Cassava Sciences Completes Patient Enrollment for Pivotal Phase 3 Clinical Trial of Oral Simufilam in Alzheimer's Disease

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- **804 Alzheimer's Patients Are Enrolled in a Pivotal Phase 3 Clinical Trial**
- **A Second Pivotal Phase 3 Clinical Trial Is Expected to Complete Enrollment Q4 2023, With a Target Enrollment of Approximately 1,100 Patients.**

AUSTIN, Texas, Oct. 02, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company, today announced the completion of patient enrollment in a pivotal Phase 3 clinical trial. Eight hundred four (804) Alzheimer's patients are enrolled in this 12-month trial. A second Phase 3 clinical trial with a target enrollment of approximately 1,100 patients is expected to complete patient enrollment in Q4 2023. Both on-going Phase 3 clinical trials are evaluating the safety and efficacy of oral simufilam in patients with 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.

Today's news comes on the heels of a recently announced positive interim safety review of simufilam in Cassava Sciences' on-going Phase 3 clinical trials in Alzheimer's disease. A recent meeting of a Data and Safety Monitoring Board (DSMB) recommended that both Phase 3 studies of simufilam continue as planned, without modification.

"We are pleased to announce the completion of patient enrollment in our first pivotal Phase 3 trial of simufilam in Alzheimer's," said James Kupiec, MD, Chief Medical Officer. "We are grateful to the patients, investigators and our CRO who have helped achieve this milestone."

"Cassava Sciences is honored to be developing a new drug treatment for people living with Alzheimer's disease," said Remi Barbier President & CEO. "Alzheimer's is a medical condition with high unmet needs. It merits the development of drug innovations that aim to go beyond removing amyloid from the brain. We think simufilam is advancing towards that goal."

On-going Phase 3 Clinical Program of Simufilam

Cassava Sciences is evaluating oral simufilam for Alzheimer's disease dementia in two global, randomized, double-blind, placebo-controlled Phase 3 clinical studies. Both Phase 3 studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration.

Our first Phase 3 trial has a 12-month treatment period and has enrolled 804 patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria. For more detailed information about our ongoing 12-month, Phase 3 trial, please visit www.ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT04994483?term=simufilam&rank=5

Our second Phase 3 trial has an 18-month treatment period and continues to enroll patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria. For more detailed information about our on-going, 18-month, Phase 3 trial, please visit: https://clinicaltrials.gov/study/NCT05026177?term=simufilam&rank=4

About Simufilam

Simufilam is Cassava Sciences' proprietary, small molecule (oral) drug candidate that restores the normal shape and function of altered filamin A (FLNA) protein in the brain. Cassava Sciences owns worldwide development and commercial rights to its research programs in Alzheimer's disease, and related technologies, without royalty obligations to any third party.

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 and efficacy 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: the completion of enrollment and number of patients enrolled in our Phase 3 studies; our current expectations regarding timing of and the target patient enrollment numbers for our Phase 3 studies; expected data or clinical results to be learned from

our Phase 3 studies; the design, scope, conduct, continuation, completion, intended purpose, or future results of our Phase 3 program of simufilam in patients with Alzheimer's disease; any findings or recommendations by the DSMB relating to the interim safety of simufilam in our on-going Phase 3 clinical trials; 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.