

# New Disease Modifying Drug for Alzheimer's Disease Fully Approved by FDA, Highlighting the Crucial Role for Cognetivity in Early Detection and Monitoring

## Vital breakthrough for Alzheimer's patients worldwide with Eisai's Leqembi FDA approval; Cognetivity Neurosciences' AI CognICA technology poised to play pivotal role in early detection and monitoring globally

Vancouver, British Columbia--(Newsfile Corp. - July 7, 2023) - **Cognetivity Neurosciences Ltd. (CSE: CGN) (OTCQB: CGNSF) (FSE: 1UB) ("the Company" or "Cognetivity")**, a technology company that has created a unique Artificial Intelligence (AI) powered brain health screening and monitoring platform for use in medical, commercial and consumer environments, is delighted to note that Eisai's (TYO: 4523) Leqembi has achieved full FDA approval for the treatment of Alzheimer's disease, news that brings hope to tens of millions of sufferers and at-risk individuals worldwide.

Leqembi received accelerated FDA approval in January 2023 thanks to its ability to clear amyloid plaques - harmful clumps of protein in the brain associated with Alzheimer's disease. Previously, the U.S. government's Medicare health plan for people aged 65 and over had restricted coverage only to patients in a clinical trial. Standard approval, the first of its kind for Alzheimer's disease, means that Leqembi will now be covered for all patients, although the Centers for Medicare and Medicaid Services (CMS) is linking reimbursement to patient participation in a health agency database, known as a registry. Since Alzheimer's is a disease of aging, most U.S. patients are insured by Medicare. "With FDA's decision, CMS will cover this medication broadly while continuing to gather data that will help us understand how the drug works," CMS Administrator Chiquita Brooks-LaSure said in a statement.

Responding to the announcement in a press release, the Alzheimer's Association stated, "With this approval, early detection and diagnosis are even more critical to ensure individuals receive the most benefit at the earliest point possible."

Cognetivity's groundbreaking Artificial Intelligence (AI) driven product, CognICA™, has [already demonstrated](#) its effectiveness in the detection of early stage cognitive impairment, tracking of cognitive function treatment of Alzheimer's disease patients using Eisai's partner Biogen's Aduhelm™ (aducanumab), which was given partial approval by the FDA in June 2021. CognICA is being used successfully to screen populations of individuals at risk of mild cognitive impairment, and reliably identifies those who show early signs of cognitive problems and require further assessment. Following clinical diagnosis, the technology platform is used to monitor changes in cognitive function among patients receiving monthly treatment, demonstrating the ability to deliver the CMS mandated reporting on patient progress. The speed, precision and ability to scale of CognICA give it a unique position in the market for the large-scale detection and monitoring of individuals with early stage Alzheimer's disease and other brain health issues.

Sina Habibi, CEO of Cognetivity Neurosciences, commented, "This is a huge breakthrough and outstanding news for sufferers worldwide of this debilitating and cruel disease, and for everyone working in the area of neurodegeneration. What this highlights is the critical importance of early stage diagnosis at population level. Currently half of patients with Alzheimer's are not diagnosed at all, and the situation is much worse when it comes to the earlier stages of the disease." He added "Our outstanding sensitivity to early-stage disease, ability to effectively monitor patient progress and to be used remotely and

regularly without taking up specialists' time are key elements in bringing transformational change to the treatment of Alzheimer's, and we encourage people working on the planning and delivery of care to get in touch with us as we are ready to help today."

Cognetivity Neurosciences remains dedicated to utilizing its AI platform technology to transform the landscape of brain health globally, enhance the quality of care provided to patients and to reduce the burden and cost to providers and payers, delivering the company's vision of A Brighter Mind for a Fuller Life.

## **About Cognetivity Neurosciences**

Cognetivity is a technology company that has developed a cognitive testing platform for use in medical, commercial, and consumer environments. Cognetivity's CognICA™ uses artificial intelligence and machine learning technology to test the performance of large areas of the brain to help detect early signs of cognitive dysfunction. CognICA is currently available for clinical use in the United States, United Kingdom, Europe, and the Middle East, with regulatory approval in other regions expected in 2023.

## **On behalf of the Board of Directors**

"Sina Habibi"

Sina Habibi

Chief Executive Officer and Director

Forward-looking statements:

Certain statements contained in this news release, including those identified by the words "anticipate," "assume," "believe," "plan," "estimate," "expect," "intend," "may," "should" and similar expressions, to the extent they relate to the Company or its management, constitute forward-looking information or statements (collectively, the "Forward-Looking Statements"). These forward-looking statements are not historical facts and reflect current expectations regarding future results or events. This news release contains forward-looking statements. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Such statements are based on current expectations and various estimates, factors and assumptions, and involve known and unknown risks, uncertainties and other factors. Such statements and information are based on a number of assumptions regarding our current and future business strategies and the environment in which we operate. We assume no responsibility to update or revise forward-looking information to reflect new events or circumstances, except as required by law. Readers are cautioned not to place undue reliance on our forward-looking statements.

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