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**ALZHEIMER'S ASSOCIATION AWARDS \$4.3 MILLION TO
ACCELERATE THE LAUNCH OF NEW DRUG TREATMENT ARMS IN
LANDMARK PREVENTION TRIAL**

*Funding Supports Testing New, Innovative Methods of Early Detection in
Individuals Destined to Develop Alzheimer's*

CHICAGO, April 23, 2016 – The Alzheimer's Association announces a new \$4.3 million research grant for a new phase of the Dominantly Inherited Alzheimer's Network Trials Unit (DIAN-TU) known as DIAN-TU Next Generation (NexGen). This award will accelerate the testing of new potential Alzheimer's therapies and a new diagnostic approach in people with genetically based, younger-onset Alzheimer's disease using an innovative trial design that is being applied to Alzheimer's for the first time. DIAN-TU is a landmark, global Alzheimer's prevention study led by researchers at Washington University in St. Louis.

DIAN-TU NexGen will add the infrastructure for new testing methods and additional drug arms designed to test experimental treatments targeting the accumulation of amyloid brain plaques, a hallmark of Alzheimer's. Amyloid plaques are deposits of the protein fragment amyloid-beta that build up in the spaces between nerve cells and are a hallmark brain change in Alzheimer's.

“This funding will quicken efforts to launch and expand the DIAN-TU NexGen trial, creating the foundation for a new generation of clinical trials. DIAN-TU NexGen will accelerate both the testing of potential therapies and allow for the consideration and execution of combination therapy, which has the potential to make a real impact on those with the disease,” said Maria Carrillo, Ph.D., Alzheimer's Association Chief Science Officer. “Having a treatment that can delay the onset of Alzheimer's is projected to reduce the number of individuals affected by the disease by 2.5 million within the first five years it is available.”

Making this Award Possible

The Alzheimer's Association funding for DIAN-TU NexGen is made possible by donations to the Alzheimer's Association from St. Louis-based financial services firm Edward Jones and Alzheimer's Association Zenith Society members John and Crystal Beuerlein, of St. Louis, and Mary Barton Smith, of Portola Valley, California. John Beuerlein is General Partner at Edward Jones. The Zenith Society is a group of individuals and organizations that have each committed \$1 million or more to the Alzheimer's Association to support research.

"The single greatest threat to financial security late into life is contracting a long-lasting disease that destroys a person's savings and leaves them dependent upon their children or Medicaid. The most expensive of those chronic diseases, in both financial and emotional costs, is Alzheimer's," said Jim Weddle, Managing Partner of Edward Jones. "That is why Edward Jones is partnering with the Alzheimer's Association to drive financial support for increasing the pace of research and is pleased that this funding will go to this highly esteemed team of scientists at Washington University."

New Testing Methods

The funding supports the inclusion of new approaches to diagnosing Alzheimer's that would enable earlier and more accurate detection of the disease if proven to be effective:

- **Tau PET Imaging** – This brain imaging technique uses positron emission tomography (PET) to visualize another hallmark of Alzheimer's, tau tangles. Past research suggests that tau PET imaging may help determine where the process of damage and death of brain cells begins and how it progresses to cause the symptoms of Alzheimer's. Including this technique in the DIAN-TU NexGen trial will enable researchers to evaluate its ability to serve as a marker for the presence and progression of the disease, and for evaluating effectiveness of potential treatments.
- **Home-based and Increased Frequency of Cognitive Testing** – This component will assess whether more frequent cognitive testing and the use of self-administered at-home cognitive assessments can better detect subtle cognitive changes over the currently used methods. If proven, this approach may eventually be used in the early detection of Alzheimer's so that a disease-modifying treatment, once available, can be given earlier in the disease process.

"Being able to move forward now with DIAN-TU NexGen as a result of this funding is critical to our mission to find a way to stop or slow the progression of Alzheimer's," said Randall Bateman, M.D., Director of DIAN-TU and DIAN-TU NexGen. "Our aim is to find ways to prevent damage and loss of brain cells by intervening early in the disease process – even before outward symptoms are evident. The new components we are adding with the DIAN-TU NexGen are designed to test ways to do exactly that." Dr. Bateman is also the Charles F. and Joanne Knight Distinguished Professor of Neurology at Washington University in St. Louis. He is an Alzheimer's Association Zenith Fellows Awardee.

More About DIAN-TU NexGen Drug Arms

In each trial arm, people who carry a deterministic gene mutation for Alzheimer's and who show mild or no symptoms of the disease will receive either an experimental drug or a placebo over a four-year time span. Researchers will compare the results of cognitive tests taken by participants at the beginning, during and at the end of the trial, and assess markers associated with Alzheimer's in body fluids and brain imaging scans to evaluate the drugs' effectiveness.

Multiple study sites around the world will be added to the 26 existing DIAN-TU sites in seven countries. Countries expected to have trial sites are Germany, Netherlands, Argentina, South Korea, Japan, Belgium, Taiwan and Bulgaria.

Individuals who carry a deterministic gene mutation for Alzheimer's are destined to develop the disease. This form of the disease is known as dominantly inherited Alzheimer's disease (DIAD). For individuals with DIAD, family history can help to predict the age of onset of Alzheimer's symptoms, which is typically during a person's 30s, 40s or 50s. While DIAD makes up less than 1% of all Alzheimer's cases, the predictable age of onset makes it possible to test drugs years before symptoms begin. This is when anti-amyloid therapies are hypothesized to be most effective.

Past research shows the biological changes observed in the brain of those with DIAD are highly similar to brain changes involving people with the more-common sporadic form of the disease, which is more likely to occur after age of 65. As a result, many scientists believe that a treatment that will work for those with DIAD will likely work for those with sporadic Alzheimer's.

The funding for DIAN-TU NexGen also supports holding an Annual DIAD Family Conference. This meeting provides DIAN-TU researchers with an opportunity to collect input on trial design features from families affected by DIAD and to communicate the scientific and medical rationale of research studies through direct engagement with these individuals.

In July 2015, the DIAN-TU and the Alzheimer's Association organized a DIAD Family Conference at the Alzheimer's Association International Conference (AAIC) in Washington, D.C. The conference offered an opportunity for families involved in the original DIAN study and DIAN-TU to meet one another in person for the first time. It also provided a forum for dialogue on critical issues, regulatory approval for Alzheimer's disease treatments and advocacy for increased research funding to find new and more effective treatments for Alzheimer's. The next DIAD Family Conference will be held at AAIC 2016 in July in Toronto, Canada.

More About DIAN-TU

DIAN-TU is the first large-scale clinical trial aimed at identifying drugs to stop or slow Alzheimer's disease in people with DIAD. Led by researchers at Washington University in St. Louis, the trial is currently testing the amyloid-targeting drugs solanezumab and gantenerumab, from Eli Lilly and Company and Hoffmann-La Roche, respectively. The trial is an outgrowth of DIAN, an international network of 17 research centers established in 2008 to conduct a long-term observational study to understand how DIAD develops. DIAN has been instrumental in validating markers to detect the presence or increased risk for Alzheimer's in body fluids and brain imaging, and has been critical for the launching of DIAN-TU. At the Alzheimer's Association International Conference 2011, the DIAN team reported interim data from 150 participants showing that, in this population, measurable brain changes appear as much as 20 years before the first detectable memory and thinking impairments.

About the Alzheimer's Association

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support and research. It is the largest nonprofit funder of Alzheimer's research. The Association's 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. Its vision is a world without Alzheimer's. Visit alz.org or call 800-272-3900.

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