Cassava Sciences Announces Patient Enrollment Update for Phase 3 Studies of Simufilam for the Treatment of Alzheimer's Disease

February 8, 2023

- **953 Alzheimer's Patients Are Now Enrolled Across Phase 3 Studies**
- **Both Phase 3 Studies Have Passed the Halfway Mark for Enrollment**
- **Goal Is to Complete Enrollment for Both Phase 3 Studies by Year-End 2023**

AUSTIN, Texas, Feb. 08, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company, today announced an update on patient enrollment for its on-going Phase 3 clinical studies of simufilam for the treatment of Alzheimer's disease dementia. Simufilam, an oral drug, is Cassava Sciences' proprietary lead drug candidate.

James W. Kupiec, MD, Chief Medical Officer of Cassava Sciences, commented, "We are pleased with the recent pickup in the pace of patient enrollment with our Phase 3 studies, which are designed to evaluate the safety and efficacy of simufilam in patients with Alzheimer's disease."

A total of 953 Alzheimer's patients are now enrolled across Cassava Sciences' Phase 3 studies. For each Phase 3 study, patient enrollment has passed the halfway mark of the target patient enrollment. The enrollment target for both (not each) Phase 3 clinical studies is approximately 1,750 patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria. There are no interim analyses in Cassava Sciences' Phase 3 studies.

"We anticipate the completion of patient enrollment for both of our Phase 3 studies by year-end 2023," said Remi Barbier, Present & CEO. "Based on recent enrollment trends, we think this is a realistic expectation for completing patient enrollment."

Phase 3 Program with Simufilam
Cassava Sciences is currently evaluating simufilam tablets for Alzheimer's disease dementia in two Phase 3 clinical studies. These are randomized, double-blind, placebo-controlled trials. Both Phase 3 studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration. Both Phase 3 studies have the same co-primary efficacy endpoints: ADAS-Cog12 (a cognitive scale) and ADCS-ADL (a functional scale). The Phase 3 studies are actively recruiting Alzheimer's patients in over 100 clinical sites in the United States, Canada, Puerto Rico, South Korea and Australia.

For detailed information regarding Cassava Sciences' Phase 3 clinical studies, please visit: https://clinicaltrials.gov/ct2/results?term=simufilam&recrs=a&age_v=&gndr=&type=&rslt=&Search=Apply

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 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: https://www.CassavaSciences.com

For More Information Contact:
Eric Schoen, Chief Financial Officer
(512) 501-2450, or eschoen@CassavaSciences.com

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 numerical targets for enrolling patients in our Phase 3 studies; our expectations for the completion of patient enrollment for both of our Phase 3 studies by year-end 2023; current enrollment trends in our Phase 3 studies; comments made by our employees regarding simufilam, our on-going Phase 3 studies and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would", "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.

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. Our interim data and analyses should not be relied upon as predictive of full study results for any of our studies. Our clinical results from earlier-stage clinical trials 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, the severity and duration of health care precautions given the COVID-19 pandemic, any unanticipated impacts of the pandemic 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, 2021, 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.