



FDA Denies Citizen Petitions Filed on Behalf of Short Selling Clients

February 10, 2022

AUSTIN, Texas, Feb. 10, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, announced today that the U.S. Food and Drug Administration ("FDA") denied a Citizen Petition that was filed in August 2021 by an attorney on behalf of short-selling clients. FDA also denied four supplements to the August 2021 Citizen Petition. FDA also denied a September 2021 Citizen Petition, and a supplement, that were also filed by the same attorney on behalf of short-selling clients.

"The news is very welcome but not surprising," said Remi Barbier, President & CEO. "We said from the outset that the allegations are false. I think the message may be that the FDA's citizen petition privilege is not to be trifled with by stock market participants."

A full copy of FDA's response letter can be found at the following link: <https://www.regulations.gov/document/FDA-2021-P-0967-0017>

In Fall 2021, Cassava Sciences advanced its lead drug candidate, simufilam, into a Phase 3 pivotal program in patients with mild-to-moderate Alzheimer's disease. This Phase 3 program is being conducted under Special Protocol Assessments (SPA) from FDA. An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, etc.).

The first clinical study protocol is titled "A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 52-Week Study Evaluating the Safety and Efficacy of Simufilam 100mg Tablets in Subjects with Mild-to-Moderate Alzheimer's Disease."

The second clinical study is titled "A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 76-Week Study Evaluating the Safety and Efficacy of Two Doses of Simufilam in Subjects with Mild-to-Moderate Alzheimer's Disease."

Both Phase 3 clinical studies continue to enroll patients.

About Cassava Sciences, Inc.

Cassava Sciences' mission is to discover and develop innovations for chronic, neurodegenerative conditions. Over the past 10 years, Cassava Sciences has combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. For more information, please visit: <https://www.CassavaSciences.com>.

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Cautionary Note Regarding Forward-Looking Statements: This press release includes forward looking statements including but not limited to those regarding the status of our on-going Phase 3 clinical studies in Alzheimer's disease, and oral or written comments made by our employees regarding simufilam or allegations made against us.

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 related to the status and patient enrollment into our Phase 3 studies of simufilam in Alzheimer's disease; and other risks described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, as supplemented by the section entitled "Risk Factors" in our Quarterly Report on SEC Form 10-Q for the quarter ended September 30, 2021, 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. Drug development involves a high degree of risk, and historically only a small number of research and development programs result in commercialization of a product.

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.