



COGSTATE
ASSESS • MONITOR • IMPROVE

ASX Announcement

8th October 2013

Merck releases new data on effectiveness of Cognigram™

Medical technology company Cogstate has today released important new evidence from partner Merck supporting Cognigram™ as a sensitive assessment to detect and monitor cognitive decline over time in healthy individuals and adults with mild cognitive impairment and who are also carriers of a biological marker in the brain – A β amyloid.

Cognigram™ is a computer-based cognitive evaluation tool that helps physicians in their clinical decision-making for their patients with cognitive impairment. Merck Canada Inc promotes Cognigram™ in Canada. The partnership is part of the ongoing commitment from Merck to improve disease management involving the central nervous system.

The announcement from Merck is attached.

ENDS

For further information contact:

Brad O'Connor
Cogstate Chief Executive Officer
+61 3 9664 1300 or 0411 888 347
boconnor@cogstate.com

Investor Relations and Media:

Australia
Rebecca Wilson
+61 3 9866 4722
rwilson@buchanwe.com.au

US
Lauren Glaser
+1 646 378 2972
LGlaser@troutgroup.com

Ben Oliver (Media)
+61 3 9866 4722
boliver@buchanwe.com.au

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.

**Media Contacts:**

Sylvie Tessier
Merck
514-428-3142
sylvie.tessier@merck.com

Alexandra Fahmey
Edelman
416-849-2996
alexandra.fahmey@edelman.com

New Data Demonstrate Cognigram™ as a Sensitive Assessment to Detect and Monitor Cognitive Decline Over Time in People with a Biological Marker in their Brain

MONTREAL, QUEBEC, October 7, 2013 – Results from two new studies add to the body of evidence that supports Cognigram™ as a sensitive assessment to detect and monitor cognitive decline over time, namely in healthy individuals and adults with mild cognitive impairment (MCI) that are carriers of a biological marker in the brain - Aβ amyloid.^{1,2} Data from two studies were presented at the Canadian Conference on Dementia (CCD), in Vancouver, British Columbia, between October 3 and 5.

“This is a true advance in the way clinicians will be able to detect and monitor the progression of cognitive disorders in older people. It is the first time that a computerized cognitive assessment has been associated with levels of Aβ amyloid in the brain,” says Dr. Paul Maruff, Chief Science Officer at Cogstate and one of the authors of the two studies. “Aβ amyloid is a biomarker that signifies abnormal proteins in the brain and provides important information to indicate that the Alzheimer’s disease process has begun. In our studies presented at CCD, we underscore the sensitivity of Cognigram™ to efficiently assess over time (up to 36 months) the decline of cognitive function in people whose brains had been scanned and showed presence of high levels of this biomarker.”

Amyloid and Cognition

Aβ amyloid biomarkers provide important insights into the clinical course of cognition. Prospective studies in healthy older adults and adults with mild cognitive impairment have shown that high levels of Aβ amyloid are often associated with the decline of cognitive function and a more rapid progression to the next clinical disease stage.¹

Cognition is the mental process of knowing, including aspects such as awareness, perception, reasoning, and judgment. Some decrease in cognition is expected at older ages, but the decline is not uniform across all cognitive tasks or for all individuals. Impaired cognition can have health consequences, such as first stroke, falls, and institutionalization. It may reduce an individual's ability to communicate pain to health care providers, carry out instrumental activities of daily living, cope with chronic disease symptoms, perform self-care and adhere to medication instructions.³

“Dementia and Alzheimer's disease are marked by a decline in overall cognition and function, having a profound impact on the daily life of patients and their caregivers,” says Dr. Louis Verret, Neurologist and Researcher, Interdisciplinary Memory Clinic, Centre hospitalier universitaire (CHU) de Québec. “As these diseases continue to escalate at an alarming rate, research looking at A β amyloid in the brain and its relationship to changes in cognition is an exciting area that may contribute to therapeutic interventions aimed at modifying the course of Alzheimer's disease-related neurodegeneration.”

The number of Canadians living with cognitive impairment, including dementia, was 747,000 in 2012 and will double to 1.4 million by 2031.⁴ The annual economic burden is expected to increase substantially from approximately \$15 billion in 2008 to \$153 billion by the year 2038.⁵

About the Studies^{1,2}

The study “*A β amyloid and cognitive change: Decline in learning and working memory across the preclinical and prodromal stages of Alzheimer's disease,*” included 177 healthy older adults and 48 adults with mild cognitive impairment (MCI) who underwent positron emission tomography (PET) neuroimaging using Pittsburgh Compound B (PiB) for A β amyloid, APOE ϵ 4 genotyping, and cognitive assessment using Cognigram™ as part of their baseline assessment in the Australian Imaging, Biomarkers, and Lifestyle (AIBL) study. Cognitive function using Cognigram™ was reassessed at 18 and 36 months later.

“*The consequences of high A β amyloid for performance on Cognigram™ in healthy older adults and mild cognitive impairment. Implications for early detection of Alzheimer's disease,*” study included 288 healthy older adults and 56 adults with amnesic MCI from the AIBL study, who underwent PET neuroimaging using PiB for A β amyloid, and completed the Cognigram™ cognitive screen.

Participants from both studies were recruited from the Australian Imaging, Biomarkers, and Lifestyle (AIBL) Study of Ageing, which aims to discover which biomarkers, cognitive characteristics, and health and lifestyle factors determine subsequent development of symptomatic Alzheimer's disease. The AIBL study is supported by the Science and Industry Endowment Fund in Australia.⁶

Funding for the studies was provided in part by the study partners [Australian Commonwealth Scientific Industrial and Research Organization (CSIRO), Edith Cowan University (ECU), Mental Health Research Institute (MHRI), Alzheimer's Australia (AA), National Ageing Research Institute (NARI), Austin Health, Cogstate Ltd., Hollywood Private Hospital, Sir Charles Gardner Hospital]. The studies also received support from the National Health and Medical Research Council (NHMRC) and the Dementia Collaborative Research Centres program (DCRC2), as well as ongoing funding from the Science and Industry Endowment Fund (SIEF).

About the Results^{1,2}

The study "*A β amyloid and cognitive change: Decline in learning and working memory across the preclinical and prodromal stages of Alzheimer's disease,*" found that compared to healthy older adults with low A β amyloid, healthy older adults and adults with MCI with high A β amyloid showed a moderate decline across 36 months on the CognigramTM learning working memory composite. In contrast, adults with MCI and low A β amyloid showed a slight improvement on the CognigramTM learning/working memory and psychomotor/attention composites across the 36 months. APOE ϵ 4 carriage did not moderate the relationship between A β amyloid and cognitive decline.

"The consequences of high A β amyloid for performance on CognigramTM in healthy older adults and mild cognitive impairment. Implications for early detection of Alzheimer's disease," study found that in healthy adults, performance on the attention/psychomotor function composite was equivalent between low and high A β amyloid groups. Performance on the learning/working memory composite was slightly worse in the high A β amyloid group compared to low A β amyloid group although this did not reach statistical significance. In MCI, performance on the attention/psychomotor function composite was equivalent between low and high A β amyloid groups however performance on the learning working memory composite was significantly worse in the MCI high A β amyloid group compared to the MCI low A β amyloid group.

About Cognigram™

Cognigram™ is a computer-based system designed to measure and monitor cognitive function for neurodegenerative diseases such as mild cognitive impairment and Alzheimer's disease. Merck Canada Inc. promotes Cognigram™ in Canada. Cognigram™ was created and is supplied by Cogstate Ltd. The partnership is part of the ongoing commitment from Merck to improve disease management involving the central nervous system.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information about our operations in Canada, visit www.merck.ca.

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on

the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2012 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

- 30-

References:

¹ Maruff, Paul et al. *A β amyloid and cognitive change: Decline in learning and working memory across the preclinical and prodromal stages of Alzheimer's disease*. Poster presented at the Canadian Conference on Dementia on October 4, 2013.

² Maruff, Paul et al. *The consequences of high A β amyloid for performance on Cognigram in healthy older adults and mild cognitive impairment. Implications for early detection of Alzheimer's disease*. Poster presented at the Canadian Conference on Dementia on October 5, 2013.

³ Gilmour, Heather. *Cognitive performance of Canadian seniors*. Statistics Canada. June 2011. Available at: <http://www.statcan.gc.ca/pub/82-003-x/2011002/article/11473-eng.pdf>.

⁴ Alzheimer Society of Canada. *A new way of looking at the impact of dementia in Canada*. Available at: http://www.alzheimer.ca/~media/Files/national/Media-releases/asc_factsheet_new_data_09272012_en.ashx.

⁵ The Alzheimer Society. *Rising Tide: The Impact of Dementia on Canadian Society. Executive Summary. 2010*. Available at: http://www.alzheimer.ca/on/~media/Files/national/Advocacy/ASC_Rising%20Tide-Executive%20Summary_Eng.ashx.

⁶ Introducing the AIBL. *The Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL)*. May 14, 2013. Available at: <http://www.aibl.csiro.au/>.