

ASX Announcement

04 May 2023

Industry News

On Wednesday 03 May 2023, USA time, Eli Lilly and Company (Lilly) announced positive results of the TRAILBLAZER-ALZ 2 Phase 3 study showing that their investigational treatment, donanemab, significantly slowed cognitive and functional decline in people with early symptomatic Alzheimer's disease.

Based on these results, Lilly have stated that they will proceed with global regulatory submissions as quickly as possible and they anticipate making a submission to the U.S. Food and Drug Administration (FDA) this quarter. Lilly stated that they will work with the FDA and other global regulators to achieve the fastest path to traditional approvals of donanemab.

Cogstate was pleased to be able to work with the team from Lilly on the TRAILBLAZER-ALZ 2 Phase 3 study.

On 17 April 2023, in an announcement to the market, Cogstate noted upcoming industry news, including the following trial readouts and regulatory decisions:

- Eli Lilly & Co top-line phase 3 data in respect of donanemab expected in the June 2023 quarter;
- Eisai & Co USA regulatory approval of LEQEMBI (lecanemab):
 - 09-JUN-23: Peripheral and Central Nervous System Drugs Advisory Committee will meet to discuss the marketing application for traditional approval.
 - 06-JUL-23: Prescription Drug User Fee Act (PDUFA) action date.

This announcement has been approved for release by a sub-committee of the Board of Cogstate Ltd.

About Cogstate

Cogstate Ltd (ASX:CGS) is the neuroscience technology company optimising brain health assessments to advance the development of new medicines and to enable earlier clinical insights in healthcare. Cogstate technologies provide rapid, reliable and highly sensitive computerised cognitive tests across a growing list of domains and support electronic clinical outcome assessment (eCOA) solutions to replace costly and error-prone paper assessments with real-time data capture. The company's clinical trials solutions include quality assurance services for study endpoints that combine innovative operational approaches, advanced analytics and scientific consulting. For 20 years, Cogstate has proudly supported the leading-edge research needs of biopharmaceutical companies and academic institutions and the clinical care needs of physicians and patients around the world. In the Healthcare market, in August 2019 Cogstate entered into an exclusive licensing agreement with the pharmaceutical company Eisai, under which Eisai will market Cogstate technologies as digital cognitive assessment tools in Japanese markets. In October 2020, Cogstate extended its agreement with Eisai to the Rest of the World. The product, branded as NouKNOW, launched in Japan on 31 March 2020 (nouknow.jp). For more information, please visit www.cogstate.com.

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Important Notices

Past performance

Past performance is given for illustrative purposes only and should not be relied upon as (and is not) an indication of Cogstate's views on its future financial performance or condition. Past performance of Cogstate cannot be relied upon as an indicator of (and provides no guidance as to) the future performance of Cogstate. Nothing contained in this announcement nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee, whether as to the past, present or future.

Future performance and forward-looking statements

This announcement contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies that are subject to change without notice and involve known and unknown risks and uncertainties and other factors that are beyond the control of Cogstate, its directors and management. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

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Readers are cautioned not to place undue reliance on forward-looking statements and except as required by law or regulation, none of Cogstate, its representatives or advisers assumes any obligation to update these forward-looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this announcement. The forward-looking statements are based on information available to Cogstate as at the date of this announcement. Except as required by law or regulation (including the ASX Listing Rules), none of Cogstate, its representatives or advisers undertakes any obligation to provide any additional or updated information, whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.
