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ASX Announcement

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Cogstate's technology chosen for major Phase III trial of Alzheimer's disease drug

Highlights:

- Cogstate test to provide key measures of cognition for the major Phase III secondary prevention drug trial for Alzheimer's disease entitled Anti-Amyloid Treatment in Asymptomatic Alzheimer's disease ("A4") trial.
- The A4 trial will assess a promising new drug which aims to prevent, or slow onset, of Alzheimer's disease in at-risk, though asymptomatic, elderly people.
- Details of the trial - to involve 1000 people across 60 trial sites in the US, Canada and Australia - published in the journal *Science Translational Medicine* this month.

Melbourne, Australia. Cognition testing technology developed by Cogstate (ASX CGS) will be used to track the neurological health of elderly people involved in the multinational Phase III clinical trial of a promising new Alzheimer's disease (AD) drug.

The "A4" trial will involve 1000 elderly people across 60 trial sites in the US, Canada and Australia, and it will assess a drug which may prevent, or slow the onset, of dementia in those considered at-risk but yet to show AD symptoms.

Details of the trial were published this month in the journal *Science Translational Medicine* on March 19, titled "The A4 Study: Stopping AD Before Symptoms Begin?" (<http://stm.sciencemag.org/content/6/228/228fs13.abstract>).

The cognition tests developed by Cogstate and delivered using an iPad assess a person's reaction time and visual memory via a series of playing card-based challenges. These scientifically validated tests allow researchers to establish a cognitive function baseline for a person and then monitor for any subtle decline over time. If the A4 trial is successful, clinically normal older individuals might undergo such screening in clinical settings in the future.

Reisa Sperling, MD A4 Study Project Director, Professor of Neurology, Harvard Medical School said: "One of the many novel aspects of the A4 Study is the use of the Cogstate tests administered on the iPad. Computerized cognitive testing is definitely the wave of the future

for prevention trials in Alzheimer's disease. We are so excited to partner with Cogstate on this landmark study.”

The trial will involve elderly people aged 65 - 85 years who are in the asymptomatic phase of AD. They have elevated brain levels of amyloid - a biomarker for AD - however they remain healthy and are yet to show any outward signs of dementia.

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 seven separate intervals during the 48 month duration of the trial.

Trial participants will be randomized to receive the anti-amyloid drug solanezumab (being developed by Eli Lilly), or a placebo, to assess whether the drug can slow or prevent onset of AD in this at-risk group. The success of these trials does not require that amyloid is the cause of AD, merely that amyloid is one critical factor that can be targeted prior to widespread, irreversible neurodegeneration. A similar situation might be the development of cholesterol-lowering medications for cardiovascular disease.

“One of the most important elements of this trial is the focus on treating patients with very early signs of disease and who are not displaying symptoms. The Cogstate test is therefore critical because of the ability to measure subtle changes in cognition”.

“We are delighted to be working with an eminent group of scientists and clinicians on such an important issue.”

Paul Maruff Cogstate Chief Scientific Officer added: “We have shown now in many studies that the Cogstate battery, now being used in the A4 study, is sensitive to amyloid related cognitive decline. These same Cogstate tests have also been shown repeatedly to be sensitive to the effects of novel and licensed drugs that modify cognitive symptoms in early AD.”

“We are therefore optimistic and excited about the potential outcomes of the A4 study and we will work hard with the study team to contribute to the success of the A4 study.”

The A4 trial is to be run by the Alzheimer’s Disease Cooperative Study (ADCS), which is a cooperative agreement between the National Institute on Aging (NIA) and the University of California, San Diego.

The ADCS is a major initiative for Alzheimer’s disease clinical studies in the US Federal government, addressing treatments for both cognitive and behavioural symptoms.

The University of Melbourne has been selected as an Australian trial site.

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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, Dainippon 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.