



ASX Announcement

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Cogstate test selected for pioneering Alzheimer's disease prevention trial

DIAN-TU-001 Highlights

- The Dominantly Inherited Alzheimer Network (DIAN) is an international research partnership of leading scientists determined to understand a rare form of Alzheimer's disease that is caused by a gene mutation.
- This worldwide clinical trial is the first study to investigate whether prospective drugs can prevent the onset of dementia in patients who have the gene mutation but have not yet developed the disease.
- Cogstate's selection as the cognitive testing for this study is an important component of the clinical trial to evaluate whether drugs can prevent or slow the onset of Alzheimer's disease.

Cogstate has been selected as part of the battery of cognition tests in a major global study investigating the early detection of Alzheimer's disease, being run by the international research partnership DIAN (Dominantly Inherited Alzheimer Network) out of the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) at Washington University School of Medicine in St. Louis. Cogstate tests are the only computerized cognitive tests included in the study.

This Phase II/Phase III clinical trial will evaluate whether two investigational drugs, currently being developed for the treatment of Alzheimer's disease, can halt or reverse pathological changes in the preclinical biomarkers known to be present in patients with the disease.

The trial will include 210 adults, of which 120 carry a gene mutation linked to a rare form of Alzheimer's disease, but have not yet demonstrated symptoms of the disease. The remaining trial participants do not carry the gene, but have a parent with the gene mutation. The study is being run across over 30 investigational sites spanning the US, UK, Canada, Australia and Europe.

"This pioneering trial is one of the most important global studies in the early treatment of Alzheimer's disease that has ever been undertaken. Cogstate is very proud to be supporting this study. Our involvement is an important validation from the global scientific community of the role the tests in our battery can play in the detection of the subtle changes in cognition that can be indicative of the earliest signs of dementia," said Brad O'Connor, Chief Executive Officer of Cogstate.

“Cognitive testing is an important part of the DIAN-TU trial,” says Dr. Randy Bateman, the Charles and Joanne Knight Distinguished Professor of Neurology at Washington University School of Medicine, and trial Director. “These tests may provide valuable insights into the earliest mental changes in pre-symptomatic Alzheimer’s disease. We are excited to move forward with this trial to determine whether it is possible to prevent or slow the onset of Alzheimer’s in patients who are genetically destined to develop the disease.”

The DIAN-TU trial will study the effects of two investigational drugs, each targeting the amyloids in the brain in slightly different ways. The selected drugs are Roche’s Gantenerumab and Lilly’s Solanezumab.

Participants in the study will undergo PET brain scans to track amyloid levels in the brain, and will also have their memory function and other cognitive abilities tested with the computer-based tests developed by Cogstate at the commencement of the study and at a total of six separate intervals during the 24 month duration of the trial.

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About Cogstate

Cogstate Ltd (ASX: CGS) is a multi-faceted cognitive assessment and training company, focused on the development and commercialisation of rapid, computerised tests of cognition (brain function). It has three distinct business units:

Clinical Trials: In the clinical drug trial market, Cogstate technology and associated services are used by pharmaceutical and biotechnology companies to quantify the effect of drugs or other interventions on human subjects participating in clinical trials. Since sales into the clinical trials market began in 2004, Cogstate has secured agreements with top pharmaceutical companies including Pfizer, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novartis, Lundbeck, Daiippon Sumitomo, Targacept, Otsuka, and Servier.

Axon Sports: The mission of Axon Sports is to “protect and train the athletic brain”. Axon’s focus is to research, develop and deliver cutting edge tools to assess, monitor and improve the athletic brain.

Axon has been developing sport specific training products, initially focussed on American football and baseball, and the resulting technologies have now been launched within a small number of elite US college programs. In addition, the first of Axon’s consumer iPad apps was launched in 2012.

In the area of sports related concussion, Cogstate's technology has been used by a number of highly regarded institutions and sporting organisations around the world for almost 10 years. That technology is now marketed to consumers as Axon Sports. Current users of Cogstate/Axon Sports in Australia include the AFL and NRL, whilst in the USA elite programs such as the NBA, WNBA, NHL as well as college programs such as University of Notre Dame, University of Michigan and University of Connecticut all use the Axon Sports system.

Healthcare: In the primary care or general practice setting, the Cogstate's COGNIGRAM™ assesses cognition in patients and the reports generated on the basis of this assessment can allow physicians to identify subtle changes that could be indicative of the early stage of a neurodegenerative disease, such as Alzheimer's disease. Cogstate intends to develop COGNIGRAM™ to monitor changes in cognitive function following concussion or after treatment with drugs or other types of interventions. In June 2012, Cogstate entered into an agreement with Merck Canada Inc. providing it with the exclusive right to market and promote COGNIGRAM™ in Canada.