

# Cognetivity Neurosciences registers Integrated Cognitive Assessment for regulatory approval as CE-marked medical device

- **Regulatory approval will establish the company's first CE-marked product.**
- **CE marking allows sale of device for medical environments across Europe.**

VANCOUVER, Dec. 19, 2019 /CNW/ - Cognetivity Neurosciences Ltd. (the "Company" or "Cognetivity") (CSE: CGN; FWB: 1UB; OTCQB: CGNSF) today announced the registration of its Integrated Cognitive Assessment (ICA) with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for CE marking.

A major milestone for the company, CE marking demonstrates conformity with EU medical device safety and performance requirements and will enable the ICA to be sold as a diagnostic aid in the UK, throughout the European Economic Area (EEA) and in other jurisdictions that accept a CE mark.

A University of Cambridge spin-out, Cognetivity developed the ICA to address the global challenge of dementia and, specifically, the unmet need for a test sensitive enough to identify the earliest stages of cognitive impairment, when healthcare interventions are most effective. The ICA's iPad-based image categorisation task takes five minutes, shows an absence of learning effects, and demonstrates resistance to cultural, educational and linguistic bias. It is powered by advanced AI techniques, enabling improvements in detection accuracy over time, and geared towards seamless integration with existing electronic health record (EHR) systems.

"The scientific validity of our product has long since been established. CE marking signifies something more," explained Dr Sina Habibi, Cognetivity's CEO. "It is a declaration that our product is ready for use and – underpinned by the clinical trial data that supports our registration – certification that the ICA is effective when deployed in a medical environment.

"It's gratifying to have reached this important milestone in line with our plans for the year. It demonstrates our commitment to potential customers we are already in conversation with. What's more, it gives us confidence in our plans to attain regulatory approval in other jurisdictions, beginning with the USA and Canada.

"Next year, we plan to bring our CE-marked ICA to the NHS and beyond, and begin to help tackle the dementia crisis for clinicians, patients and their families."

## **About Cognetivity Neurosciences Ltd.**

Cognetivity is a technology company developing a cognitive testing platform, the Integrated Cognitive Assessment (ICA) 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, potentially allowing early diagnosis of dementia. Cognetivity aims to develop the ICA through ongoing clinical studies to the market in North America, Europe and elsewhere in the world.

For more information, please visit: [www.cognetivity.com](http://www.cognetivity.com)

ON BEHALF OF THE BOARD  
"Sina Habibi"

Sina Habibi  
Chief Executive Officer and Director

**FORWARD LOOKING STATEMENTS:**

The forward-looking information contained in this press release is made as of the date of this press release and, except as required by applicable law, the Company does not undertake any obligation to update publicly or to revise any of the included forward-looking information, whether as a result of new information, future events or otherwise, except as may be required by law. By its very nature, such forward-looking information requires the Company to make assumptions that may not materialize or that may not be accurate. This forward-looking information is subject to known and unknown risks and uncertainties and other factors, which may cause actual results, levels of activity and achievements to differ materially from those expressed or implied by such information.

The Exchange does not accept responsibility for the adequacy or accuracy of this release.

SOURCE Cognetivity Neurosciences Ltd

View original content: <http://www.newswire.ca/en/releases/archive/December2019/19/c0721.html>

%SEDAR: 00039034E

**For further information:** Email: [info@cognetivity.com](mailto:info@cognetivity.com); For media enquiries contact: Josh Stanbury, Email: [josh@sjspr.co.uk](mailto:josh@sjspr.co.uk)

CO: Cognetivity Neurosciences Ltd

CNW 09:00e 19-DEC-19