Cassava Sciences Announces Clinical Update and Business Progress Across Neuroscience Pipeline

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AUSTIN, Texas, March 19, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced clinical updates and business progress across its pipeline of product candidates under development.

"Our clinical programs show no signs of slowing down," said Remi Barbier, President & CEO. "Alzheimer's continues to be a devastating disease in need of solutions, and I believe impressive scientific progress across the industry will accelerate into 2020 and beyond. Now more than ever, we feel it's important to communicate our values and progress. With this backdrop, we are pleased to report that our business is firing on all cylinders."

Business Update
Cassava Sciences is building a leading position in Alzheimer's R&D by focusing on the development of a first-in-class program for treating and detecting Alzheimer's disease. The Company's scientific approach for the treatment of Alzheimer's disease seeks to simultaneously improve *both* neurodegeneration and neuroinflammation. Cassava Sciences believes the ability to improve multiple vital functions in the brain represents a new, different and crucial approach to address Alzheimer's disease.

Drug Update – Goal is to treat *both* neurodegeneration and neuroinflammation
Cassava Sciences' lead therapeutic product candidate, PTI-125, is a proprietary small molecule oral drug. PTI-125 targets an altered form of a protein, called filamin A (FLNA), that is widely found in the Alzheimer's brain. This altered form of FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation. PTI-125 improves brain health by reverting altered FLNA back to its native, healthy confirmation. This drug effect restores the normal function of three key brain receptors: the alpha-7 nicotinic acetylcholine receptor; the N-methyl-D-aspartate (NMDA) receptor; and the insulin receptor. These receptors have pivotal roles in brain cell survival, cognition and memory. In animal models, treatment with PTI-125 resulted in dramatic improvements in brain health, such as reduced amyloid and tau deposits, improved receptor signaling and improved learning and memory. In 2019, a proof-of-concept Phase 2a clinical study showed that open-label treatment with PTI-125 twice-daily for 28 days significantly improved key biomarkers of neuroinflammation and neurodegeneration ($p<0.001$) in patients with Alzheimer's disease. To the Company's knowledge, no other drug candidate has improved an entire panel of biomarkers of disease in Alzheimer's patients. By restoring proper function to multiple receptors and exerting powerful anti-inflammatory effects, the Company believes PTI-125 may slow neurodegeneration in Alzheimer's patients. The Company's science is published in multiple, peer-reviewed journals. In addition, its scientific programs continue to be supported by multiple research grant awards from the National Institute of Health (NIH), the nation's foremost medical research agency.

Phase 2b Study Update – Top-line results expected mid-year 2020
In September 2019, Cassava Sciences announced the initiation of a Phase 2b confirmatory clinical study in Alzheimer's patients, with funding provided by NIH. This Phase 2b clinical study is designed to evaluate safety, tolerability and drug effects of PTI-125 on biomarkers of disease. This blinded, randomized, placebo-controlled, multi-center, multi-dose research study has finished enrolling 64 patients with mild-to-moderate Alzheimer's disease. Study patients received either PTI-125 100 mg, 50 mg or matching placebo, twice-daily for 28 continuous days. The study was conducted in the U.S. across 9 clinical sites. The primary endpoint is improvements in levels of biomarkers of disease from baseline to Day 28.

In January 2020, the Company announced the completion of patient enrollment for its Phase 2b study. In February 2020, the last study participants were successfully dosed. In March 2020, the last study participants underwent final, routine follow-ups. No safety issues were found. Cerebrospinal fluid and plasma samples from study participants were recently shipped to independent, third party labs for biomarker analysis. Study samples will be analyzed under blinded conditions, meaning no one will know whether a test sample came from a study participant who was on drug or placebo until the study is unblinded. Lab testing, statistical analysis, data analytics and interpretation of results are expected to run through approximately May 2020. The company expects to announce top-line results approximately mid-year 2020.

Open-label Study – Initiation expected shortly
Cassava Sciences is planning to conduct a one-year, open-label extension study of PTI-125 in approximately 100 patients with mild-to-moderate Alzheimer's disease. Every study participant receives drug treatment in an open-label study. This study is intended to provide an opportunity for patients from prior studies of PTI-125 to participate in additional clinical research directed at improving their health, and to increase the company's knowledge of the long-term safety profile of PTI-125. The Company expects to initiate this study shortly.

Diagnostic Update – Name change to SavaDx; validation study expected second half 2020
Cassava Sciences' diagnostic program, now called SavaDx (formerly known as PTI-125Dx), is focused on detecting Alzheimer's disease from a small sample of blood, possibly years before the overt appearance of clinical symptoms. The goal of SavaDx is to make the detection of Alzheimer's disease as simple as getting a blood test. In September 2017, the Company announced a $1.8 million research grant award from NIH to fund the on-going development of SavaDx. The Company is still developing proprietary antibodies and other detection systems for use with SavaDx. Assuming technical success with on-going efforts, the Company expects to run validation studies with SavaDx in the second half of 2020. In addition, the Company expects to present a technical update for SavaDx at a major scientific conference in 2020.

Operations Update – No disruptions, for now
Employees of Cassava Sciences continue to perform with high fidelity despite an unprecedented outbreak of disease across the nation. A system of remote clinical site monitoring has been put in place to ensure operational efficiency, resolve tactical issues and collect clinical documentation. The Company has not experienced disruptions across its drug manufacturing operations or supply of materials. Routine regulatory communication with the FDA appears to be normal. The Company's broad spectrum of technical consultants, scientific advisors and service providers continue to provide timely services. The Company plans to hold its Annual Meeting of Stockholders on May 7, 2020 in its corporate office in Austin, Tx, although a virtual

component may be added to respect health policies that discourage in-person gatherings. Any of the above may change and adversely impact operations if the scope and severity of health precautions extend beyond a few weeks.

Finance Update – $5 million cash use expected in FY2020, against $26 million cash-on-hand; new NIH research grant award; non-deal roadshow expected

Cassava Sciences expects to shortly announce full-year 2019 earnings and to file its Annual Report on Form 10-K. As of January 31, 2020, the Company had approximately $26 million of cash and no debt. Net cash use is expected to be approximately $5 million for full year 2020. Also, in March 2020, NIH awarded the Company supplemental research funding in the amount of $374,000. This new, non-dilutive research funding is intended to strengthen the Company's clinical program of PTI-125 in patients with Alzheimer's disease.

In addition, the Company's trading window is now closed for employees and directors. A closed trading window prohibits insiders from trading in the securities of the Company prior to the announcement of clinical results of study Phase 2b and other unpublished material information.

Finally, in the weeks ahead, management may conduct one or more non-deal roadshow (NDRS). A NDRS is a multi-city series of meetings, virtual or in-person, with institutional investors to share public information and updates on the Company's business and vision for the future. Historically, Cassava Sciences has benefited from NDRSs by educating institutional investors about the Company, and by listening and learning from industry analysts, experts and investors.

About PTI-125

Cassava Sciences' lead therapeutic product candidate is for the treatment of Alzheimer's disease. PTI-125 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. PTI-125 seeks to simultaneously improve *both* neurodegeneration and neuroinflammation. The underlying science is published in peer-reviewed scientific journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, *Journal of Biological Chemistry 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.

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 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 technologies, 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, expected cash use in future periods; statements regarding the status of clinical studies with PTI-125 and validation studies with SavaDx; the interpretation of results of clinical studies, including potential health benefits, if any, of changes in levels of biomarkers; verbal commentaries made by Cassava Sciences' employees; potential benefits, if any, of the Company's product candidates for Alzheimer's disease; the intended future timing of our Annual Meeting of Stockholders; non-deal road shows; and SavaDx technical updates at scientific conferences, are all 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 international outbreak of an infectious disease, 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. The content of this press release is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health (NIH). 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: https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf

Source: Cassava Sciences, Inc.