



28 January 2020

## Cancellation of Mente Autism Device from Australian TGA Register

**Neurotech International Limited (ASX: NTI) (Neurotech or the Company)** announces that it has received notification from the Australian Government's Therapeutic Goods Administration (**TGA**) of the cancellation of the device from entry on the Australian Register of Therapeutic Goods (**ARTG or Register**) under the *Therapeutic Goods Act 1989 (Act)*, effective on 24 February 2020.

The TGA's decision follows a process whereby in response to a broad review of products with claims relating to bioresonance and bio-feedback, the Company in early 2019 and in December 2019 supplied extensive information in response to the TGA's requests, but has been unable to satisfy the TGA that the device complies with all "Essential Principles" under the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002 (Regulations)*.

Specifically, the TGA has informed Neurotech that the information and clinical evidence supplied by the Company with respect to the device, including excerpts of the clinical trial (The Treatment of Autism Spectrum Disorder With Auditory Neurofeedback: A Randomized Placebo Controlled Trial Using the Mente Autism Device - carried out by the Carrick Institute) has not been sufficient to substantiate compliance with the Regulations.

The Company has not received reports from the TGA in terms of adverse effects and does not consider that the cancellation amounts to a determination by the TGA that Mente is inherently unsafe to use.

### Effect of cancellation

The effect of the cancellation of the present registration (ARTG 287606) will be that the Mente Autism device cannot be sold or supplied as a Medical Device to help children on the autistic spectrum in Australia.

Cancellation of the Mente Autism device's registration under the Act is not anticipated to have any material effect on the Company's revenue and current operations as to date only a very limited number of Mente Autism devices have been sold in Australia. The Company will, however, need to reconsider its approach for marketing of the device in Australia.

Importantly, the cancellation does not affect the continued sale and marketing of the Mente Autism device in the European Union, the primary market for Mente at present. The Company recently passed a surveillance audit with the EU certified body and Mente retains its CE Medical Marking (CE 0426) certifying the device complies with European health, safety and environment protection requirements for the marketing of the device as a Medical product to help children on the autistic spectrum in the European Union. Additionally, the Company will continue to work on developing market opportunity in the USA under the FDA registration as a BioFeedback device.

This announcement has been authorised for release by the Company's Board of Directors.

For further information please contact:

Peter Griffiths

Managing Director - Neurotech International Limited

E: [peter.griffiths@mentetech.com](mailto:peter.griffiths@mentetech.com)

P: +356 99328532

---

### Neurotech International Ltd

ABN 73 610 205 402

Suite 5 CPC, 145 Stirling Highway

Nedlands, Western Australia 6009

[www.neurotechinternational.com](http://www.neurotechinternational.com)

-ends-

### **About Neurotech**

Neurotech International Limited is a medical device and solutions company incorporated in Australia and operating through its wholly-owned, Malta-based subsidiary AAT Research Limited. Neurotech's primary mission is to improve the lives of people with neurological conditions, with a vision of becoming the global leader in home-use and clinical neurotechnology solutions that are both accessible and affordable. Through flagship device Mente and its associated platform, Neurotech is focused on the development and commercialisation of technological solutions for the screening and treatment of symptoms associated with conditions such as autism.

Mente is the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

For more information about Neurotech and Mente Autism please visit:

<http://www.neurotechinternational.com>.

<http://www.mentetech.com>.