Cassava Sciences Announces Positive Interim Safety Review of Simufilam On-going Phase 3 Trials in Patients with Alzheimer's Disease

Sep 18, 2023

- **An Independent Data and Safety Monitoring Board (DSMB) Recently Evaluated the Interim Patient Safety Database for Simufilam in On-Going Phase 3 Clinical Trials.**

- **The DSMB Recommended the Phase 3 Trials of Simufilam Continue as Planned, Without Modification**

AUSTIN, Texas, Sept. 18, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced a positive 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' Phase 3 studies of simufilam continue as planned, without modification.

"I think this first interim safety review is an important milestone for the clinical development of simufilam," said Remi Barbier. "I find it very encouraging. We look forward to announcing the completion of patient enrollment for both Phase 3 studies 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. The next routine meeting of the DSMB is scheduled for March 2024.

On-going Phase 3 Studies with Simufilam
Cassava Sciences is evaluating simufilam oral tablets for Alzheimer's disease dementia in two global Phase 3 clinical studies. These are randomized, double-blind, placebo-controlled trials. The Phase 3 program aims to enroll a total of approximately 1,750 patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria. Patient enrollment is expected to be completed for both Phase 3 studies by yearend 2023. Both Phase 3 studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration.

About Simufilam
Simufilam is Cassava Sciences' proprietary, small molecule (oral) drug candidate that restores the normal shape and function of altered filamin A (FLNA) protein in the brain.

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.

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

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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 role, findings and recommendations of the DSMB; the design, scope, conduct or intended purpose of our Phase 3 program of simufilam in patients with Alzheimer's disease; any findings by the DSMB for the interim safety of simufilam in our on-going Phase 3 clinical trials; our current expectations regarding timing of and the target patient enrollment numbers for our Phase 3 studies; any expected clinical results of Phase 3 studies; the treatment of patients with Alzheimer's disease dementia; comments made by our employees regarding simufilam, drug effect, and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would", "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.

Simufilam is our investigational product candidate. It is not approved by any regulatory authority in any jurisdiction and its safety, efficacy or other desirable attributes 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.