# Neurotech

21 July 2021

## Phase I/II Clinical Trial Update

- NTI Clinical Trial progressing as planned.
- · Extensive medical data is being collected and psychological assessments being carried out.
- Planning is underway to map out Phase III registration.
- Clinical Trial is due to finish towards the end of calendar Q3 with final results available in Q4 2021.
- NTI is successfully building NTI/Dolce lead strain levels to maintain large stock volumes.

**Neurotech International Limited (ASX: NTI)** ("Neurotech" "NTI" or "the Company") is pleased to announce an update with respect to its Phase I/II open label clinical study in 20 children aged between 5-17 years with Autism Spectrum Disorder (ASD). The Study is being conducted under the guidance and supervision of A/Professor Michael Fahey, Head of Paediatric Neurology Monash Children's Hospital. This is the first time in the world that full-spectrum <0.3% natural THC medicinal cannabis strains are being assessed in ASD.

The clinical study is progressing as planned. Extensive medical data is being collected and psychological assessments being carried out throughout the program.

The study has been designed with strong rigour and robustness and as a result the Company has seen substantial support and interest from the hospital and clinical community. The Company is now in discussions with various clinical and development groups to pave the way forward with respect to Phase III clinical trials and product registration program.

Furthermore, the data collected by the Company will allow it to consider opportunities to achieve early near-term cashflows via the development, production and sale of an over the counter ("OTC") CBD product ("Registered Product").

Given the unique profile of the NTI/Dolce strains (having less than 0.3% THC) and subject to successful clinical trials, the Company is assessing an OTC (sold via pharmacy) neuro anti-inflammatory product which will target general health and well-being categories. \*Inflammation is now commonly accepted as the foundation or cause of many neurological illnesses. NTI/Dolce strains have demonstrated the ability to suppress and regulate neuro-inflammation in a range of pre-clinical studies and have been shown to be more effective than CBD alone.

Neurotech has also successfully scaled up production of NTI/Dolce lead strains with its partners Dolce Cann and CannaPacific Pty Ltd to ensure sufficient supply for the current study and enabling the Company to expand its pre-clinical program and to rapidly move to further human clinical studies.

Neurotech's Non-Executive Director, Professor Emeritus Allan Cripps AO commented:

"We are extremely pleased with the progress of our trial. There is a real need for new treatments for patients suffering from ASD and the potent neuro anti-inflammatory, neuroregulatory and neuro-modulatory activities of our NTI/Dolce strains will hopefully contribute to better clinical outcomes."

\*The Role of Inflammation in Neurological Disorders
Diana Degan 1, Raffaele Ornello 1, Cindy Tiseo 1, Antonio Carolei 1, Simona Sacco 1, Francesca Pistoia
Current Pharm Des: 2018;24(14):1485-1501.

Neurotech's Chairman, Mr Brian Leedman added:

"We are excited by the opportunities that this detailed study brings – potential short-term opportunities to create an OTC market product that would bring near-term revenues and longer-term development of a pharmaceutical product that could be a company-maker."

The clinical study is due to finish towards the end of calendar Q3 with final results available in Q4 2021.

#### **Ends**

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

#### **Further Information**

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#### **About Neurotech**

Neurotech International Limited is a medical device and solutions company conducting clinical studies to assess the neuro-protective, anti-inflammatory and neuro-modulatory activities of our proprietary NTI/Dolce cannabis strains. Neurotech is also commercialising Mente, 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 <a href="http://www.neurotechinternational.com">http://www.neurotechinternational.com</a>





NTI/Dolce strains grown under license at the CannaPacific facility in NSW and extracted oil used in clinical study.