



Cassava Sciences Initiates a Second Phase 3 Study of Simufilam for the Treatment of Patients with Alzheimer's Disease

November 18, 2021

Second Phase 3 Study is Designed to Evaluate Safety and Efficacy of Simufilam Over 78 Weeks in 1,000 Patients with Alzheimer's Disease

AUSTIN, Texas, Nov. 18, 2021 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company, announced today it has initiated a second Phase 3 study of simufilam, the Company's investigational drug for patients with Alzheimer's disease. This second Phase 3 study is designed to evaluate the safety and efficacy of simufilam over 78 weeks in approximately 1,000 patients with Alzheimer's disease across clinical sites in the U.S. and Canada.

"Alzheimer's disease isn't going away anytime soon, and neither are we," said Remi Barbier, President & CEO. "Developing a new drug solution for Alzheimer's is a daunting task during the best of times. During these times of outlandish allegations made against us by short sellers, we stand committed to translate what we believe is a promising scientific breakthrough into a potentially meaningful treatment for people with Alzheimer's disease. The rest is noise."

Cassava Sciences' Phase 3 program in Alzheimer's is being conducted under Special Protocol Assessments (SPA) from the U.S. Food and Drug Administration (FDA). The SPAs document that FDA has reviewed and agreed on the key design features of each Phase 3 study protocol.

Cassava Sciences is developing simufilam in accordance with high ethical standards and sound scientific principles. Cassava Sciences is committed to transparency and sharing information related to its Phase 3 program – for clinical protocol details, including patient eligibility, please visit: <https://clinicaltrials.gov/ct2/results?cond=&term=simufilam&cntry=&state=&city=&dist=>

About The First Phase 3 Study (RETHINK-ALZ)

The first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg in enhancing cognition and slowing cognitive and functional decline over 52 weeks. Secondary objectives include the assessment of simufilam's effect on neuropsychiatric symptoms and caregiver burden. This randomized, double-blind, placebo-controlled study plans to enroll approximately 750 patients with mild-to-moderate Alzheimer's disease in the U.S. and Canada and, eventually, overseas. We commenced patient screening for RETHINK-ALZ in October 2021, followed by patient dosing in November 2021.

About The Second Phase 3 Study (REFOCUS-ALZ)

The second Phase 3 study, called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 78 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 1,000 patients with mild-to-moderate Alzheimer's disease in the U.S. and Canada and, eventually, overseas.

About Simufilam

Simufilam (sim-uh-FILL-am) is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA) protein in the brain. Altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. The underlying science for simufilam is published in peer-reviewed journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, *Journal of Biological Chemistry*, *Neuroimmunology and Neuroinflammation* and *Journal of Prevention of Alzheimer's Disease*. 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' mission is to discover and develop innovations for chronic, neurodegenerative conditions. Over the past 10 years, Cassava Sciences has combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. For more information, please visit: <https://www.CassavaSciences.com>.

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Cautionary Note Regarding Forward-Looking Statements: *This press release includes forward looking statements including but not limited to those regarding the size and scope of our Phase 3 program with simufilam in Alzheimer's disease, the expected treatment benefits of simufilam for people with Alzheimer's disease and oral or written comments made by our employees regarding simufilam and its clinical development.*

Drug development involves a high degree of risk, and historically only a small number of research and development programs result in commercialization of a product. Clinical results from our 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 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 initiation, conduct or completion of our 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, 2020, as supplemented by the section entitled “Risk Factors” in our Quarterly Report on SEC Form 10-Q for the quarter ended September 30, 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.