



Cassava Sciences Announces Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer's Disease

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Phase 3 Study Initiation Still Expected Fall 2021

AUSTIN, Texas, Aug. 24, 2021 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for both of its pivotal Phase 3 studies of oral simufilam for the treatment of patients with Alzheimer's disease.

These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences' Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer's disease.

"I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences," said Remi Barbier, President & CEO. "The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer's disease."

Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer's disease in Fall 2021.

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

The second clinical study protocol under the SPA 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*".

For details regarding the Phase 3 program please visit Cassava Sciences' Corporate Presentation: <https://www.cassavasciences.com/static-files/a518d6f8-be82-4a23-b676-e8b5a75cf9e6>

About Special Protocol Assessments

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.). These elements are critical to ensure that Cassava Sciences' planned Phase 3 studies of simufilam in Alzheimer's disease can be considered adequate and well-controlled studies in support of a future regulatory submission and marketing application. For more information on Special Protocol Assessments, please visit: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-protocol-assessment-guidance-industry>

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 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 treatment or diagnosis of Alzheimer's disease; our intention to initiate a Phase 3 clinical program with simufilam and the timing, enrollment, duration and other details thereof; verbal commentaries made by our employees; 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.*

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. Clinical results from our earlier-stage clinical trials may not be indicative of full results or 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. 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, the severity and duration of health care precautions given the COVID-19 pandemic, any unanticipated impacts of the pandemic 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, 2020 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.