



Cassava Sciences Initiates Phase 2b Clinical Study in Alzheimer's Patients

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First two patients dosed with lead drug candidate, PTI-125

Study initiation follows positive Phase 2a results demonstrating 100% response rate

AUSTIN, Texas, Sept. 16, 2019 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biopharmaceutical company focused on neuroscience, today reported initiation of a Phase 2b study of its lead drug candidate, PTI-125, in Alzheimer's patients. PTI-125 is a small molecule that targets the massive neuroinflammation and neurodegeneration observed in the Alzheimer's brain. In conjunction with the initiation of this Phase 2b study, Cassava Sciences also reported dosing of the first two patients for this study, both of which were uneventful. This Phase 2b study is supported by a research grant award from the National Institutes of Health (NIH).

"There is a profound and timely need to develop new drug therapies for this devastating disease," said Remi Barbier, President & CEO. "We are pleased to advance PTI-125 into this randomized, placebo-controlled study in approximately 60 Alzheimer's patients, and are eager to report how results of this study will expand upon the clinical data set for PTI-125."

Initiation of the Phase 2b study follows the positive results reported from a Phase 2a study, demonstrating 100% responder rate and statistically significant decreases in key biomarkers of Alzheimer's pathology, neuroinflammation and neurodegeneration.

Phase 2b Study Design

This Phase 2b clinical study is designed to evaluate safety, tolerability and drug effects of PTI-125 on validated biomarkers of Alzheimer's disease. This is a blinded, randomized, placebo-controlled, multi-center, multi-dose research study in approximately 60 patients with mild-to-moderate Alzheimer's disease. Patients will be dosed with PTI-125 100 mg, 50 mg, or matching placebo, twice daily for 28 continuous days. The primary endpoint is improvement in biomarkers of Alzheimer's disease from baseline to Day 28. Patient enrollment may take up to 12 months.

About PTI-125 and Cassava's Scientific Approach

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 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 several prestigious peer-reviewed technical journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, and *Journal of Biological Chemistry*. As previously announced, in 2018 the National Institute on Aging (NIA) of the NIH awarded Cassava two research grants following an in-depth, confidential review of its science and technology. These two NIH grants 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 2019.¹ 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 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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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 disclaims any intent or obligation to update these forward-looking statements and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, statements regarding the timing of initiation or completion of Phase 2 clinical studies; the interpretation of clinical results; and potential benefits, if any,

of the Company's drug programs in neurodegeneration, including Alzheimer's disease. The Company cautions that forward-looking statements are inherently uncertain. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the ability 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's Annual Report on Form 10-K for the year ended December 31, 2018. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. 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 U.S. Securities and Exchange Commission (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: <https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf>



Source: Cassava Sciences, Inc.