Cassava Sciences Announces Completion of an Interim Safety Review of Oral Simufilam On-going Phase 3 Trials

Mar 25, 2024

- **An Independent Data and Safety Monitoring Board (DSMB) Recently Evaluated the Interim Patient Safety Database for Oral Simufilam in On-going Phase 3 Trials.**
- **The DSMB Recommended Both Phase 3 Trials Continue as Planned, Without Modification.**
- **Final Clinical Safety Data for Simufilam Are Expected at the Conclusion of the Phase 3 Program.**

AUSTIN, Texas, March 25, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced the completion of another interim safety review of simufilam in on-going Phase 3 clinical trials in patients with Alzheimer's disease. A routine, scheduled meeting of a Data and Safety Monitoring Board (DSMB) recommended that both of Cassava Sciences' on-going Phase 3 studies continue as planned, without modification.

"This interim safety review is yet another milestone for the clinical development of simufilam," said Remi Barbier, President & CEO. "I find it encouraging and look forward to the final clinical safety dataset, which we expect at the conclusion of the Phase 3 program. We also look forward to announcing top-line efficacy data for our 12-month Phase 3 study late this year."

The DSMB is composed of independent clinical research experts who periodically review interim patient safety data for Cassava Sciences' on-going Phase 3 trials of simufilam in Alzheimer's disease. This DSMB only reviews patient safety. It does not assess drug efficacy.

On-going Phase 3 Studies with Simufilam
Cassava Sciences' simufilam is a novel, small molecule drug candidate for the proposed treatment of Alzheimer's disease dementia. The drug is in late-stage clinical evaluation in a pair of pivotal Phase 3 trials. These Phase 3 trials are fully enrolled. Over 1,900 patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria are randomized into the trials.

The first Phase 3 trial (NCT04994483) has a 52-week treatment period; 804 Alzheimer's patients were randomized into this trial, as announced in October 2023. Top-line results for the 52-week Phase 3 trial are currently expected approximately year-end 2024.

The second Phase 3 trial (NCT05026177) has a 76-week treatment period; 1,125 Alzheimer's patients were randomized into this trial, as announced in November 2023. Top-line results for the 76-week Phase 3 trial are currently expected approximately mid-year 2025.

Patients with mild-to-moderate Alzheimer's disease dementia who met study eligibility criteria were recruited into the Phase 3 program from clinical sites in the U.S., Puerto Rico, Canada, Australia and South Korea. Cassava Sciences is conducting its on-going Phase 3 program in collaboration with Premier Research International, a global contract research organization (CRO).

Today's news follows interim safety MRI data announced in October 2023, which suggests simufilam is not associated with treatment-emergent amyloid-related imaging abnormalities (ARIA). In addition, a September 2023 meeting of the DSMB recommended that both Phase 3 trials continue as planned, without modification. Final safety data are expected at the conclusion of the Phase 3 program.

About Simufilam
Simufilam is Cassava Sciences' proprietary drug candidate. This investigational drug binds to altered filamin A protein in the brain and restores its normal shape and function. By targeting altered filamin A, simufilam may help patients with Alzheimer's achieve better health outcomes.

Cassava Sciences owns exclusive, worldwide rights to its investigational product candidates and related technologies, without royalty obligations to any third party.

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 novel science is based on stabilizing—but not removing—a critical protein in the brain.

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 and Other Notices:
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. These statements may be identified by words such as "anticipate," "believe," "could," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," and other words and terms of similar meaning.

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, complete or announce top-line results of our clinical studies on expected timelines; the ability to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates in people with Alzheimer's disease dementia ; the interim safety status or profile of simufilam to date in our Phase 3 clinical studies; our current expectations regarding timing of clinical data for our Phase 3 studies; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; verbal comments made by our employees regarding simufilam, safety, drug effects, and the treatment of Alzheimer's disease with simufilam ; potential benefits, if any, of our product candidates and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, 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.

All our pharmaceutical assets under development are all investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates are approved or available for sale anywhere in the world, and you should not assume that they may ever be approved or available for sale at any time.

Our clinical results from earlier-stage clinical trials may not be indicative of future results from later-stage 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.

We are in the business of new drug discovery and development. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our current Annual Report on Form 10-K in its entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.

Source: Cassava Sciences, Inc.