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# ALZHEIMER'S ASSOCIATION ISSUES \$7 MILLION CHALLENGE TO SCIENTISTS TO SPEED DRUG DISCOVERY

# INNOVATIVE CLINICAL TRIAL COMPETITION TARGETS BRAIN INFLAMMATION AND IMMUNE SYSTEM

- Four Projects Receive \$1 Million Each; Compete for \$3 Million More -

**CHICAGO**, **August 2**, **2016** – The Alzheimer's Association, in partnership with a fundraising initiative led by philanthropist Michaela "Mikey" Hoag, announces a new \$7 million investment in clinical trials that target brain inflammation as an innovative avenue for Alzheimer's disease therapy.

Four cutting-edge studies will each receive \$1 million to advance current research to the next stage of clinical trials. A unique, goal-driven competition offers an additional \$3 million to the clinical trial that demonstrates the most promise for treating this devastating disease.

The Part the Cloud Challenge on Neuroinflammation is the vision of Mikey Hoag, of Atherton, California, who has a personal connection to Alzheimer's. The innovative funding program targets a critical gap in understanding and treating Alzheimer's, and absorbs some of the financial risk associated with advancing these studies across a space in drug development where many promising ideas stall due to lack of funding.

"When my father passed away with Alzheimer's, I decided to use my personal story to rally others in support of Alzheimer's research. When my mother started to show signs of the disease, I knew I had to kick these efforts into high gear," said Hoag. "We hope the competition we're creating for additional funding will speed the rate of discovery and deliver a new and effective treatment or prevention strategy to doctors' offices and people's medicine cabinets more quickly."

Hoag's efforts in partnership with the Alzheimer's Association, including the Part the Cloud Challenge on Neuroinflammation, have raised more than \$17 million for Alzheimer's research with the help of more than 300 donors — many of them leaders in the technology industry in California's Silicon Valley. Funding from Part the Cloud is focused on moving promising laboratory research into early-stage human clinical trials. It supports both academic and company-based research; 100 percent of the proceeds from Part the Cloud go directly to Alzheimer's Association-supported research.

"Innovative paths to discovery are critical to advancing Alzheimer's disease research," said Maria Carrillo, Ph.D., Alzheimer's Association chief science officer. "We welcome the collaboration with Mikey and other donors to provide a blueprint for targeting new avenues for Alzheimer's treatment, and overcoming funding challenges to maximize our chances for success."

## Neuroinflammation as a Pathway to Discovery

"Increasing evidence suggests neuroinflammation plays an important role in the brain changes that occur in Alzheimer's and other neurodegenerative diseases," said Carrillo. "By further understanding the role and the timing of neuroinflammation and immune responses, we will be able to further accelerate novel candidate Alzheimer's therapies."

Inflammation is a natural immune system response where defense cells are directed to fight infection or repair damaged tissue. However, persistent or misdirected inflammation can damage otherwise healthy tissue, such as the destruction of joint cartilage that occurs in arthritis or nerve damage in multiple sclerosis. Similarly, inflammation in the brain may help protect it from harm, such as the formation of the hallmark amyloid plaques of Alzheimer's, but too much inflammation may damage the brain's delicate nerve cells and intricate connections.

# **Challenge Funding for Four New Clinical Trials**

The four selected projects will receive \$1 million over two years for either a Phase I or Phase II trial. Projects will be evaluated for their ability to advance in human testing, such as being safe for use in people and the ability to influence the underlying biological process they are designed to target. The project that demonstrates the most viable translation to advanced clinical trials will be eligible to receive an additional prize of up to \$3 million to further the proposed therapy's development. Three of the four studies are testing potential therapies developed for other conditions that are being repurposed for Alzheimer's.

"A genuinely new Alzheimer's drug has not been approved since 2003, and the currently approved Alzheimer's medications are ineffective in stopping or slowing the course of the disease," said Carrillo. "The more than five million Americans living with Alzheimer's, and the many millions more worldwide, demand new and innovative approaches. We are obligated to pursue all legitimate avenues for treatment, such as targeting neuroinflammation."

#### The funded projects are:

- A Phase II clinical trial of the FDA-approved drug Leukine, to determine whether it is safe and can
  help slow or prevent the progression of Alzheimer's, led by Huntington Potter, Ph.D., Professor and
  Director of Alzheimer's disease research, Department of Neurology, Linda Crnic Institute for Down
  Syndrome, University of Colorado Anschutz Medical Campus. Leukine is approved for reducing and
  preventing infection in people who have received chemotherapy.
- A Phase II clinical trial to determine if the drug Sativex, a cannabis-based liquid medication that was
  previously tested for the alleviation of cancer-related pain, reduces brain inflammation and helps slow
  the progression to Alzheimer's disease in people with mild cognitive impairment, led by Isidro Ferrer,
  M.D., Ph.D., Coordinator of the group Neuropathology at CIBERNED (Network Center for
  Biomedical Research in Neurodegenerative Diseases), Institute of Health Carlos III, Barcelona,
  Spain.
- A study to test if treatment with the drug Senicapoc can reduce brain inflammation, alter the rate of brain amyloid accumulation, and improve memory in people with early Alzheimer's disease or mild cognitive impairment. In previous research, a drug similar to Senicapoc helped to reduce brain inflammation, prevent nerve cell damage, and improve memory in mice with an Alzheimer's-like condition. The project includes a Phase II clinical trial led by John Olichney, M.D., Professor and Neurologist at the University of California, Davis. Senicapoc has been shown to be safe in clinical trials of sickle cell anemia and asthma, but has yet to be tested in people with Alzheimer's.

• A Phase I clinical trial to examine the safety and efficacy to reduce brain inflammation of a novel therapy manufactured by Longeveron LLC using stem cells derived from healthy adult donors and that are delivered into the bloodstream of people with mild Alzheimer's disease. Anthony Oliva, Ph.D., senior scientist at Longeveron, will serve as principal investigator, and Bernard Baumel, M.D., will serve as the clinical investigator of the trial at the University of Miami Miller School of Medicine. Longeveron is a life sciences company located in Miami, Florida. In past research, this type of stem cell has demonstrated the ability to target and reduce inflammation, promote tissue repair, and improve brain function in mouse models of Alzheimer's disease.

### **About the Alzheimer's Association®**

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer's. For more information, visit the Alzheimer's Association at alz.org or call the 24/7 helpline at 800-272-3900.

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