## Cognetivity Neurosciences Secures Critical Quality Standard Certification

- ISO 13485 certification for medical device development a critical prerequisite for global regulatory applications
- Certification confirms Cognetivity's internal quality systems comply with international standards as required for global medical device sales

VANCOUVER, March 13, 2019 /CNW/ - Cognetivity Neurosciences Ltd. (the "Company" or "Cognetivity") (CSE: CGN; FWB: 1UB; OTCQB: CGNSF) announced today that its wholly owned subsidiary, Cognetivity Ltd., has received ISO 13485:2016 certification for its Quality Management System (QMS) following review by Lloyd's Register Quality Assurance Limited (LRQA). ISO 13485:2016 is an internationally recognized quality standard specific to the medical device industry, and its award demonstrates Cognetivity's commitment to the highest level of medical device quality controls and to meeting customer and international regulatory expectations. The certification is a critical prerequisite to securing regulatory approval around the world, including European CE Marking and other regulatory certifications.

ISO 13485:2016 is the international standard for quality management systems for medical devices, under which an organization has shown via an in-depth auditing process that it is able to create medical devices and related services that meet applicable regulatory requirements. ISO is an independent, non-governmental, global organization that sets standards for compliance with industry best practices, and in May 2018 the US Food and Drug Administration (FDA) announced its intention to use ISO 13485:2016 as the new basis for its future quality system legislation.

"This ISO 13485 certification represents a key milestone on the path towards the full commercialization of our ICA tool. It illustrates our commitment to quality, our ability to reach the stringent criteria required for certification and further reinforces our dedication to ensuring our ICA platform is able to help as many people as possible in this critical area for healthcare." said Cognetivity CEO, Dr. Sina Habibi.

With this certification, Cognetivity will be in a position to be able to proceed towards a CE Mark application in Europe, a Health Canada Medical Device License Application for Canada and a Therapeutic Goods Association application for Australia once its clinical validation study is completed.

## About Cognetivity Neurosciences Ltd.

Cognetivity is a technology company developing a cognitive testing platform, the Integrated Cognitive Assessment (ICA) for use in medical and commercial 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 is developing the ICA, through planned clinical studies, to support market launches in North America and Europe.

For more information please visit – <u>www.cognetivity.com</u>

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.

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