

Cassava Sciences' Phase 2b Clinical Results in Alzheimer's Selected as Late-Breaking News at CTAD 2020

September 30, 2020

AUSTIN, Texas, Sept. 30, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biopharmaceutical company focused on Alzheimer's disease, today announced that clinical results of its Phase 2b study of sumifilam have been selected as a late-breaking oral presentation by the 13th international conference on Clinical Trials on Alzheimer's Disease (CTAD). CTAD is a prestigious annual conference focused on Alzheimer's research and development and takes place this year as a virtual event on November 4-7th, 2020. Members of CTAD's scientific committee select research abstracts for late-breaking, oral presentation based on medical and scientific significance, quality of data and methodology.

Details of Late-breaking Presentation:

Title: "Sumifilam (PTI-125) Significantly Improves Eleven CSF Biomarkers in A Randomized, Placebo-Controlled, One-Month Clinical Trial in Alzheimer's Disease Patients."

Presentation Type:	Late-Breaking, Oral Presentation (LB21)
Presenter:	Lindsay H. Burns, PhD, SVP Neuroscience, Cassava Sciences
Date/Time:	November 7, 2020, 11:10 am EST
Venue:	Virtual conference

Cassava Sciences' late-breaking CTAD presentation will be made available on the day of the presentation on its corporate website (<u>www.CassavaSciences.com</u>) in the 'Investors' page.

Cassava Sciences recently announced final results of a Phase 2b study with sumifilam, its lead drug candidate, in Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), Alzheimer's patients treated with 50 mg or 100 mg of sumifilam twice-daily for 28 days showed statistically significant (p<0.05) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients treated with sumifilam showed improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Size 17-46%). Cognitive improvements correlated most strongly (R²=0.5) with decreases in levels of P-tau181.

Phase 2b Study Conclusions

A small, well-controlled study of sumifilam showed promising treatment effects in patients with mild-to-moderate Alzheimer's disease. In this study, sumifilam treatment over 28 days improved an entire panel of validated biomarkers of Alzheimer's disease, decreased measurements of neuroinflammation, showed a 98% responder rate, was safe and well-tolerated, and appears to benefit cognition. Importantly, the data are consistent with prior clinical and preclinical results, the drug's mechanism of action and over 10 years of basic research.

Ongoing Open-label Study

Cassava Sciences is currently conducting a long-term, open-label, multi-center study of sumifilam 100 mg twice-daily for 12 months. The study's target enrollment is approximately 100 patients with mild-to-moderate Alzheimer's disease. This study is over 50% enrolled.

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. In the U.S. alone, approximately 5.8 million people are currently living with Alzheimer's disease, and approximately 487,000 people age 65 or older developed Alzheimer's in 2019. ¹ The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, resulting in a growing social and economic burden.²

About Sumifilam

Sumifilam 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 sumifilam 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. The Company is also developing an investigational diagnostic, called SavaDx, to detect Alzheimer's disease with a simple blood test.

Sumifilam 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. 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. Patent protection in this area currently runs beyond 2037, plus extensions, and includes seven issued patents and related patent filings and applications.

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

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Cassava Sciences' Phase 2b study of sumifilam in Alzheimer's disease was funded by clinical research grant #AG060878 from the National Institutes of Health (NIH/NIA).

The content of this press release is solely the responsibility of Cassava Sciences and does not necessarily represent the official views of the NIH/NIA.

Cautionary Note Regarding Forward-Looking Statements: This press release contains "forward-looking statements" for purposes of the Private Securities Litigation Reform Act of 1995 (the Act). Cassava Sciences claims the protection of the Safe Harbor for forward-looking statements contained in the Act. All statements other than statements of historical fact contained in this press release including, but not limited to, statements regarding the status of current and future clinical studies with sumifilam; the interpretation of results of our Phase 2 clinical studies including cognition data and plans to discuss clinical results at CTAD 2020; potential health benefits, if any, of changes in levels of biomarkers; verbal commentaries made by Cassava Sciences' employees and scientific advisors; and potential benefits, if any, of the Company's product candidates for Alzheimer's disease are forward-looking statements. Such statements are based largely on the Company's current expectations and projections about future events. Such statements speak only as of the date of this press 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 Cassava Sciences' Annual Report on Form 10-K for the year ended December 31, 2019 and future reports to be filed with the SEC. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this press 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, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press 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.

1,2 Source: Alzheimer's Association. 2019 Alzheimer's Disease Facts and Figures. Available online at: <u>https://www.alz.org/media/documents</u> /alzheimers-facts-and-figures-2019-r.pdf



Source: Cassava Sciences, Inc.