

Cassava Sciences Announces Completion of Patient Enrollment of a Phase 2b Study in Alzheimer's Disease

January 28, 2020

Top-Line Results Expected Mid-year 2020

AUSTIN, Texas, Jan. 28, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced it has initiated dosing for the last patient in a Phase 2b study of PTI-125. This completes patient enrollment in a randomized, double-blind, placebo-controlled, Phase 2b study of PTI-125, Cassava Sciences' investigational drug to treat Alzheimer's disease. A total of 64 patients were enrolled in this study and top-line results are expected mid-year 2020.

"This study again brought together leaders from the research community who share our commitment to improving outcomes for patients with Alzheimer's disease," said Remi Barbier, President & CEO. "Our previously announced results of a Phase 2a study with PTI-125 generated promising biomarker data in Alzheimer's patients. Based on those positive results, we believe our on-going Phase 2b study is a critical point of clinical validation for PTI-125."

Cassava Sciences is conducting its Phase 2b study with scientific and financial support from the National Institutes of Health (NIH).

About the Phase 2b Study

Phase 2b is a randomized, double-blind, placebo-controlled, multi-center study of PTI-125 in patients with mild-to-moderate Alzheimer's disease in the United States. Patients receive placebo, 50 mg or 100 mg of PTI-125 twice-daily over 28 days. The objective of this study is to investigate the safety and effects of PTI-125 on biomarkers of disease. The primary endpoint is improvement in patients' biomarkers of disease from baseline to Day 28. Further information on our Phase 2b study may be found on www.ClinicalTrials.gov (study identifier: NCT04079803).

About PTI-125

The target of PTI-125 is an altered form of filamin A (FLNA), a scaffolding protein. 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 proprietary 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, slows neurodegeneration and exerts powerful anti-neuroinflammatory effects. 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*.

Cassava Sciences is also developing an investigational diagnostic, called PTI-125Dx, to detect Alzheimer's disease with a simple blood test.

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. ¹ 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.²

About Cassava Sciences, Inc.

The mission of Cassava Sciences is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. 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. 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; comments and 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 <u>www.sec.gov</u>.

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.