

NTI164 Clinical Program Update | Pivotal Paediatric Study in ASD

- NTI is conducting the world's first study using full-spectrum medicinal cannabis with less <0.3% THC (NTI164) in children with ASD.
- The study is designed to vigorously assess the safety and efficacy of NTI164 in a dose escalation regime as well as assess the behaviour, focus and cognitive related parameters using internationally validated neuro-psychological tools – completed and assessed under the supervision of internationally accredited neuro-psychologists.
- This is a pivotal study and will form the foundation for follow up studies in therapies relating to the treatment of a wide range of neuro disorders.
- An expanded pre-clinical program targeted at other neurological conditions where inflammation is a major contributing factor such as Multiple Sclerosis are progressing.
- Several provisional patents relating to the novel neuro-regulatory and anti-inflammatory properties of the NTI/Dolce medicinal cannabis strains nearing finalisation.

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

Neurotech is now in the process of mapping out Phase III – multi cohort registration studies in ASD to be conducted as a follow up study to the current Phase I/II study. The Phase III program is scheduled to commence in early calendar 2022 and, in addition to the potential formal registration of NTI164 for paediatric ASD treatment, the company will also consider other Neuro-Orphan Diseases to provide urgent medical therapy for rarer neuro-disorders and accelerate the registration and development process by working under the FDA: Orphan Disease Development Category and TGA Special Access Scheme Category B.

The clinical team are managing the complex COVID related situation which currently exists in Victoria by minimizing study disruptions caused by COVID imposed restrictions and expanding the online medical data and study collection portal. The clinical team are providing patients and families with all the necessary additional support and thereby minimising patient hospital visits to manage potential risks. At this stage, anticipated initial reportable results should be available in November. Outside of minor COVID related delays, the study remains on schedule and progressing as planned.

Commenting on the Study, Professor Michael Fahey said:

"This pivotal study is a world first and I am satisfied that we are progressing well given that the trial needs to be done in a rigorous and thorough way. I look forward to expanding this program multi-cohort registration studies in 2022. We are setting a platform to assess other complex neurological disorders beyond ASD"

As the ASD Phase I/II study continues, NTI is pleased to report on additional progress in respect of the following:

The Company continues to build its IP position over the novel neuro-regulatory and anti-inflammatory properties of the NTI/Dolce medicinal cannabis strains. The Company is in the process of filing several provisional patents relating to the novel neuro-regulatory and anti-inflammatory properties of the NTI/Dolce medicinal cannabis strains.

NTI has also strengthened its preclinical program. Working in collaboration with RMIT and Monash University, NTI is progressing a series of preclinical investigations in Multiple Sclerosis and related progressive neuro-inflammatory disorders with results expected shortly. Additional studies are underway in respect of neuro inflammatory conditions such as concussion, pain and cognitive enhancement.

Neurotech's Chairman, Mr Brian Leedman added:

"We look forward to releasing the results of our Phase I/II clinical study in ASD and preparations are well underway for the commencement of our pivotal Phase III registration study. The imminent IP filings together with the expanded pre-clinical work on neuro-inflammation in particular, position Neurotech as a class leading cannabinoid drug discovery company".



Authority

This announcement has been authorised for release by the Board of Neurotech International Limited.

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>