Cassava Sciences Provides a Business Update

Jan 07, 2025

Topline data from Phase 3 REFOCUS-ALZ study of simufilam in patients with mild-to-moderate Alzheimer's disease expected late first-quarter/early second-quarter 2025

Implementing cost curtailment including a workforce reduction of approximately 33%

Approximately $128.6 million cash and cash equivalents at December 31, 2024 (unaudited)

AUSTIN, Texas, Jan. 07, 2025 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (NASDAQ: SAVA, "Cassava", the "Company"), a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system diseases including Alzheimer's disease dementia, today provided a business update.

In November 2024, Cassava reported that the topline results from the Phase 3 RETHINK-ALZ study evaluating simufilam as a potential treatment for patients with mild-to-moderate Alzheimer's disease did not meet its prespecified co-primary endpoints and that the Company intended to share a detailed analysis of data from the study at a future medical meeting. The Company also outlined its plan to discontinue the Phase 3 REFOCUS-ALZ study and Open Label Extension study and to analyze the complete 52-week dataset from the REFOCUS-ALZ study, along with a large portion of 76-week data. The Company is on track to complete these efforts and plans to release top-line REFOCUS-ALZ results late first-quarter/early second-quarter 2025.

The Company today announced that it is reducing its workforce by 10 employees, or approximately 33%, in the first quarter of 2025, as well as continuing strategic expense management efforts. Expense reductions include halting the planned biomarker analysis of additional plasma samples from prior Phase 2 studies. The Company estimates that it will incur approximately $0.4 million of one-time costs in Q1 2025 related to the workforce reduction.

The Company's unaudited cash and cash equivalents balance as of December 31, 2024 was approximately $128.6 million.

"Cassava continues to be dedicated to its mission of developing novel medicines for central nervous system disorders and enhancing shareholder value. We are in the final stages of discontinuing the REFOCUS-ALZ study and expect to report topline results late first-quarter/early second-quarter 2025. In addition, we continue to carefully review the data from the RETHINK-ALZ study and plan to incorporate the results of the REFOCUS-ALZ study into our evaluation of next steps for Cassava. With that in mind, following the announcement that the RETHINK-ALZ study did not meet its primary endpoints and that the REFOCUS-ALZ and Open Label Extension studies will be discontinued, we believe it is prudent to implement additional cost saving measures, including a reduction in force," said **Rick Barry, President and Chief Executive Officer**. "Cassava is a closely-knit organization, and so I want to thank each one of our employees being affected by this workforce reduction. We recognize and appreciate with deep and heartfelt gratitude your fine and dedicated service to Cassava's mission, to our clinical programs and to patients with Alzheimer's disease."

About RETHINK-ALZ

RETHINK-ALZ (NCT04994483) is a Phase 3 trial designed to evaluate the safety and efficacy of simufilam compared to a placebo in a multi-center, double-blinded, placebo-controlled, randomized parallel group study involving over 75 clinical trial sites in the U.S., Canada and Australia. The trial randomized 804 people with confirmed mild or moderate Alzheimer's disease, as defined by several well validated parameters including a mini-mental state exam (MMSE) of >16 and <27, stratified as mild or moderate. Subjects were randomized 1:1 to receive a 100 mg tablet of simufilam (n=403) or a matched placebo (n=401), dosed orally twice daily (BID) for 52 weeks. On November 25, 2024, the Company reported that the RETHINK-ALZ study did not meet the co-primary endpoints for the study. The Company also indicated that it planned to fully analyze the results and share the data at a future medical meeting.

The co-primary endpoints for this study included the change in cognition and function from baseline to the end of the double-blind treatment period at week 52, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing simufilam to placebo. Secondary endpoints included several well validated measures of neuropsychiatric symptoms and caregiver burden. Safety was evaluated by adverse event monitoring, as well as standard laboratory and ECG assessments. The study also included a pharmacokinetic and plasma biomarker sub-study comprised of approximately 100 subjects, evaluated at three timepoints. RETHINK-ALZ was conducted under a Special Protocol Assessment ("SPA") with the U.S. Food and Drug Administration ("FDA").

REFOCUS-ALZ (NCT05026177) is a Phase 3 trial designed as a multi-center, double-blinded, placebo-controlled, randomized parallel group study to evaluate the safety and efficacy of two doses of simufilam compared to a placebo in a study involving over 75 clinical trial sites in the U.S., Canada, Puerto Rico and South Korea. The clinical trial sites that conducted REFOCUS-ALZ were completely distinct from the clinical trial sites that conducted RETHINK-ALZ. REFOCUS-ALZ randomized approximately 1,125 people utilizing the same eligibility criteria as RETHINK-ALZ. Subjects were randomized 1:1:1 to receive simufilam, dosed in 50 mg or 100 mg tablets, or a matched placebo, dosed orally twice daily (BID) for 76 weeks. The Company announced on November 25, 2024 plans to discontinue the REFOCUS-ALZ study and intends to report topline data from that trial, including the complete 52-week dataset and a large portion of 76-week data. The Company expects to report topline data for this study late first-quarter/early second-quarter 2025.

The co-primary endpoints for this study included the change in cognition and function from baseline to the end of the double-blind treatment period at week 76, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing each dose of simufilam to placebo. Secondary endpoints included

several well validated measures of neuropsychiatric symptoms and caregiver burden. Safety was evaluated by adverse event monitoring, as well as standard laboratory and ECG assessments. The study also included an evaluation of changes in plasma and cerebrospinal fluid biomarkers from baseline to week 76, including P-tau181, P-tau217 and neurofilament light chain, as well as an evaluation of various brain volumes using magnetic resonance imaging (MRI) and amyloid and tau deposition using positron emission tomography (PET) scans from baseline to week 76. REFOCUS-ALZ was also conducted under an SPA with the FDA.

About Simufilam

Simufilam is a proprietary, investigational oral small molecule that targets the filamin A protein.

About Cassava Sciences, Inc.
Cassava Sciences is a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system diseases including Alzheimer's disease dementia. The Company is based in Austin, Texas.

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

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Cautionary Note Regarding Forward-Looking Statements:
This news release contains forward-looking statements that include but are not limited to statements regarding: the planned discontinuation of the REFOCUS-ALZ and open-label extension studies and the status of their ongoing wind-down; our intent to share topline data from REFOCUS-ALZ; our intent to share detailed study results from RETHINK-ALZ and REFOCUS-ALZ at a future medical meeting; the timing of anticipated milestones; the reduction in force of employees at the Company; and the anticipated costs associated with the reduction in force. These statements may be identified by words such as "anticipate", "before," "believe", "could", "expect", "forecast", "intend", "may", "pending," "plan", "possible", "potential", "prepares for," "will", and other words and terms of similar meaning .

Such statements are based 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; the clinical results related to studies of simufilam in Alzheimer's disease, results of the RETHINK-ALZ study reported on November 25, 2024; our current expectations regarding timing of analysis of clinical data for our Phase 3 studies; the potential for unexpected costs associated with our announced reduction in force; and other risks inherent in drug discovery and development or specific to Cassava Sciences, Inc., as described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Report on Form 10-Q for the period ended September 30, 2024, 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. 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 of our pharmaceutical assets under development are 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 is approved or available for sale anywhere in the world.

Source: Cassava Sciences, Inc.