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ALZHEIMER’S ASSOCIATION AWARDS LARGEST EVER RESEARCH GRANT TO THE DOMINANTLY INHERITED ALZHEIMER’S NETWORK (DIAN) FOR INNOVATIVE THERAPY TRIALS

- Donors Respond to the Alzheimer’s Association’s Call for Funding to Accelerate Discovery -

Chicago, IL March 20, 2012– The Alzheimer’s Association announced today the awarding of its largest ever research grant – nearly $4.2 million over four years – to the Dominantly Inherited Alzheimer’s Network–Therapeutic Trials Unit (DIAN-TTU), based at Washington University School of Medicine in St. Louis, to enable the program to move forward more quickly with innovative drug and biomarker trials in people with genetically-based, young-onset Alzheimer’s disease.

“The Association feels confident that by rapidly launching the DIAN-TTU, we will accelerate the scientific community’s ability to answer the question of whether an earlier intervention will change the trajectory of the disease process and delay or stop Alzheimer’s,” said William Thies, Ph.D. Alzheimer’s Association Chief Medical and Scientific Officer.

Thies added, “This project has the potential to dramatically accelerate the pace of discovery of treatment and prevention strategies for Alzheimer’s disease. In addition, we’re very pleased that an exceptional group of donors quickly responded to the Association’s call for critical funding for this project, as they are committed to making strategic and impactful investments in the global Alzheimer’s research field.”

The Dominantly Inherited Alzheimer’s Network (DIAN)
DIAN is an international network of 11 leading research centers established in 2008 by funding from the National Institute on Aging to investigate Alzheimer’s disease caused by rare, dominantly inherited genetic mutations. Children of individuals who carry one of these genetic mutations have a 50-50 chance of inheriting the gene mutation, and those who do are destined to develop the disease. Mutation carriers have a young-onset version of Alzheimer’s disease; symptoms typically begin in their 30s, 40s, or 50s.

DIAN now has the largest and most extensive worldwide research network investigating dominantly inherited Alzheimer’s disease, and includes facilities in the United States, United Kingdom, and Australia. DIAN is directed by John C. Morris, M.D., of Washington University School of Medicine, director of the University’s Knight Alzheimer’s Disease Research Center, and former member of the Alzheimer’s Association Medical & Scientific Advisory Council.

At the Alzheimer’s Association International Conference 2011, the DIAN team reported interim data from 150 participants showing that, in this population, measurable brain chemistry changes appear as much as 20 years before the first detectable memory and thinking impairments.

“That means we can detect the beginnings of Alzheimer’s disease at least 10 years, and maybe even 20 years, before the age that their parents saw Alzheimer’s symptoms and when they too would be expected to see them,” Morris said.

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In this group, family history predicts what age the onset of symptoms will begin, which allows for a treatment window during which to test potential therapies. According to the DIAN researchers, the results demonstrate the feasibility and promise of performing Alzheimer’s prevention studies in this special population.

**DIAN-TTU**
The DIAN Therapeutic Trials Unit (TTU), funded by this grant of $4,172,658, will leverage the existing DIAN network to rapidly launch biomarker and prevention trials that otherwise would be difficult without the ongoing DIAN study.

“No single research center has sufficient numbers of people with dominantly inherited Alzheimer’s to conduct a large enough study to generate meaningful results,” said Randall Bateman, M.D., Associate Professor of Neurology at the Washington University School of Medicine and Director of the DIAN-TTU. “This underscores the value of the DIAN clinical studies.”

The Alzheimer’s Association grant will be used to create the infrastructure for the first ever clinical testing of experimental drug therapies within a global network of individuals who have a rare genetic form of Alzheimer’s, but have not yet experienced the onset of symptoms.

“We want to prevent damage and loss of brain cells by intervening early in the disease process – even before outward symptoms are evident, because by then it may be too late,” Bateman said.

The DIAN team says that the U.S. Food and Drug Administration and European Medicines Agency – both are government agencies that regulate drug trials – have expressed support for prevention trials in this special population. Eleven compounds have been nominated by the pharmaceutical industry for use in these trials.

People from families with known gene mutations that cause Alzheimer’s represent an ideal study group. For example, currently asymptomatic mutation carriers – all of whom are destined to eventually develop symptomatic Alzheimer’s – can be compared with their non-carrier siblings. Such clinical trials would be transformational and without precedent in the history of global clinical trials in Alzheimer’s disease.

“By studying the rare individuals who are destined to get Alzheimer’s because of their genes, we can learn a great deal more about the majority of people whose Alzheimer’s develops later in life as a result of complex interactions among their genes, life experiences and other factors,” Thies said. “Earlier detection and treatment are crucial if we are to curb the growing epidemic of Alzheimer’s disease.”

The Alzheimer’s Association grant will enable an accelerated launch of DIAN-TTU and:

- Expand the global registry of DIAN enrollees. (www.alz.org/Trialmatch or www.DIANexpandedregistry.org)
- Direct preclinical studies to increase the chance of success of treatment trials.
- Evaluate treatment compounds for the first studies.
- Design and launch international biomarker and prevention trials.
- Function as the infrastructure to manage and run DIAN trials.

According to the DIAN scientists, a six-month reduction in the treatment discovery timeline may translate into a reduction of up to 2.5 million cases of Alzheimer’s. The first biomarker studies may be completed within 12-18 months from the start of the trials.

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**Current Status of Treatments and Testing**
The currently-approved Alzheimer’s drugs, while modestly helpful to many people, are less than satisfactory. They do not change the course of the disease, but provide some symptomatic relief to some people with Alzheimer’s for roughly a year.

At the same time, several recent late stage Alzheimer’s drug studies have shown the tested compounds to not be any different than placebo, at best. So researchers are desperately searching for more and better treatment options for people with Alzheimer’s – ones that slow or stop the progression of the disease.

Up until now, experimental therapies have been studied in people with Alzheimer’s dementia. The consensus in the field is a need to move treatment interventions, and thus research studies, earlier in the course of the disease to have beneficial impact.

Genetic versus Sporadic Alzheimer’s Disease
The vast majority of cases of Alzheimer’s disease are sporadic, late onset disease – with prevalence greatly increasing after age 65 and roughly doubling with every ten years of increasing age. Several genes have been identified that impact one’s risk of getting Alzheimer’s disease though exactly how much they change a person’s risk is unclear. The most well established risk gene for Alzheimer’s is apolipoprotein E-e4 (APOE-e4).

Genetically determined Alzheimer’s is rare – occurring in less than one percent of cases. Nonetheless, many insights into sporadic Alzheimer’s have been gained from investigating this special, young onset Alzheimer’s population. For example, the known genes that trigger young onset Alzheimer’s (amyloid precursor protein (APP), presenilin-1 (PS-1) and presenilin-2 (PS-2)) directly affect the processing of a protein called amyloid, virtually guaranteeing an important role for that protein in the sporadic version of the disease.

About the Alzheimer’s Association
The Alzheimer’s Association is the largest non-profit funder of Alzheimer’s disease research having awarded more than $292 million to more than 2,100 peer-reviewed scientific projects. The Alzheimer’s Association is the world’s leading voluntary health organization in Alzheimer’s care, support and research. Our mission is to eliminate Alzheimer’s disease through the advancement of research, provide and enhance care and support for all affected, and reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer’s. For more information, visit www.alz.org.