



Cassava Sciences Provides Mid-Year Corporate Update, Clinical Development Progress and Announces Guidance on Clinical Data Release

June 21, 2021

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**
- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2nd Half 2021**

AUSTIN, Texas, June 21, 2021 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.

"Patients with Alzheimer's want clear and present evidence of drug efficacy," said Remi Barbier, President & CEO. "The recent regulatory approval of a new drug for Alzheimer's was a bit of a donnybrook over this very topic. Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study. Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients."

Clinical progress across Cassava Sciences' product portfolio is summarized below.

Update on Open-label Study with Simufilam

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study protocol has pre-specified interim analyses on safety and cognition for the first 50 subjects who complete 6, 9 and 12 months of drug treatment. The study protocol also specifies biomarker measurements from baseline to Month 6 on a cohort of 25 study subjects, and baseline to Month 12 on another cohort of 25 study subjects.

The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

Guidance on Clinical Data Release

Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the *2021 Alzheimer's Association International Conference (AAIC)* in Denver, CO, the week of July 26-30th. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:

- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.
- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).
- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.

Update on the Cognition Maintenance Study (CMS)

In May 2021, Cassava Sciences initiated a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease called the *Cognition Maintenance Study (CMS)*. Patients who previously completed at least one year of open-label treatment with simufilam qualify to enroll in the CMS. Study subjects are randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment. The target enrollment for the CMS is 100 subjects or more; as of mid-June, approximately 30 subjects were enrolled.

Update on the Phase 3 Clinical Program

Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

Cassava Sciences' Phase 3 program consists of two double-blind, randomized, placebo-controlled studies in patients with mild-to-moderate Alzheimer's disease.

The first Phase 3 study is designed to evaluate *symptomatic improvement* in Alzheimer's disease. The goal is to demonstrate improved cognition and daily function in subjects treated with simufilam compared to baseline and to placebo. Approximately 600 subjects will be enrolled, randomized (1:1) to simufilam 100 mg or placebo BID, and treated for 12 months. Efficacy endpoints are ADAS-Cog, a cognitive scale, and ADCS-ADL, a scale of daily function.

The second Phase 3 study is designed to evaluate *disease-modifying* effects of simufilam in Alzheimer's disease. The goal is to demonstrate a slower rate of decline in cognition and daily function in subjects treated with simufilam compared to placebo. Approximately 1,000 subjects will be enrolled, randomized (1:1:1) to simufilam 100 mg, 50 mg or placebo BID, and treated for 18 months. Efficacy endpoints are ADAS-Cog and ADCS-ADL.

Update on SavaDx

SavaDx is an investigational diagnostic candidate to detect Alzheimer's disease with a simple blood test. SavaDx was evaluated for its ability to detect treatment effects of simufilam versus placebo in a randomized, controlled study completed in 2020. This was a Phase 2b study that enrolled 64 patients with Alzheimer's disease. The SavaDx clinical dataset will be presented at AAIC the week of July 26-30th.

Update on Corporate Outlook

As of March 31, Cassava Sciences had approximately \$282 million in cash. This affords Cassava Sciences a financial runway to support the Phase 3 clinical development program of simufilam.

In addition, in May 2021, Cassava Sciences announced a new \$2.7 million research grant award from the National Institutes of Health (NIH). This NIH research grant is intended to fund clinical readiness activities in support of the upcoming Phase 3 program with simufilam.

Net cash use for operations for full-year 2021 is still expected to be approximately \$20 to \$25 million, with variance depending on how quickly new clinical study sites are onboarded for the Phase 3 program with simufilam and the study's rate of patient enrollment.

To support current and future expected clinical progress, Cassava Sciences continues to grow its internal team, while also continuing to rely on an external network of industry experts and scientific advisors. In 2021, the Company expects to significantly increase its square footage of office and R&D space to accommodate growth in its operations.

Cassava Sciences is also committed to monitor and, as appropriate, to upgrade its policies and procedures around board-level governance, sustainability and societal goals as it continues to execute its corporate and clinical strategies. To help with such efforts, a new Board member, Richard (Rick) Barry was recently appointed to the Board of Directors.

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), 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*. Simufilam is substantially supported by peer-reviewed research grant awards from the National Institutes of Health (NIH).

About SavaDx

SavaDx is Cassava Sciences' investigational diagnostic to detect Alzheimer's disease. The goal of SavaDx is to make the detection of Alzheimer's as simple as getting a blood test, possibly years before the appearance of any overt clinical symptoms. SavaDx is substantially funded by a peer-reviewed research grant award from the National Institutes of Health (NIH).

Simufilam and SavaDx were both developed in-house. 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 2050.¹ 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: <https://www.CassavaSciences.com>.

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¹ *Alzheimer's Disease International, Dementia Statistics*, available on-line and accessed June 20, 2021.

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: the Company's anticipated data presentations at AAIC; expectations regarding convergence of biomarker and cognition data, and treatment benefits of simufilam; the Company's execution on its strategy to initiate a Phase 3 clinical program in Alzheimer's disease in 2021; expected cash use in future periods and ability of existing cash to

support the Phase 3 clinical development program of simufilam; planned growth in personnel and facilities; and Mr. Barry's anticipated contributions to the Board of Directors. 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 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 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 www.sec.gov.



Source: Cassava Sciences, Inc.