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Cassava Sciences Announces Additional Clinical Data from a Phase 2b Study of Sumifilam in Alzheimer's Disease

04 nov. 2020 08h15 HE | Source: [Cassava Sciences, Inc.](#)[Form de contact](#)**Cassava Sciences, Inc.****Industrie:** Pharmaceuticals**Site Internet:**<https://paintrials.com>[Communiqués de presse -
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**Alzheimer's Patients Treated with Sumifilam Showed a Statistically
Significant ($p < 0.001$) Treatment Benefit on HMGB1,
a Protein that Triggers Neuroinflammation and Loss of Neurons**



**Alzheimer's Patients Treated with Sumifilam Also Showed
a Treatment Benefit ($p < 0.05$) on Blood-brain Barrier Integrity**



**Clinical Dataset to be Presented November 7th at CTAD 2020
Conference**



AUSTIN, Texas, Nov. 04, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA) today announced additional clinical data of a Phase 2b study with sumifilam, its lead drug candidate, in patients with Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), sumifilam decreased levels of a protein called HMGB1 and improved measurements of the integrity of the blood-brain barrier (BBB). The ability of a drug candidate to decrease HMGB1 and improve BBB integrity in patients with Alzheimer's disease has not been previously reported in the science literature. Sumifilam is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A protein in the brain.

"The ability to improve multiple biomarkers of disease with one drug is a unique achievement," said Remi Barbier, President & CEO of Cassava Sciences. "We believe these exciting clinical results create

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Additional clinical data include changes in levels of HMGB1 protein and measurements of the integrity of the blood-brain barrier from baseline to Day 28 (all p-values versus placebo):

Sumifilam Significantly Reduced Levels of HMGB1 in Cerebrospinal Fluid (CSF):

- HMGB1 decreased 33% (p<0.001) in patients treated with 50 mg sumifilam
- HMGB1 decreased 32% (p<0.001) in patients treated with 100 mg sumifilam

Sumifilam Significantly Improved the Integrity of the Blood-brain Barrier (BBB):

- CSF IgG decreased 30% (p<0.05) in patients treated with 50 mg sumifilam
- CSF IgG decreased 30% (p<0.05) in patients treated with 100 mg sumifilam
- CSF albumin decreased 15% (p<0.05) in patients treated with 50 mg sumifilam
- CSF albumin decreased 28% (p<0.05) in patients treated with 100 mg sumifilam

Sumifilam Improved the Albumin Ratio, a Test of Blood-brain Barrier (BBB) Permeability:

- BBB permeability can be clinically evaluated by comparing levels of albumin in CSF and plasma. The albumin ratio is a test for BBB permeability because albumin protein is not synthesized in CSF. Hence, albumin in CSF necessarily comes from plasma through the BBB. The albumin ratio is frequently elevated in patients with dementia and various other disorders.
- In the Phase 2b study, the albumin ratio was unchanged for Alzheimer's patients on placebo. The albumin ratio improved by approximately 5 and 7 points for patients treated with sumifilam, 50 mg and 100 mg, respectively, over 28 days.

Changes in the Albumin Ratio by Treatment Group

Treatment	Day 0	Day 28	Change-Day 0 to 28
Placebo	24	24	No change
50 mg sumifilam	25	20	- 5
100 mg sumifilam	25	18	- 7

About HMGB1

HMGB1 is an endogenous and potent pro-inflammatory protein that is sometimes called a 'danger molecule.' HMGB1 is elevated in patients with Alzheimer's disease and other neurodegenerative

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PubMed® reports nearly 6,000 scientific publications of HMGB1 research in the past decade, highlighting the molecule's potential importance in clinical research.

About the Blood-brain Barrier (BBB)

The BBB is a complex border of cells along blood vessels that prevent unwanted substances in blood from entering the brain. BBB integrity is essential to brain health. A healthy BBB system selectively allows the passage of some molecules into the brain, such as water and glucose, while blocking passage to molecules that may damage the brain. Levels of IgG antibodies and albumin protein in the cerebrospinal fluid (CSF) are an index of BBB integrity, with elevated levels evidence of a 'leaky', impaired BBB. Albumin protein is found at high levels in plasma and low levels in CSF because it does not normally cross the BBB.

Late-breaking Presentation at CTAD 2020

Clinical results of a Phase 2b study of sumifilam were selected as a late-breaking oral presentation by the 13th international conference on Clinical Trials on Alzheimer's Disease (CTAD). CTAD is a prestigious annual conference focused on Alzheimer's clinical research and takes place this year as a virtual event on November 4-7th, 2020.

On Saturday, November 7th, Company scientists will present an oral presentation titled, *"Sumifilam Significantly Improves Eleven CSF Biomarkers in a Randomized, Placebo-Controlled, One-Month Clinical Trial in Alzheimer's Disease Patients."*

The Company's CTAD presentation is available on its website:

<https://www.CassavaSciences.com>

Phase 2b Study Design

Phase 2b was a double-blind, randomized, placebo-controlled, multi-center clinical study of sumifilam (formerly, PTI-125). Sixty-four patients with mild-to-moderate Alzheimer's disease, age 50-85, were randomized (1:1:1) to 100 mg or 50 mg oral sumifilam or matching placebo. Treatment was administered twice daily for 28 days. Nine U.S. study sites enrolled patients. A clinical diagnosis of Alzheimer's disease was confirmed with the Mini-Mental State Examination (MMSE) ≥ 16 to ≤ 26 and a CSF T-tau/A β_{42} ratio ≥ 0.28 . Safety was assessed by ECGs, clinical labs, adverse event monitoring and physical examinations.

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improvements in eight biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with sumifilam showed improvements in validated tests of Episodic Memory and Spatial Working Memory, versus patients who took placebo (Effect Sizes 17-46%). Cognitive improvements correlated most strongly ($R^2=0.5$) with decreases in P-tau181, a biomarker that leads to tangles in the brain. Sumifilam decreased brain levels of Ptau-181 by 8-11%, versus placebo. The study achieved a 98% response rate, defined as the proportion of study participants taking sumifilam who showed improvements in biomarkers.

On-going Open-label Study

In March 2020, we announced the initiation of an open-label study to evaluate sumifilam in patients with Alzheimer's disease. This is an open-label, multi-center, extension study to monitor the long-term safety and tolerability of sumifilam 100 mg twice-daily for 12 months. The study's target enrollment is approximately 100 patients with mild-to-moderate Alzheimer's disease. This study has exceeded 60% enrollment. The open-label study employs *The Alzheimer's Disease Assessment Scale-Cognitive Subscale* (ADAS-Cog-11) to assess cognitive symptoms of dementia and *The Neuropsychiatric Index* (NPI) to assess behavioral symptoms. Cassava Sciences plans to announce results of an interim analysis as additional safety and cognition data is collected from patients enrolled in the open-label study.

About Alzheimer's Disease

Alzheimer's disease is a progressive brain disorder that destroys memory and thinking skills. Currently, there are no drug therapies to halt Alzheimer's disease, much less reverse its course. In the U.S. alone, approximately 5.8 million people are currently living with Alzheimer's disease, and approximately 487,000 people age 65 or older developed Alzheimer's in 2019.¹ The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, resulting in a growing social and economic burden.²

About Sumifilam

Sumifilam is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA), a scaffolding protein, in the brain. Altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. The underlying science for sumifilam is published in peer-reviewed journals, including

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Sumifilam and SavaDx were both developed in-house. Both product candidates are substantially funded by peer-review research grant awards from the National Institutes of Health (NIH). 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. Patent protection in this area runs through 2037, plus extensions, and includes seven issued patents and related patent filings and applications.

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>

For More Information Contact:

Eric Schoen, Chief Financial Officer

Cassava Sciences, Inc.

eschoen@CassavaSciences.com

(512) 501-2450

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Cautionary Note Regarding Forward-Looking Statements: This press release contains "forward-looking statements" for purposes of the Private Securities Litigation Reform Act of 1995 (the Act). Cassava Sciences claims the protection of the Safe Harbor for forward-looking statements contained in the Act. All statements other than statements of historical fact contained in this press release including, but not limited to, statements regarding the status of current and future clinical studies with sumifilam, including our intention to conduct a Phase 3 clinical program; the interpretation of results of our Phase 2 clinical studies including cognition data; plans to announce results of an interim analysis of an ongoing open-label study; potential health benefits, if any, of changes in levels of biomarkers; verbal commentaries made by Cassava Sciences' employees; and potential benefits, if any, of the

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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 Cassava Sciences' Annual Report on Form 10-K for the year ended December 31, 2019 and future reports to be filed with the SEC. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this press 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, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press 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.

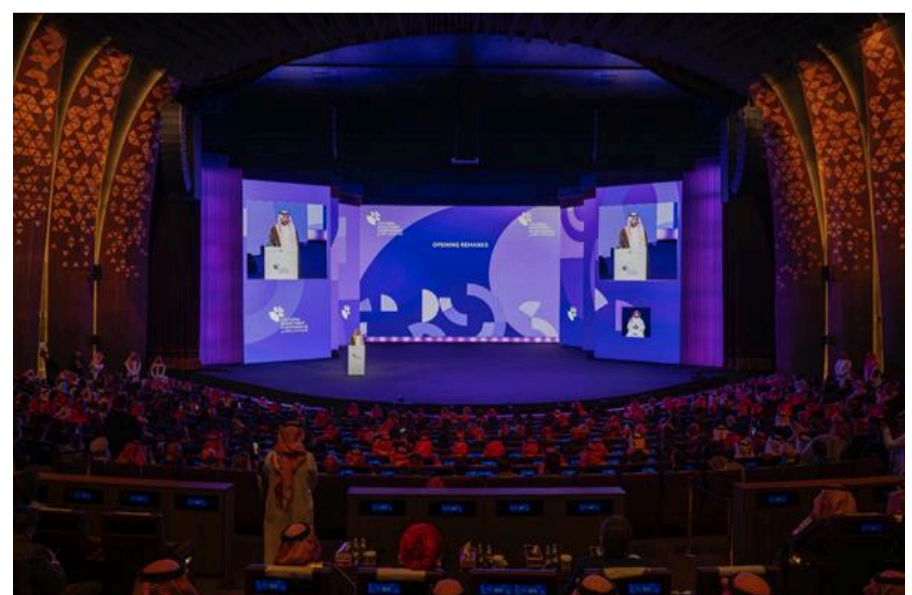
^{1,2} Source: Alzheimer's Association. 2019 Alzheimer's Disease Facts and Figures. Available online at: <https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf>

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