Cognetivity Neurosciences Granted FDA Clearance for Commercial Distribution of ICA Throughout US Healthcare Market

Completed US FDA registration of CognICA Integrated Cognitive Assessment allows the company to market its ICA as a medical device across the United States

VANCOUVER, BC, Oct. 20, 2021 /CNW/ - Cognetivity Neurosciences Ltd. (the "Company" or "Cognetivity") (CSE: CGN) (OTCQB: CGNSF) (FWB: 1UB) today announced that it has received notification from the US Food and Drug Administration (FDA) that its 510(k) submission for the CognICA Integrated Cognitive Assessment (ICA) has been reviewed and found to meet the requirements of regulations 21 CFR 882.1470; Class II Exempt Medical Device. The notification allows the company to market the medical device for commercial distribution in the US.

The ICA is a five-minute, computerized cognitive assessment, delivered on iPad devices. It offers numerous benefits to clinicians and patients, particularly in comparison to traditional, pen-and-paper-based tests. These include its high sensitivity to early-stage cognitive impairment, avoidance of cultural or educational bias and absence of learning effect upon repeat testing. Owing to its computerized nature, the ICA is also capable of supporting remote, self-administered testing at scale and is geared towards seamless integration with existing electronic health record (EHR) systems.

The ICA has already received European regulatory approval as a CE-marked medical device and has been deployed in both primary and specialist clinical care in the UK's National Health Service (NHS). Registration with the FDA now grants Cognetivity access to the vast US healthcare market, which is the largest of any country in the world.

US national healthcare expenditure reached USD 3.8 trillion in 2019 and is estimated to rise to USD 6.2 trillion by 2028. Alzheimer's and other dementias make up a substantial proportion of that figure, costing the nation USD 355 billion in 2021, according to the Alzheimer's Association. That figure could grow to more than USD 1.1 trillion by 2050, by which time the number of Americans aged 65 and older living with Alzheimer's alone is expected to have more-than-doubled to 12.7 million. As such, there is enormous demand for improvements in the diagnosis and treatment of such conditions.

Commenting on the announcement, Dr Sina Habibi, Cognetivity's CEO, said: "We're delighted to have reached this major company milestone, which is the culmination of many years of hard work. This grants us access to the world's largest healthcare market, where, sadly, there is much more to be done to tackle the massive problem of dementia. Of course, we're excited about the opportunity to revolutionize the way cognitive impairment is assessed and managed in the US and make a positive impact on the health and wellbeing of millions of Americans."

Cognetivity plans to execute a vigorous business development strategy to achieve US-wide commercial rollout, including the establishment of regional outposts in the coming months. This will build on the company's existing networks and recent successes in being selected to join two of the most prestigious and competitive accelerator programs in the US: the TMCx Innovation Accelerator at the Texas Medical Center – the largest medical city in the world – and Plug and Play's Silicon Valley Health Batch 13.

While FDA registration is critical for US commercial rollout specifically, it also has advantages for Cognetivity's plans in other parts of the world. "The benefits of reaching this milestone will extend far beyond the US itself," Dr Habibi explained. "The FDA is the global exemplar in medical regulation; its name carries great weight all over the world. Without a doubt, this mark of certification will bolster

our regulatory and commercial efforts in other international jurisdictions as we continue to pursue our ambitions for deployment on a truly global scale."

About Cognetivity Neurosciences Ltd.

Cognetivity is a technology company that has created a cognitive testing platform for use in medical, commercial and consumer environments. Cognetivity's ICA uses Artificial Intelligence and machine learning techniques to help detect the earliest signs of impairment by testing the performance of large areas of the brain to support diagnosis of dementia. It has achieved regulatory approval for clinical use in the UK and Europe with future clinical approval anticipated in North America and elsewhere in the world.

For more information, please visit: www.cognetivity.com or contact: info@cognetivity.com

ON BEHALF OF THE BOARD

"Sina Habibi"

Sina Habibi
Chief Executive Officer and Director

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Certain statements included in this news release constitute forward-looking information or statements (collectively, "forward-looking statements"), including those identified by the expressions "anticipate", "assume" "believe", "plan", "estimate", "expect", "intend", "may", "should" and similar expressions to the extent they relate to the Company or its management. The forward-looking statements are not historical facts but 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 which 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 numerous assumptions regarding present and future business strategies and the environment in which the Company will operate in the future. The Company assumes no responsibility to update or revise forward-looking information to reflect new events or circumstances unless required by law. Readers should not place undue reliance on the Company's forward-looking statements.

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CNW 09:00e 20-OCT-21