# Cassava Sciences Completes Enrollment for Pivotal Phase 3 Program of Simufilam in Alzheimer's Disease

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- **1,929 patients randomized in a pair of Phase 3 trials to evaluate oral simufilam in Alzheimer's disease dementia.**
- **Top-line results for on-going, 52-week Phase 3 trial expected approximately year-end 2024.**
- **Top-line results for on-going, 76-week Phase 3 trial expected approximately mid-year 2025.**

AUSTIN, Texas, Nov. 06, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company, today announced the completion of patient enrollment in a pair of Phase 3 trials to evaluate the safety and efficacy of oral simufilam versus placebo in Alzheimer's disease dementia.

Simufilam is Cassava Sciences' proprietary oral drug candidate. This investigational drug binds to altered filamin A protein in the brain and restores its normal shape and function. By targeting altered filamin A, simufilam may help patients with Alzheimer's achieve better health outcomes.

"We completed target enrollment for our Phase 3 program in approximately two years," said Remi Barbier, President and CEO. "This achievement exemplifies our unwavering commitment to develop a new treatment option for Alzheimer's. We are so thankful to the patients and their families, clinical investigators and operational partners who are helping us reach this goal."

A total of 1,929 patients were randomized in two on-going Phase 3 trials of simufilam. These are registrational studies (aka, pivotal), meaning if positive data and results are generated, they can support the filing of a new drug application (NDA) for simufilam in Alzheimer's disease. Both Phase 3 studies received a Special Protocol Assessment (SPA) from the FDA.

The first Phase 3 trial (NCT04994483) has a 52-week treatment period; 804 Alzheimer's patients were randomized into this study, as announced in October 2023. Top-line results for the 52-week Phase 3 study are currently expected approximately year-end 2024.

The second Phase 3 trial (NCT05026177) has a 76-week treatment period; 1,125 Alzheimer's patients were randomized into this study. Top-line results for the 76-week Phase 3 study are currently expected approximately mid-year 2025.

Patients with mild-to-moderate Alzheimer's disease dementia who met study eligibility criteria were recruited into the Phase 3 program from clinical sites in the U.S., Puerto Rico, Canada, Australia and South Korea. Cassava Sciences is conducting its on-going Phase 3 program in collaboration with Premier Research International, a global contract research organization (CRO).

Today's news follows recently announced interim safety MRI data that suggests simufilam is not associated with treatment-emergent amyloid-related imaging abnormalities (ARIA). In addition, a September 2023 meeting of a Data and Safety Monitoring Board (DSMB) recommended that both Phase 3 studies of simufilam continue as planned, without modification. Final safety data are expected at the conclusion of the Phase 3 program.

**About Cassava Sciences, Inc.**

Cassava Sciences is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Our product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established in humans.

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, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our current expectations regarding timing of data and results for our on-going Phase 3 clinical trials; the design, scope, conduct, continuation, completion, intended purpose, or future results of our on-going Phase 3 program of simufilam in patients with Alzheimer's disease; the suitability of clinical data from our Phase 3 program to support the filing of an NDA; any findings or recommendations by the DSMB relating to the interim safety of simufilam in our on-going Phase 3 clinical trials; interim MRI safety data for the Phase 3 program, including ARIA; the risk of current or future findings of treatment-emergent ARIA in our clinical program of simufilam; the treatment of patients with Alzheimer's disease dementia; comments made by our employees regarding simufilam, drug effect, safety, and the treatment of Alzheimer's disease; the continued development of simufilam; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "look forward," "would", "forecast," "intend," "plan," "possible," "potential," and other words, phrases, and terms of similar meaning.*

*Simufilam is our investigational product candidate. Its safety, efficacy or science has not reviewed or approved by any regulatory authority in any jurisdiction and its desirable clinical attributes, if any, have not been established in patients.*

*Drug development involves a high degree of risk, and only a small number of research and development programs result in regulatory approval and commercialization of a product. Clinical results from our prior studies may not be indicative of results of future 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.*

*Such statements are based largely 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 conduct or complete clinical studies on expected timelines, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, any unanticipated impacts of inflation on our business operations, and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, 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 contained in this news release. 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.*

Source: Cassava Sciences, Inc.