: Cassava Sciences, Inc.