Cassava Sciences Completes Patient Enrollment for a Phase 2a Study in Patients with Alzheimer's Disease

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AUSTIN, Texas, April 15, 2019 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company, announced the completion of patient enrollment in a clinical study evaluating the safety of its investigational drug, PTI-125, in patients with Alzheimer's disease. Cassava Sciences is conducting this Phase 2a study with scientific and financial support from the National Institutes of Health (NIH).

"This study brings together leaders from the research community who share our commitment to improving outcomes for patients with Alzheimer's disease," said Remi Barbier, President & CEO. "The on-time completion of enrollment in this challenging study is testimony to the expertise of our collaborators, the experience of our clinical team and an enthusiastic response to PTI-125."

Cassava Sciences expects to announce results of its Phase2a study in the second half of 2019, after study participants complete drug treatment and their data are analyzed.

PTI-125 is a small molecule drug with a novel mechanism of action. Importantly, this drug does not seek to clear amyloid out of the brain. Our scientific approach is to stabilize a critical protein in the brain. PTI-125 has demonstrated both cognitive improvement and slowing of disease progression in animal models of disease.

About Cassava Sciences' Phase 2a Study
Cassava Sciences is conducting in the U.S. a multi-center, open-label study of PTI-125 in patients with mild-to-moderate Alzheimer's disease. Twelve or more patients, 50-85 years of age, each receive 200 mg of oral PTI-125 daily over a 28-day treatment period. Among other inclusion criteria, patients must undergo a standardized procedure for a lumbar puncture and drawing of *cerebrospinal fluid* for biomarker assessments that indicate the presence of Alzheimer's disease. The objectives of this Phase 2a study is to investigate the safety, pharmacokinetics and effect on biomarkers of PTI-125 following 28-day repeat-dose oral administration.

Our Scientific Approach
The target of PTI-125 is an altered form of filamin A (FLNA). FLNA is a scaffolding protein found throughout the body. The function of a scaffolding protein is to bring multiple proteins together and to ensure they interact properly. However, an altered and highly toxic form of FLNA is found in the Alzheimer's brain. Altered FLNA disrupts the normal function of neurons, leading to neurodegeneration and brain inflammation. Our investigational drug candidate, PTI-125, restores the normal shape of FLNA in the brain. This drug effect improves the function of multiple brain receptors and exerts powerful anti-neuroinflammatory effects.

In animal models of disease, treatment with PTI-125 resulted in dramatic improvements in brain health, such as reduced amyloid and tau deposits; improved insulin receptor signaling; improved learning and memory; and significant reductions in levels of inflammatory cytokines in the brain.

We are also developing a biomarker/diagnostic to detect Alzheimer's disease with a simple blood test. This program, called PTI-125Dx, also receives scientific and financial support from NIH.

The underlying science for our 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, NIH awarded us two research grants in 2018 following an in-depth, confidential review of our science and technology. The 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. Eventually, a person with Alzheimer's disease may be unable to carry out even simple tasks. Currently, there are no drug therapies to halt Alzheimer's disease, much less reverse its course. Unless effective treatments are developed soon, Alzheimer's disease is likely to become one of the world's most serious health care crises.

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, we have combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. We own worldwide development and commercial rights to our 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 clinical studies and the potential benefits of the Company's programs in Alzheimer's disease, including our ongoing*

Phase II program. 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 candidatesand 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.

Source: Cassava Sciences, Inc.