

# Cassava Sciences Announces Initiation of Cognition Maintenance Study in Alzheimer's disease

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### - Randomized, Controlled Study is Designed to Evaluate Cognition in Patients Who Continue Versus Discontinue Simufilam Over Six Months –

## - Target Enrollment is 100 Study Participants -

AUSTIN, Texas, May 10, 2021 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced the initiation of a Cognition Maintenance Study (CMS) to evaluate simufilam in patients with Alzheimer's disease. Simufilam is a drug candidate that seeks to reduce neurodegeneration and neuroinflammation. Cassava Sciences believes the ability to impact more than one aspect of Alzheimer's disease represents a new and crucial approach to treatment.

"We've observed good safety and cognitive improvements in study participants treated with open-label simufilam," said Remi Barbier, President & CEO. "The CMS is a randomized, controlled study designed to evaluate changes in cognition over six months in study participants who continue with drug treatment versus those who stop treatment. We believe clinical data from the CMS may inform the benefit-risk assessments that drive regulatory decisions."

In addition to initiating the CMS and conducting an on-going open-label study, Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 program in Alzheimer's disease, to complete clinical readiness activities in support of the Phase 3 program, and to continue to lead the Company to deliver the full potential of its product portfolio.

## About the Cognition Maintenance Study (CMS)

The CMS is a double-blind, multi-center, randomized, placebo-controlled clinical study in subjects with mild-to-moderate Alzheimer's disease. Upon enrolling into the CMS, all study participants will already have completed at least one year of open-label treatment with simufilam. CMS participants will be randomized (1:1) to simufilam 100 mg tablets twice-daily or matching placebo for six months. The CMS design includes measures of safety and a single primary endpoint of cognition, measured on ADAS-Cog (Alzheimer's Disease Assessment Scale-Cognitive subscale). Target enrollment is up to 100 subjects across multiple study sites in the U.S. and Canada.

#### About Simufilam

Simufilam is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA), a scaffolding 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 is also developing an investigational diagnostic, called SavaDx, to detect Alzheimer's disease with a simple blood test. Simufilam and SavaDx were both developed in-house. Both product candidates are substantially funded by peer-review research grant awards from the National Institutes of Health (NIH). 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 Alzheimer's Disease

Alzheimer's disease is a progressive brain disorder that destroys memory and thinking skills. Currently, there are no drug therapies to halt Alzheimer's disease, much less reverse its course. As of 2020, there were approximately 50 million people worldwide living with dementia, a figure expected to increase to 150 million by 2050.<sup>1</sup> The annual global cost of dementia is now above \$1 trillion, according to *Alzheimer's Disease International*, a charitable organization.

## 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: <u>https://www.CassavaSciences.com</u>

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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; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of an interim analysis of an open-label study; planned enrollment targets; our intention to initiate a Phase 3 clinical program with simufilam and the timing, enrollment, duration and other details thereof; verbal commentaries made by our employees; 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, 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 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 <u>www.sec.gov</u>.

<sup>1</sup> Alzheimer's Disease International, Dementia Statistics, available on-line and accessed May 7, 2021.



Source: Cassava Sciences, Inc.