Top-line Results from a Phase 2b Study of PTI-125 in Alzheimer's Disease Does Not Meet Primary Endpoint

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- Study Showed High Variability in Levels of CSF Biomarkers Over 28 Days -

- Drug Was Safe and Well-tolerated -

AUSTIN, Texas, May 15, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA) today reported top-line results from a Phase 2b study of PTI-125, its lead investigational drug, in patients with Alzheimer's disease. This study did not meet its primary endpoint. The pre-specified primary endpoint was a statistically significant effect of PTI-125 versus placebo on cerebrospinal fluid (CSF) levels of tau protein and other biomarker assessments from baseline to Day 28. PTI-125 significantly reduced a secondary endpoint, CSF levels of IL1-beta ($p<0.035$), a core biomarker of neuroinflammation, from baseline to Day 28. Drug was safe and well-tolerated.

A post-hoc analysis of biomarker data revealed high variability in levels of CSF biomarkers over 28 days. For example, placebo-treated patients recorded changes in levels of CSF tau and p-tau ranging from -54% to +34% and -49% to +253%, respectively, from baseline to Day 28. Biomarker analysis was conducted by outside labs.

The drug effects of PTI-125, if any, may have been masked in this study by high variability in levels of biomarkers of disease. In the months ahead the Company plans to re-analyze CSF biomarkers from all study participants.

"Today's top-line results disappoint and are not consistent with previous clinical experience for reasons that are unclear at the moment," said Remi Barbier, President & CEO. "We plan to thoroughly analyze these top-line data, and to re-analyze CSF biomarkers from study participants, to better understand the outcome of this study. Alzheimer's is a disease in dire need of new treatments. It is worth reflecting on what we can learn from this study and how to move forward with drug development plans for PTI-125 in Alzheimer's disease."

Phase 2b Study Design
Phase 2b was a double-blind, randomized, placebo-controlled study of PTI-125 in 64 patients with mild-to-moderate Alzheimer's disease, 50-85 years of age, with MMSE 16 to 26. Participants received PTI-125 100 mg, 50 mg or matching placebo, twice-daily, for 28 continuous days.

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, Inc. 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.

For more information, please visit: https://www.CassavaSciences.com

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 clinical studies with PTI-125; the interpretation of results of clinical studies, potential health benefits, if any, of changes in levels of biomarkers; variability in levels of biomarkers of disease; plans to have CSF samples from all Phase 2b study participants re-analyzed; verbal commentaries made by Cassava Sciences' employees; and potential benefits, if any, of the Company's product candidates for Alzheimer's disease 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 COVID-19 pandemic, any unanticipated impacts of the pandemic on our business operations, 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, 2019 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.*

[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.