



## Cassava Sciences Announces Additional Positive Phase 2a Clinical Data in Alzheimer's Disease at CTAD 2019

December 6, 2019

- New Data Shows Clinical Evidence of Target Engagement and Target Validation –

- Company Expects Data Publication in a Peer-reviewed Medical Journal –

AUSTIN, Texas, Dec. 05, 2019 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biopharmaceutical company focused on Alzheimer's disease, today announced additional clinical data from a Phase 2a study of PTI-125, its investigational drug candidate for Alzheimer's disease. Company scientists presented the new data during a late-breaking oral presentation today at the 12<sup>th</sup> International Conference on Clinical Trials on Alzheimer's Disease (CTAD), in San Diego, Ca.

Consistent with over 10 years of basic research and pre-clinical data, the new data show clinical evidence of PTI-125's mechanism of action and drug-target engagement, including:

- Improvements in biomarkers of Alzheimer's disease in plasma and lymphocytes;
- Consistency across biomarker improvements in CSF, plasma, and lymphocytes;
- Significant reductions ( $p < 0.01$ ) in both nitrated and phosphorylated forms of tau protein;
- Evidence that each individual patient showed biomarker responses to PTI-125;
- Evidence that PTI-125 reversed the shape of altered filamin A in lymphocytes;
- Early clinical validation of the drug target – altered filamin A – as a facilitator protein between amyloid beta and both neuroinflammation and tau pathology.

Cassava Sciences expects to publish a manuscript of these new clinical data in a peer-reviewed medical journal.

"Today's data milestone is exciting because it provides additional support for the clinical benefits of slowing down both neurodegeneration and neuroinflammation in patients with Alzheimer's," said Remi Barbier, President & CEO of Cassava Sciences. "We're eager to gain more insight on the effects of PTI-125 in Alzheimer's after we conclude, in 2020, an on-going Phase 2b study."

Details of CTAD Presentation:

**Title: "One-Month Oral Treatment With PTI-125, A New Drug Candidate, Reduces CSF and Plasma Biomarkers of Alzheimer's Disease."**

Presentation Type:	Late-Breaking Oral Presentation
Presenter:	Lindsay H. Burns, PhD, VP Neuroscience
Date/Time:	Thursday, December 5 <sup>th</sup> at 6:00 pm Pacific time
Location:	Hilton Bayfront, San Diego

The CTAD presentation is available on-line at [CassavaSciences.com](http://CassavaSciences.com) under the 'Investors' page.

PTI-125 targets both neurodegeneration and inflammatory components of Alzheimer's disease. As previously reported, in a Phase 2a study funded by the National Institutes of Health (NIH), open-label treatment with PTI-125 for 28 days significantly improved key CSF biomarkers of Alzheimer's pathology, neuroinflammation and neurodegeneration ( $p < 0.001$ ).

Cassava Sciences is now evaluating PTI-125 in a confirmatory Phase 2b study. This blinded, randomized, placebo-controlled, multi-dose study is enrolling approximately 60 patients with mild-to-moderate Alzheimer's disease. The primary endpoint is improvement in biomarkers of Alzheimer's disease from baseline to Day 28. Top-line study results are expected in 2020.

### About PTI-125

The target of PTI-125 is an altered form of filamin A (FLNA), a scaffolding protein. Published studies have shown that altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. Cassava Sciences' lead drug candidate, PTI-125, is a small molecule that restores the normal shape and function of FLNA in the brain. This action improves the function of certain receptors in the brain, which slows neurodegeneration and exerts powerful anti-neuroinflammatory effects.

Cassava Sciences is also developing an investigational diagnostic to detect Alzheimer's disease with a simple blood test. This program, called PTI-125Dx, also receives significant scientific and financial support from NIH.

The underlying science for Cassava Sciences' programs in neurodegeneration is published in prestigious peer-reviewed technical journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, and *Journal of Biological Chemistry*. As previously announced, NIH has awarded Cassava Sciences two research grants following an in-depth, confidential review of its science and technology. These two grant awards represent up to \$6.7 million of non-dilutive financing.

### **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 will develop Alzheimer's in 2019.<sup>1</sup> The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, which may also result in a growing social and economic burden.<sup>2</sup>

### **About Cassava Sciences, Inc.**

The mission of Cassava Sciences is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Over the past ten years, Cassava Sciences has combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. Cassava Sciences owns worldwide development and commercial rights to its research programs in Alzheimer's disease, and related technology, without royalty obligations to any third-party.

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**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 Phase 2 clinical studies; the interpretation of clinical results, including potential health benefits, if any, of changes in levels of biomarkers; commentaries made by Cassava Sciences' employees; and other 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 trials on expected timelines, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates 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, 2018 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](http://www.sec.gov).

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



Source: Cassava Sciences, Inc.