

# Neurotech

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## Neurotech initiates Phase I/II Open Label Study in Children with Autism

### Highlights:

- World's first study to assess full spectrum medicinal cannabis containing little to no THC in children with ASD.
- Results will be used to plan out future Phase II/III studies.
- Safety and efficacy will be assessed in paediatric patients aged between 5-17 years.
- Study will be coordinated and managed using centralised medical databases systems.
- Interim results and study updates to be provided during study duration.
- Study will involve daily administration of NTI / Dolce FEN 164 delivered in a neutral tasting oil system.
- Study will measure standardised outcomes relating to behaviour, agitation, irritability and quality of life.
- Studies to date demonstrate that NTI/Dolce strains have potent neuro anti-inflammatory, neuro-regulatory and neuro-modulatory activities.
- NTI continues with further in vitro study research in respect to other neurological disorders as part of its ongoing research and development program.

**Neurotech International Limited (ASX: NTI)** ("Neurotech" "NTI" or "the Company") is pleased to announce the commencement of a 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 full-spectrum <0.3% THC medicinal cannabis strains will be assessed in ASD. NTI/Dolce lead strain (FEN 164) will assess key behaviours in ASD over 16 weeks including a 4-week washout period (no treatment).

This study plan follows the successful completion of a series of in vitro studies that demonstrated that the NTI/Dolce strains, with the newly discovered rarer cannabinoids CBDP and CBDB, have powerful, unique properties that extend beyond CBD alone in results that are summarised below:

- Reduced inflammation within the brain cells;
- Improve mitochondrial viability in the presence of an external toxic insult (glutamate);
- Increased cell health and viability in the presence of an external insult;
- More potency than CBD isolate alone in all tests – between 30% and 80%;
- Increased number of mitochondrial cells without any toxic insult;
- Have no negative effects on cell health and maintain cell viability;
- Demonstrate neuroprotective activity in the presence of insult.

Commenting on the Study, A/Professor Michael Fahey said,

***"It is exciting to undertake a properly planned and executed study on a novel CBD product. Many other studies do not have the rigor to ensure that the results are translatable to evidence based clinical treatments".***

NTI has commenced discussions with the TGA and relevant regulatory agencies for the therapeutic expansion and registration of these novel full spectrum plants. Studies have been designed to assess dose escalation, efficacy and a 4-week wash out period. All patients will be monitored and assessed by A/Prof Fahey and his team which comprise of senior autism / behavioural clinical psychologists. The Company's Mente device will also be assessed in combination with the NTI/Dolce medicinal cannabis strains.

***"This is a very exciting and novel approach to the treatment of ASD for which there is the need for***

***safe, effective therapies with no side effects that can improve a patient's quality of life,” said Brian Leedman, Chairman of Neurotech International. “Medicinal cannabis has the potential to provide this treatment, but only NTI/Dolce naturally derived strains offer full-spectrum CBDs with little to no THC, an important consideration when treating children”.***

#### **Authority**

This announcement has been authorised for release by the Board 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 <http://www.neurotechinternational.com>