Cassava Sciences Announces Initiation of an Open-label Extension Study

October 13, 2022

- **Alzheimer's Patients Who Complete Participation in a Phase 3 Study of Simufilam are Eligible to Enroll**
- **52-week Study of Simufilam 100 mg**
- **Up to 1,600 Patients Are Expected to Enroll**

AUSTIN, Texas, Oct. 13, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced the initiation of an open-label extension study. This study is designed to provide no-cost access to simufilam, an investigational drug, to patients with Alzheimer's disease who complete either one of Cassava Sciences' on-going Phase 3 studies, which are double-blind, placebo-controlled trials.

"We believe this open-label study is the right thing to do," said Remi Barbier, President & CEO. "Alzheimer's patients who complete one of our Phase 3 studies are eligible to enroll, knowing there is no placebo and no blinding in our open-label extension study."

Open-label Extension Study Design
This multi-center, multi-national, open-label extension study is expected to generate long-term safety and tolerability data for (oral) simufilam 100 mg twice daily over 52 weeks. Each clinical investigational site must choose whether to participate in this open-label extension study. Patient enrollment for this study is expected to begin early November 2022.

For more information about the open-label-extension study, please visit ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT05575076?term=simufilam&draw=2&rank=1

Overview of On-going Phase 3 Clinical Program
Our Phase 3 program consists of two double-blind, randomized, placebo-controlled studies of simufilam, with an enrollment target of approximately 1,750 patients with mild-to-moderate Alzheimer's disease. Both Phase 3 studies have Special Protocol Assessments (SPA) from the U.S. Food and Drug Administration. For more information about our Phase 3 studies, please visit ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT04994483?term=simufilam&draw=2&rank=3
https://www.clinicaltrials.gov/ct2/show/NCT05026177?term=simufilam&draw=2&rank=4

About Simufilam
Simufilam, an investigational drug, is Cassava Sciences' proprietary, small molecule (oral) drug 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, Inc. 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. 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 the open-label extension study; comments made by our employees regarding simufilam 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 and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Our clinical results from earlier-stage clinical trials may not be indicative of full 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, 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.