



## Neurotech files pre-submission package with the US FDA

**Perth, Australia & Malta – 30 March 2017** – Neurotech International Limited (ASX: NTI) (“Neurotech” or “the Company”), developer of quality medical solutions in the neuroscience space, has filed a pre-submission package with the United States Food and Drug Administration (**FDA**) for Neurotech’s innovative neurofeedback device for children on the autism spectrum, Mente Autism.

Neurotech has requested a meeting with the FDA to work cooperatively on the regulatory and clinical plan to support FDA clearance of Mente Autism. The FDA’s Center for Devices and Radiological Health has confirmed receipt of the submission and Neurotech management expects the meeting to take place in the third quarter of 2017.

The pre-submission is a written request for feedback from the FDA, provided either as a formal written response or a meeting in which the feedback is documented. It is intended to allow applicants the opportunity to obtain targeted FDA feedback regarding product development, including planned non-clinical evaluations, proposed clinical study protocols or data requirements, prior to making a submission to the FDA.

Neurotech currently plans to market Mente Autism in the US as a Class II regulated device, supported by clinical data. An independent, randomised, double blind clinical study is currently being conducted by the Carrick Institute in Florida, USA.

“Filing the pre-submission package is a major step towards obtaining FDA clearance for Mente Autism, our innovative home-based neurofeedback therapy for children on the autism spectrum. The planned meeting with the FDA will provide us with feedback on our clinical and regulatory plan as well as clarify the requirements for us to market our technology in the US market,” said Neurotech CEO Wolfgang Storf.

### WORLD AUTISM DAY

In conjunction with World Autism Awareness Day on Sunday 2 April, Neurotech is undertaking marketing and public relations initiatives in Europe.

The activities will focus on Germanic speaking countries including Germany and Austria, aimed at creating awareness around Neurotech’s Mente Autism device and its ability to improve attention, communication and relaxation in children on the autism spectrum.

Neurotech has appointed Hamburg-based PapendorfPR to drive the public relations activities.

Running annually since 2009, World Autism Awareness Day is a day designated by the United Nations to promote international awareness of the need to help improve the quality of life of those with autism, so that they can lead full and meaningful lives as an integral part of society. It has evolved into a worldwide fundraising and awareness event, supported by various autism organisations.

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As part of promoting awareness, Neurotech's Mentetech website is also being updated with various articles of interest regarding autism, neurofeedback therapy and other news relevant to the Company. This can be viewed at: <http://www.mentetech.com/about-us/news/>.

For more information about Neurotech and Mente Autism please visit:

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

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

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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. For more information, visit: <http://www.neurotechinternational.com>.

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