

Dominantly Inherited Alzheimer Network Trial Completes Participant Enrollment for Two Drugs in a Phase II/III Study of Amyloid Therapies

First global trial in autosomal dominant Alzheimer's disease focuses on prevention, testing anti-amyloid therapeutics from Eli Lilly and Company and Roche

The Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), headquartered at Washington University School of Medicine, has completed the first stage of participant enrollment in the first Alzheimer's prevention trial for autosomal dominant Alzheimer's disease (ADAD), also referred to as early-onset Alzheimer's disease. The goal of the first stage of the study is to determine the biomarker and cognitive effects of two different drugs targeting amyloid beta. With this enrollment milestone, first biomarker results may be available at the end of 2016 with the final cognitive endpoint data expected in late 2019.

The DIAN-TU is a public-private partnership of academic centers, the Alzheimer's Association, Eli Lilly and Company, Roche and the U.S. National Institute on Aging. Other supporters include Cogstate, Avid Radiopharmaceuticals, GHR Foundation, Fidelity Biosciences Research Initiative, Accelerating Medicines Partnership and the DIAN-TU Pharma Consortium (members include Amgen, AstraZeneca, Biogen, Eisai, Forum, Janssen/J&J, Lilly, Roche and Sanofi).

"We believe this study will dramatically increase the pace of discovery of treatment and prevention strategies for Alzheimer's," said Maria Carrillo, Ph.D., Alzheimer's Association Chief Science Officer. "The Alzheimer's Association feels confident that DIAN-TU, along with the other four ongoing prevention trials, will accelerate the scientific community's ability to determine whether an early intervention can delay or stop Alzheimer's disease."

"In addition, by studying people who are genetically destined to dementia due to Alzheimer's, we believe we can learn a great deal more about the majority of people whose Alzheimer's develops sporadically later in life. Earlier detection and treatment are essential to stopping the growing Alzheimer's epidemic," Carrillo added.

The DIAN-TU trial is testing Lilly's solanezumab, a monoclonal antibody targeting soluble amyloid beta, and Roche's gantenerumab, an antibody binding fibrillar amyloid beta, in participants with ADAD. Both aim to lower levels of the substance that forms amyloid plaques - believed by some scientists to be the first step in a process leading to memory and thinking impairment and eventually death. Both companies are also testing these drugs in their own phase III studies in sporadic Alzheimer's disease.

"Alzheimer's disease is one of society's greatest public health challenges and requires strong partnership between patients, academic groups and industry, such as DIAN, in order to make progress in developing medicines to help people living with this disease," said Paulo Fontoura, Global Head of Clinical Development Neuroscience at Roche. "Today's announcement is a very positive step forward. The DIAN-TU study is a landmark in AD research and Roche is very proud of its involvement and contribution."

“The DIAN-TU trial has the opportunity to help improve the lives of families around the world who are impacted by ADAD,” said Phyllis Ferrell, vice president of the Alzheimer’s global team at Lilly. “We are proud to be a part of this ground-breaking study.”

While ADAD 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. The ADAD population has historically been excluded from Alzheimer’s trials due to their age of symptom onset beginning in the 30s, 40s and 50s. The DIAN-TU trial is the first global trial to enroll dominantly inherited Alzheimer’s participants and is currently operational at 24 sites in seven countries and four languages.

The DIAN-TU has begun work on the next generation of drug arms and innovative study design updates to accelerate discovery of Alzheimer’s therapies. The team expects enrollment for new drugs to begin in 2016. Dr. Randall J Bateman of Washington University School of Medicine, the study’s principle investigator, said, “The important milestone of reaching the first stage of enrollment brings us one step closer to finding out whether these two drugs will work as preventive therapies. We will keep going until there are drugs to effectively prevent and treat Alzheimer’s disease.”