

# Neurotech

15 February 2021

## PHASE ONE AND TWO CLINICAL PROGRAM UPDATE

**Neurotech International Limited (ASX: NTI)** ("Neurotech" or "the Company") is pleased to provide an update on its clinical study program.

As previously reported, Neurotech successfully completed 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.

The neuro-modulatory activity of CBD has been well characterised and documented over the last five years. Recent studies and discoveries have confirmed that the rarer cannabinoids (CBDP and CBDB) have wider - novel neuro-modulatory and neuro-protective modes of action when compared to CBD alone<sup>i</sup>. The discovery and research into these new cannabinoids offers an exciting new chapter in the field of medicinal cannabis, with the potential of offering a wider range therapeutic options to patients.

Since the successful in vitro findings, under the guidance of A/Professor Michael Fahey, the Company has been engaging with international clinical experts in the field of translational medicinal cannabis to design a phase I/II study to assess the safety and the efficacy of the novel NTI/Dolce strains in a paediatric population, along with the efficacy of the Mente device when used in combination with the novel NTI/Dolce medicinal cannabis strains. If successful, this combination of the cannabis strains and the Mente device has the potential to be a "world-first" in the management of neurological diseases.

Neurotech is on-track to initiate its phase I/II clinical program through Monash Children's Hospital toward the end of this current quarter.

The Company is in the process of developing a child friendly product delivery form for its NTI/Dolce cannabis strains. Working together with RMIT and the Victorian College of Pharmacy, prototypes are being developed which will be used in the upcoming clinical program. All regulatory documentation for program initiation is currently underway in line with TGA and hospital ethics requirements.

This study is intended to form the basis for larger future studies which will assess the efficacy of these strains in a broader patient population in respect of autism and other neurological disorders.

Concurrently the Company has been working with national and international regulatory experts to map out its preferred path forward regarding product development and registration for Australia and globally. The Company welcomes the recent TGA developments regarding the 'over the counter' sale of CBD products and notes that these clinical studies are one important step toward any approval to sell CBD products.

The study will be the first to assess the safety and efficacy of the newly discovered rarer cannabinoids CBDP and CBDB with regards to neurological disorders.

The NTI/Dolce full spectrum plants have demonstrated through in vitro testing to date an "entourage effect"<sup>ii</sup> and have very powerful properties in relation to suppressing and inhibiting inflammation in neuronal and microglial cells derived from the human brain.

NTI/Dolce full spectrum plants exhibited properties that are far more powerful and novel when compared to CBD alone. CBD products are currently the market leaders and considered to be the 'gold standard' in the medicinal cannabis field.

When compared in pre-clinical studies to Aricept and CBD alone, the Dolce/NTI strains demonstrated 30%

and 80% more potency respectively. Aricept is the leading therapy in the early treatment of Alzheimer's Disease and currently has annual sales of over \$1 billion USD<sup>iii</sup>.

These studies demonstrated that the DOLCE/NTI full spectrum strains:

- Reduced inflammation within the brain cells;
- Were able to improve mitochondrial viability in the presence of an external toxic insult (glutamate);
- Increased cell health and viability in the presence of an external insult;
- Were more potent than CBD isolate alone in all tests – between 30% and 80%;
- Increased the number of mitochondrial cells without any toxic insult;
- Do not have any negative effects on cell health and maintain cell viability;
- Demonstrate neuroprotective activity in the presence of insult.

Commenting on the commencement of the forthcoming clinical study, Brian Leedman, Chairman of Neurotech International said, ***“It is exciting to be able to conduct these first-in-human studies at Monash Children’s Hospital to assess the safety and efficacy of our cannabis strains in children with autism. Positive results will pave the way for larger studies to address the unmet need for effective treatments in broader neurological conditions”.***

### 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>

<http://www.mentetech.com>

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<sup>i</sup> Nature.com: A novel phytocannabinoid isolated from Cannabis sativa L. with an in vivo cannabimimetic activity higher than  $\Delta^9$ -tetrahydrocannabinol:  $\Delta^9$ -Tetrahydrocannabiphorol

<sup>ii</sup> The entourage effect is a mechanism where the various phytocompounds (“phyto” means plant) found in cannabis such as cannabinoids cooperate to attain a compounded effect – one that is greater than the sum of its parts

<sup>iii</sup> Researchgate.net database December 2012-2019

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