Cassava Sciences Reports Topline Phase 3 REFOCUS-ALZ Data

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- *Simufilam did not show a significant reduction in co-primary endpoints of cognitive or functional decline versus placebo in patients with mild-to-moderate Alzheimer's disease*
- *Simufilam continued to demonstrate an overall favorable safety profile*
- *Cassava's Alzheimer's disease development program with simufilam will be completely discontinued by the end of Q2 2025*

AUSTIN, Texas, March 25, 2025 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (NASDAQ: SAVA, "Cassava", the "Company"), a clinical-stage biotechnology company focused on developing a novel, investigational treatment for central nervous system disorders, including Alzheimer's disease (AD) dementia and tuberous sclerosis complex (TSC)-related epilepsy, today shared topline results from the Phase 3 REFOCUS-ALZ study of simufilam in mild-to-moderate AD.

Topline data indicate that REFOCUS-ALZ did not meet each of the prespecified co-primary, secondary and exploratory biomarker endpoints. The co-primary endpoints were 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 simufilam to placebo. REFOCUS-ALZ enrolled 1,125 patients and was discontinued on November 25, 2024, following the report that a prior 52-week Phase 3 study, RETHINK-ALZ, did not meet its co-primary endpoints. A large portion of subjects enrolled in REFOCUS-ALZ completed their final study visit prior to the termination of the trial. Simufilam continued to demonstrate an overall favorable safety profile.

"We are disappointed that the results of REFOCUS-ALZ and RETHINK-ALZ showed no treatment benefit for patients with mild-to-moderate Alzheimer's disease. These results were unambiguous. Working with patients, their families and their caregivers has brought a special dignity to our Phase 3 Alzheimer's disease clinical trial program and to each of us at Cassava. We are deeply grateful for the dedication and committed efforts of study investigators and site teams, who enabled us to conduct these trials with integrity and scientific rigor and whose efforts provided a clear data read out," said **Rick Barry, President and Chief Executive Officer** of Cassava.

"Cassava will discontinue all efforts to develop simufilam for Alzheimer's disease and we expect to phase out the program by the end of Q2 2025," continued **Mr. Barry**. "We remain dedicated to our mission of developing novel medicines for central nervous system disorders. While we have initiated preclinical studies to evaluate simufilam's potential as a treatment for TSC-related epilepsy, we maintain ongoing strategic expense management efforts."

Eric Schoen, Chief Financial Officer of Cassava commented, "We remain focused on the interests of Cassava shareholders and are committed to enhancing shareholder value. Cassava is well-capitalized with approximately $128.6 million in cash and cash equivalents as of December 31, 2024."

Summary Study Results:

Primary Endpoint Data

Co-Primary Endpoint Data*	Simufilam 100 mg BID	Simufilam 50 mg BID	Placebo BID	Delta	P-value
Co-Primary Endpoints LS means change from baseline to the end of the double-blind treatment period					
	N=372	**N=376**	**N=372**		
ADAS-COG12 (±SE)	4.97 (± 0.46)		4.70 (± 0.46)	0.27 (± 0.63)	P=0.67
		5.26 (± 0.46)	4.70 (± 0.46)	0.56 (± 0.63)	P=0.37
	N=373	**N=376**	**N=373**		
ADCS-ADL (±SE)	- 6.27 (± 0.57)		- 5.32 (± 0.57)	- 0.95 (± 0.79)	P=0.23
		- 6.43 (± 0.57)	- 5.32 (± 0.57)	- 1.10 (± 0.79)	P=0.16
*Based on the intent-to-treat population BID = twice daily ADAS-COG12 = The Alzheimer's Disease Assessment Scale – Cognitive Subscale (a lower number represents less cognitive impairment) ADCS-ADL = Alzheimer's Disease Cooperative Study – Activities of Daily Living (a higher number represents less functional impairment)					

Company Profile

Cassava Sciences, Inc.

Industry: Pharmaceuticals

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Metrics for Simufilam and Placebo	Simufilam 100 mg BID	Simufilam 50 mg BID	Placebo BID
Baseline*			
	N=374	**N=376**	**N=375**
Age, mean (SD), in years	73.6 ± 8.2	74.5 ± 7.6	73.7 ± 7.9
Sex, n (%) female	208 (55.6%)	207 (55.1%)	214 (57.1%)
MMSE Score (No.%,)			
21-27	240 (64.2%)	242 (64.4%)	235 (62.7%)
16-20	134 (35.8%)	134 (35.6%)	138 (36.8%)
Race/Ethnicity			
White	326 (87.2%)	326 (86.7%)	313 (83.5%)
Black	17 (4.5%)	23 (6.1%)	21 (5.6%)
Asian	28 (7.5%)	21 (5.6%)	32 (8.5%)
Other	3 (0.8%)	6 (1.6%)	9 (2.4%)
Safety**			
	N=374	**N=376**	**N=373**
Any Adverse Event (AE)	286 (76.5%)	288 (76.6%)	282 (75.6%)
Serious AEs	43 (11.5%)	61 (16.2%)	45 (12.1%)
Death	2 (0.5%)	6 (1.6%)	3 (0.8%)
AEs leading to discontinuation from the study	32 (8.6%)	34 (9.0%)	17 (4.6%)
Most Frequent AEs ≥ 5.0%			
1: COVID-19	45 (12.0%)	49 (13.0%)	40 (10.7%)
2: Urinary Tract Infection	32 (8.6%)	41 (10.9%)	34 (9.1%)
3: Fall	32 (8.6%)	43 (11.4%)	51 (13.7%)
4: Dizziness	26 (7.0%)	11 (2.9%)	23 (6.2%)
5: Diarrhea	14 (3.7%)	19 (5.1%)	15 (4.0%)

*Based on the intent-to-treat population
**Based on the safety population
BID = twice daily
AD = Alzheimer's disease
MMSE = Mini-Mental State Examination

About REFOCUS-ALZ

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. On November 25, 2024, the Company announced plans to discontinue the REFOCUS-ALZ study and its intention to report topline data from that trial, including the complete 52-week dataset and a large portion of 76-week data.

The prespecified 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-tau217 (phosphorylated tau at threonine 217), GFAP (glial fibrillary acidic protein) and NFL (neurofilament light chain), as well as an evaluation of various brain volumes using MRI (magnetic resonance imaging) and amyloid and tau deposition using PET (positron emission tomography) scans from baseline to week 76.

About Simufilam

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

About Cassava Sciences, Inc.

Cassava Sciences, Inc. (NASDAQ: SAVA), a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system disorders, including Alzheimer's disease and tuberous sclerosis complex (TSC)-related epilepsy. Simufilam is a proprietary, investigational oral small molecule that targets the filamin A protein. 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: REFOCUS-ALZ and RETHINK-ALZ, the timing for discontinuation of our Alzheimer's disease development program, our plans for the development of investigational treatments for central nervous system disorders, our plans to conduct preclinical studies of simufilam relating to seizures in TSC, the potential for simufilam as a treatment for TSC-related epilepsy, our strategic expense management efforts and the timing of anticipated milestones. 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 efficiently discontinue the Company's Alzheimer's disease development program, the ability to advance preclinical studies related to TSC-related epilepsy, 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, 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. They 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.

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, development and commercialization. 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 Annual Report on Form 10-K and Quarterly Reports on Form 10-Q in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery, development and commercialization, 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.

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