Cassava Sciences Announces Completion of Dosing in Open-label Study of Simufilam for Alzheimer's Disease

December 6, 2022

- **Outside Biostatisticians with Specific Expertise in Alzheimer's Disease Will Conduct an Independent Statistical Analysis on The Clinical Dataset.**

- **Clinical Dataset May Be Announced Approximately Year-End 2022, Pending Completion of Study Report by Outside Biostatisticians.**

AUSTIN, Texas, Dec. 06, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company, today announced the completion of drug administration in an open-label study of simufilam for Alzheimer's disease. This study was designed to evaluate long-term drug safety and to measure cognitive changes (ADAS-cog) over 12 months in approximately 200 patients with mild-to-moderate Alzheimer's disease treated with open-label simufilam 100 mg twice daily. Simufilam is Cassava Sciences' oral drug candidate for Alzheimer's disease dementia.

To ensure the highest integrity of data analysis, outside biostatisticians with specific expertise in Alzheimer's disease will conduct an independent statistical analysis on the clinical dataset. Cassava Sciences may announce study results approximately year-end 2022, pending completion of a study report by outside biostatisticians.

"We are thrilled with the progress made to date in the clinical development of simufilam, our oral drug candidate for people with Alzheimer's disease," said Remi Barbier, President & CEO. "We applaud recent clinical advances with anti-amyloid antibody drugs for Alzheimer's, but these may not be enough. I think innovations are needed around new targets, new molecules, drug safety and dosing. I believe Cassava Sciences may be at the forefront of this effort to innovate."

Overview of On-going Phase 3 Clinical Program
Cassava Sciences is evaluating simufilam for Alzheimer's disease dementia in two Phase 3 clinical studies. Both studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration. Over 750 patients are now enrolled in the Phase 3 program.

Cassava Sciences' RETHINK-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg in enhancing cognition and slowing functional decline over 52 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 750 patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1) to simufilam 100 mg or matching placebo twice daily.

Cassava Sciences' REFOCUS-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 76 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 1,000 patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1:1) to simufilam 100 mg, 50 mg, or placebo twice daily.

Both Phase 3 studies have the same co-primary efficacy endpoints: ADAS-Cog12 (a cognitive scale) and ADCS-ADL (a functional scale).

About Simufilam
Simufilam (sim-uh-FILL-am) 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 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

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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 strategy and plans; expectations regarding clinical results of our open-label study of simufilam in Alzheimer's disease; the size or composition of patient enrollment in this open-label study; plans to release clinical results of our open-label study, and the timing thereof; the treatment of Alzheimer's disease; the timing, enrollment, duration, geography and other details of a Phase 3 clinical program with simufilam; and potential benefits, if any, of simufilam. 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 interim data and analysis 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 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.