MRI Data Suggest Simufilam is Not Associated with Amyloid-related Imaging Abnormalities (ARIA)

Oct 25, 2023

- **Safety Finding Based on Blinded MRI Brain Data at Week 40**
- **ARIA is a Known Risk Factor for Anti-Amyloid Antibody Drugs**
- **MRI Data Presented at the 16th CTAD Conference in Boston, MA**

AUSTIN, Texas, Oct. 25, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company, today announced a potentially significant safety finding based on interim magnetic resonance imaging (MRI) brain data from Alzheimer's patients who are enrolled in a Phase 3 clinical trial of simufilam. The MRI data suggest simufilam is not associated with treatment-emergent amyloid-related imaging abnormalities, or ARIA. MRIs were all analyzed for ARIA by board-certified neuroradiologists.

ARIA is a medical term used to describe a spectrum of brain MRI imaging abnormalities, such as edema and brain bleeds. ARIA is also a known risk factor for Alzheimer's patients taking the class of drugs known as monoclonal antibodies directed against beta amyloid. In contrast to such class of drugs, simufilam is Cassava Sciences' small-molecule (oral) drug candidate. Oral simufilam is currently in Phase 3 clinical testing in patients with Alzheimer's disease dementia.

The new safety finding is based on an independent, interim neuroradiological evaluation of brain MRIs taken at week 40 in a blinded sub-study of 180 Alzheimer's patients enrolled in Cassava Sciences' on-going 76-week Phase 3 clinical trial of simufilam in mild-to-moderate Alzheimer's (NCT#05026177). Final MRI data is expected at the conclusion of this Phase 3 study.

All Phase 3 clinical data remains blinded.

The MRI data and two other datasets will be presented at the 16th Clinical Trials on Alzheimer's Disease (CTAD) conference taking place in Boston, MA, October 24-27th, 2023:

- **LP036: "*Interim MRI Safety Analysis from a 76-week Phase 3 Clinical Trial of Simufilam in Alzheimer's Disease.*"** Poster publication.
- **LB23: *"Results of a Phase 2 Randomized Withdrawal Study of Simufilam in Mild-to-moderate Alzheimer's Disease."*** Late-breaking oral presentation by Suzanne Hendrix, PhD, Pentara Corporation, Friday, Oct 27th, 3:30pm ET.
- **LP107: *"Simufilam's Primary Mechanism of Action Confirmed by Time-resolved FRET."*** Poster presentation.

Access to these presentations may be available at CTAD in Boston or on-line at CTAD's website, and are expected to be posted shortly in the publication section of: www.CassavaSciences.com

About Cassava Sciences, Inc.
Cassava Sciences is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Our product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established in humans.

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

For More Information Contact:
Eric Schoen, Chief Financial Officer
(512) 501-2450
ESchoen@CassavaSciences.com

Cautionary Note Regarding Forward-Looking Statements:
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: the continuation of our Phase 3 clinical program; results of research relating to simufilam and to the mechanism of action underlying simufilam; the treatment of patients with Alzheimer's disease dementia; the results and potential clinical implications, if any, of blinded MRI data taken from 180 Alzheimer's patients enrolled in our 76-week Phase 3 clinical trial of simufilam; the risk of current or future findings of treatment-emergent ARIA in our clinical program of simufilam; comments made by our employees at CTAD or elsewhere regarding our blinded MRI data, our science or simufilam and the treatment of Alzheimer's disease, or CTAD presentations #LP036, LB23 or LP107; the continued development of simufilam; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may,"

“anticipate,” “believe,” “could,” “expect,” “look forward,” “would”, “forecast,” “intend,” “plan,” “possible,” “potential,” and other words, phrases, and terms of similar meaning.

Simufilam is our investigational product candidate. Its safety, efficacy or science has not been reviewed or approved by any regulatory authority in any jurisdiction and its desirable clinical attributes, if any, have not been established in patients.

Drug development involves a high degree of risk, and only a small number of research and development programs result in regulatory approval and commercialization of a product. Clinical results from our prior studies may not be indicative of results of future or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

Such statements are based largely on our current expectations and projections about future events. Such statements speak only as of the date of this news 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, any unanticipated impacts of inflation on our business operations, and including those described in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news 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, we disclaim any intention or responsibility for updating or revising any forward-looking statements contained in this news 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.

Source: Cassava Sciences, Inc.