# Neurotech announces new direction for US market

- *Defers De Novo application for Mente Autism with US Food and Drug Administration*
- *Neurotech to establish network of clinicians and build on success of US clinical trial*
- *Enables earlier entry into US market – first shipment expected H1 CY2019*

**Perth, Australia & Malta** – *21 December 2018* – Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company") has announced a new strategy for US market entry which will focus on delivering Mente using partnerships with certified clinicians. This change will enable the Company to enter the market earlier than planned with Mente under registration as a device aimed at patients' wellbeing. First shipments are expected in H1 CY2019.

Following the successful US clinical trial result in July, as well as feedback received from clinicians and experts in the field, the Company has decided to build on this success by partnering with clinicians to collect more data and further validate Mente's use as a home-based therapy. The change in strategy means the Company will defer its current De Novo application with the US Food and Drug Administration (FDA).

Neurotech said it had several discussions with the FDA since submitting its De Novo application and the latter advised that the protocol design and data needed to be revised and expanded to meet the requirements for a De Novo application. They also recommended that the best option would be to work with them to update the protocol and create a new study in the US. While this decision will impact the Company's US market entry for Mente Autism, Neurotech said it welcomed the feedback and opportunity to work with the FDA to meet the requirements of a new study design.

Neurotech CEO Peter Griffiths said: "We have decided to shift our focus on US market entry. The Company's De Novo application is a valid step on our journey but is likely to take several years and significant resources to process.

"Given our current stage of development, combined with the successful US clinical trial results and advice from our US partners, we have decided to focus our resources on entering the US market under registration as a device aimed at improving patients' wellbeing. We are preparing plans to offer Mente's unique home-based therapy through certified clinics and clinicians."

Prof. Frederick R. Carrick, of the Carrick Institute and lead investigator of the US trial, said: "Interest in the publication of the results of the US trial has been phenomenal. Neurotech's plans to work directly with clinicians will not only help to gather more data on Mente and thus offer further opportunities for clinical research, but it will also enable clinicians with another important tool with which they can help their patients."

Neurotech will announce further details of its US strategy in the coming months, however, clinicians who are interested in signing up to use Mente as a complementary tool with their patients can do so via this link.

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**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 Autism and its associated platform, Neurotech is focused on the development and commercialisation of technological solutions for the diagnosis and treatment of such conditions, starting with autism.

Mente Autism is a clinical-quality EEG device that uses neurofeedback technology to help children with autism spectrum disorder. Designed for home use, it helps relax the minds of children on the spectrum which in turn helps them to focus better and engage positively with their environment.

For more information about Neurotech and Mente Autism please visit:

http://www.neurotechinternational.com.
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