

Recent Support for a New Drug Application Filing for Alzheimer's Disease

Source: Cassava Sciences, Inc.

Cassava Sciences, Inc. "CSI", a biotechnology company developing drugs for Alzheimer's disease, announced a successful meeting with the U.S. Food and Drug Administration (FDA) for simufilam, its new drug candidate treating Alzheimer's disease in

March. During the meeting the FDA and CSI agreed on key elements of a study on a New Drug Application filing for simufilam in Alzheimer's disease. Those agreements provide a clear path for simufilam to move into Phase 3 studies in the second half of 2021.

"For over 10 years we've been doing basic research and early drug development with simufilam," said Remi Barbier, President & CEO. "We are excited to finally advance simufilam into Phase 3 clinical studies in people with Alzheimer's disease. We believe
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Enhancing Well-Being with the Creative Arts

By Janice Downing

"Every child is an artist. The problem is how to remain an artist once [we grow] up." An insightful quote from artist Pablo Picasso, and a great reminder that each of us has the potential for artistic expression. Creativity is good for us at any age and especially as we get older. Studies have shown that older adults who participate in creative activities have a better quality of life and maintain independence more easily.

Renowned geriatric psychiatrist Gene Cohen

conducted "The Creativity and Aging Study". Participants in the controlled study consisted of 300 adults aged sixty-five years or older. The study was conducted over a three-year period and included 2 groups of participants- those who participated in artistic activities weekly and those who did not. The study revealed the group that participated in weekly art activities reported better physical health, fewer doctor visits, less medication use, fewer instances of falls, and fewer problems than
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Art Links program participant painting watercolor daffodils and Spring flowers

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the underlying science is solid, the drug appears safe and the clinical roadmap makes sense.”

“We appreciate the valuable guidance and flexibility FDA has provided,” added Jim Kupiec, MD, CSI’s Chief Clinical Development Officer. “We look forward to continuing a collaborative dialogue throughout the Phase 3 clinical development program.”

Simufilam is a drug discovered at CSI that targets both inflammation

of nervous tissue, especially of neurons in the brain, and degeneration of neurons in the brain. The meeting discussion was supported by years of scientific and clinical data, including positive results from Phase 2 of the program with simufilam in Alzheimer’s disease. Those results showed that simufilam improved cognition in subjects with Alzheimer’s disease in a study, with no safety issues.

CSI’s Phase 3 clinical program involves two studies. This program

is designed to evaluate disease-modifying effects of simufilam in Alzheimer’s disease. The goal is to show a slower rate of decline in cognition and health function in subjects treated with simufilam compared to placebo.

The FDA provided further flexibility to Cassava Sciences by agreeing to review the final version of each protocol for the two Phase 3 studies and to conduct a Special Protocol Assessment (SPA) for each Phase 3 study. An SPA is a

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Dear Friends,

Spring is such a welcome season. As the days grow longer and the snow recedes, it's easier to get outdoors and enjoy our beautiful land while we feel the sun's warmth return. It's a great time to "Amble for Alzheimer's", and I hope many of you will join us doing just that now through the end of May. Amblin' remains our biggest annual fundraiser, and we appreciate any support you can offer.



We're mindful of the fact that most of the state remains at high risk alert for community spread of COVID. It's for that reason that our Amblin' will be virtual again this year. Go to www.alzalaska.org/amblin for more information. And to keep enthusiasm high, follow our Amblin' Facebook group (www.fb.com/groups/amblin21) to see all of the ways our friends and neighbors are showing their support as they celebrate spring's return. If you don't use Facebook, you can submit your photos here: <https://www.alzalaska.org/submit-an-amblin-photo>.

As I write this, case rates are on the increase. But vaccination rates are also rising and that bodes well for the return to more normal operations. If you come to our Anchorage office, you will be greeted with new, beautiful, original art on display. Rather than surround an open work area with clear barriers for everyone's safety, we've surrounded it with landscapes crafted by our friend, Rhonda Scott, and supported by the gift of an anonymous donor. These colors have been bringing us cheer every day since.

I think you'll enjoy the front page story written by Janice Downing, ARA Education Specialist and first published in the *Senior Voice*. Janice writes about enhancing well-being with the creative arts. Whether drawing, painting, singing, dancing or making music, engaging with creative arts is a well established pathway to better health and well-being. The subject is one our Education Team knows well, and applies every day in serving Alaskans.

Very Best Wishes,

Pamela Kelley
Executive Director

Enhancing Well-Being with the Creative Arts

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the comparison group. Most importantly, participants in this group experienced less loneliness, higher morale, and enhanced daily well-being.

How do you interest someone living with dementia

in creative activities? For care partners for someone living with dementia, it is understandable that sometimes the focus is on what has been lost. A focus on what remains and exploring

those strengths can enhance the person's mood and well-being. When we provide access to the creative arts, we often discover hidden talents and abilities.

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formal regulatory procedure that confirms the details of the studies meet FDA's standards of approvability.

Open-label Study

Cassava Sciences recently expanded the size of an ongoing open-label study of simufilam. The study's target enrollment was increased to 150 additional subjects with mild-to-moderate Alzheimer's disease. To accommodate increased enrollment, the Company is opening new clinical sites in the U.S. and Canada.

The Company plans to analyze the study mid-year 2021. Much like the first pre-planned interim analysis (6 months), the second pre-planned interim analysis (12 months) is expected to generate clinical data around long-term safety, cognition

and dementia-related behavior.

Cognition Maintenance Study (CMS)

In the second quarter of 2021, Cassava Sciences plans to initiate a study in subjects with Alzheimer's disease who have completed at least one year of open-label treatment with simufilam. In this Cognition Maintenance Study (CMS), subjects who complete one year of open-label treatment will be randomized (1:1) to simufilam or placebo for 6 months. The CMS is designed to compare simufilam's effects on cognition and dementia-related in subjects



Two researchers check test tubes – Stock photo

who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, subjects who successfully complete the 6-month CMS will be given the option to return to open-label simufilam again. ★

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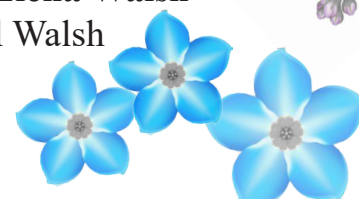
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Enhancing Well-Being with the Creative Arts

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The key to discovering what sparks creativity for your loved one is to explore ideas and approaches. Take a moment to reflect on what your partner enjoyed in the past and what they enjoy now. Then choose a small creative project that will help them be successful, modify or downsize as needed. Following are some creative ways to explore these different artistic mediums with your loved one.

Storytelling: Creating stories from old photographs and pictures is a wonderful individual or group activity. These stories can be shared verbally or in writing. You may be tickled by some of the stories you hear. Just

one picture can bring back a multitude of emotions and encourage creativity for a person living with dementia.

Drawing and Painting: Expressing thoughts and emotions through art can open up a whole new world for people living with dementia. As words fail, a person can continue to communicate through drawings and paintings.

Sculpting: Using clay to sculpt objects stimulates the senses and can often connect to memories. It's also a very calming and relaxing activity.

Music: Music has the power to re-engage people touched by dementia. It can help us retrieve memories and helps create moments of

peace and happiness. It is one of the best creative outlets, especially when it is music that speaks to our hearts.

Dancing: Music and dance complement each other. Put on some well-loved music and watch the reactions of your partner. It's hard not to move to music we love.

Creativity and the arts can open up new ways of connecting with people living with dementia. It can improve our emotional well-being and help combat loneliness. It has the power to stimulate our brains and improve the quality of life for children, adults and seniors alike. As Albert Einstein says, "Creativity is contagious, pass it on!" ★

Walk, Ride, Run - then show us how you Amble

Register at:

alzalaska.org/amblin

- Raise funds to serve Alaska's elders and Alaskans living with a Alzheimer's or related dementias and other disabilities.
- Prizes will be given for sharing photos and/or videos on our Amblin' [facebook group](#) or on alzalaska.org/amble.



Now – May 31st

Classes & Events around the State



Classes and events are being offered statewide via Zoom. All classes listed below require registration.

CAREGIVING 101

For more information or registration assistance
contact: [907-561-3313](tel:907-561-3313)

The GEMS®: Using Skills that Make a Difference

Tuesday, 4/6, 1pm-2:30pm
REGISTER HERE

Meaningful Activities

Friday, 4/16, 1-2:30pm
REGISTER HERE

Driving and Dementia

Tuesday, 4/20, 5:30 -7p
REGISTER HERE

Understanding Supported Decision Making Agreements for Seniors

Monday, 4/26, 1-2:30pm
REGISTER HERE

When Does Forgetting Become a Worry?

Friday, 5/14, 1-2:30pm
REGISTER HERE

Wandering and Dementia

Tuesday, 5/18, 5:30 -7pm
REGISTER HERE

Coping with Social Isolation and Loneliness

Monday, 5/24, 1-2:30pm
REGISTER HERE

Being the Decision Maker

Friday, 6/4, 1-2:30pm
REGISTER HERE

The Related Dementias in ADRD

Saturday, 6/12, 1-2:30pm
REGISTER HERE

What, When and How of Assisted Living

Tuesday, 6/15, 5:30-7pm
REGISTER HERE



Alzheimer
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for the latest information



Memory Café

To register contact
Ann Farris at

[561-3313](tel:907-561-3313) or email:
afarris@alzalaska.org

Thursday, 4/8, 1pm
Thursday, 5/12, 1pm
Thursday, 6/10, 1pm



Art Links 1-1:45pm

To register contact:

Janice Downing at
[746-3413](tel:907-746-3413) or email:
jdowning@alzalaska.org

Thursday, 4/1 & 4/15
Thursday, 5/6 & 5/20
Thursday, 6/3 & 6/17



Brain Games

To register contact:

Debbie Chulick at
[907-561-3313](tel:907-561-3313) or email:
dchulick@alzalaska.org

Thursday, 4/22, 1-2pm
Thursday, 5/27, 1-2pm
Thursday, 6/24, 1-2pm



Professional Webinars

Questions or registration assistance, contact:

Amber Smith: [586-6044](tel:586-6044) or asmith@alzalaska.org

Navigating Resources: Finding the Right Fit

Tuesday, 4/20, 12 pm - 1:00pm
REGISTER HERE

Using Plain Language: Tools for making health information clear and effective

Tuesday, 5/18, 12 pm - 1:00pm
REGISTER HERE

What Is It Like to Have Dementia?

Tuesday 6/15, 12 pm - 1:00pm
REGISTER HERE

Mind Matters | Brain Works

Support for those who have been recently diagnosed with Alzheimer's or related dementia, or those living with moderate memory loss, and their care partners.

*Screening &
Pre-registration required*

For more info contact:
Amy Becia at
[907-561-3313](tel:907-561-3313) or email:
abecia@alzalaska.org



Grants Available — Apply Today

The Alaska Mental Health Trust Authority provides grants up to \$2,500 per fiscal year; available for individuals with Alzheimer's disease or related dementia (ADRD) to purchase items or services that are not covered by other funding sources to help improve quality of life and increase independent functioning. www.alzalaska.org/mini-grant

For more information contact:
Kevin Silver at [907-561-3313](tel:907-561-3313)
or email ksilver@alzalaska.org

Savvy Caregiver

*Screening &
Pre-registration required*

To register contact:
Gay Wellman at
[907-822-5620](tel:907-822-5620) or email:
gwellman@alzalaska.org

Saturdays, 4/10-5/15
1:00pm-3:00pm

Statewide Support Groups [Click here](#)



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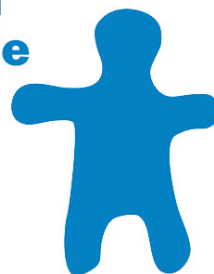
Now – May 2021

**Walk, Ride, Run – then
Show us how you Amble**

Amblin' for Alzheimer's is a friendly,
non-competitive fundraising
walk/virtual event for all ages.

Details and registration:

www.alzalaska.org/amblin



Amblin'
for Alzheimer's



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