# Cassava Sciences Completes Patient Dosing in a Randomized Controlled Trial of Simufilam in Alzheimer's Disease

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- **The Cognition Maintenance Study (CMS) is a 6-month, Randomized Controlled Trial of Simufilam in Over 125 Patients with Alzheimer's Disease.**
- **Primary Outcome Measures Are Safety and Change in Cognition Scores.**
- **Top-line Clinical Results of the CMS Are Expected in Q3 2023.**

AUSTIN, Texas, May 11, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company, today announced the completion of patient dosing in a 6-month, randomized controlled trial of simufilam in over 125 patients with Alzheimer's disease. This trial is known as the Cognition Maintenance Study (CMS). Simufilam is Cassava Sciences' investigational oral drug treatment for Alzheimer's disease dementia.

"We all know that Phase 3 studies, if successful, provide evidence of efficacy," said Remi Barbier, President & CEO. "Our Cognition Maintenance Study addresses a flip side of the drug efficacy question: What happens when Alzheimer's patients who were taking simufilam for a year stop taking the drug for six months? Differences that emerge between the group of patients that continued to take simufilam versus the group of patients randomized to placebo may suggest evidence of simufilam's efficacy."

The CMS is a randomized, double-blind, placebo-controlled, 6-month trial designed to evaluate the safety and efficacy of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The CMS follows a randomized withdrawal study design. To enroll in the CMS, patients must have previously completed 12 months or more of open-label treatment with simufilam. Enrollment in the CMS was open to all patients who responded to open-label treatment, as well as to all patients who had no apparent response to open-label treatment.

CMS study participants were randomized (1:1) to simufilam or placebo. The primary outcome measures are safety and change in cognition scores (ADAS-Cog) over 6 months in over 125 patients who completed dosing. The CMS dataset remains locked and blinded. After unlocking, the dataset will be analyzed by outside biostatisticians. Subgroup analyses may include patients by stage of disease, prior response to open-label treatment, baseline scores or other crucial shared characteristics.

Cassava Sciences expects to announce CMS top-line data in Q3 2023.

**About Simufilam**
Simufilam is a novel drug candidate designed to treat and slow the progression of Alzheimer's disease. Simufilam binds tightly to an altered conformation of the filamin A protein (FLNA) that is present in the brain of the Alzheimer's patient and is critical to the toxicity of Aβ42. Simufilam is wholly owned by Cassava Sciences, without royalty or payment obligation 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 novel science is based on stabilizing—but not removing—a critical protein in the brain. Our product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established. For more information, please visit our website: 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, that may include but are not limited to: our clinical strategy and plans; the size, scope and design of our Cognition Maintenance Study (CMS) and its likelihood of success; our use of a randomized withdrawal study design in the CMS; the expected interpretation of clinical data generated in our CMS; any actual or assumed standards of drug efficacy in clinical trials, including Phase 3 studies; the timing of top-line clinical results of the CMS; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; verbal commentaries made by our employees; and potential benefits, if any, of the our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.*

*Simufilam and SavaDx are our investigational product candidates. They are not approved by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes have not been established in patients.*

*Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Clinical results and analyses of our CMS study should not be relied upon as predictive of Phase 3 studies or any other*

*study. Top-line clinical results from our CMS may not be indicative of full study results or 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.*

*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.