## ASX Announcement 12 May 2022



## **Key Development in Current Paediatric Autism Spectrum Disorder Study**

- At the demand of parents/caretakers, the Principal Investigator and HREC at Monash, the ASD study protocol is being modified to accommodate the ongoing treatment of study participants using NTI164
- Patient parents and caretakers have formally requested for the "wash out" period to be removed from the study protocol
- Patients will continue to receive treatment with NTI164 and be monitored and treated under the guidance of Prof. M. Fahey and the Neuro-psychology team at Monash Children's Hospital
- Study scheduled to progress to Phase II/III registration trial at Monash Children's Hospital

**Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company")** is pleased to announce important developments relating to the study protocol assessing NTI164 in children with Autism Spectrum Disorder (ASD).

Given the significant number of requests from patient's parents/caretakers, the Principal Investigator and Human Research Ethics Committee (HREC) at Monash Children's Hospital, the Company advises that the study protocol is being modified to accommodate the ongoing treatment of study participants using NTI164. NTI164 is the lead strain being used in the Company's world's first full-spectrum medicinal cannabis product (less than 0.3% THC) to be successfully trialled in children with ASD at Monash Children's Hospital in Melbourne.

The original study design was developed in line with similar study protocols whereby participants would undertake a wash out period, where they reduce and subsequently stop taking the trial treatment.

As a result of the positive impacts that the treatment is having on the children's 'overall functioning' (refer ASX Announcement dated 5 April 2022), patient parents and caretakers have requested that the "wash out" period be removed from the study protocol. This is based on the consensus that it will allow participants to continue to benefit from the trial treatment.

These patients will remain on the treatment and will continue to be monitored and treated under the guidance of Prof. M. Fahey and the Neuro-psychology team at Monash Children's Hospital. Data relating to safety and efficacy will be collected and available to support relevant regulatory filings.

Dr Alexandra Andrews, CEO of Neurotech International commented, "NTI is very pleased that the trial participants have elected to remain on the NTI164 treatment regimens and is providing additional product and resources during this period."

The Company is looking forward to announcing the phase I/II efficacy results next month and, subject to outcomes, moving forward with its Phase II/III program which is scheduled to commence in Q3/22.

## **Authority**

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

ABN: 73 610 205 402

ASX: NTI



**Further Information** 

Dr Alexandra Andrews aa@neurotechinternational.com +61 (0)405 339 788

Brian Leedman Chairman b.leedman@neurotechinternational.com +61 (0)41 228 1780

Media:

**Amalie Schreurs** White Noise Communications amalie@whitenoisecomms.com +61 (0)431 636 033

## **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 has submitted key provisional patents relating to the composition and use of NTI164 for the treatment of a range of neurological disorders including ASD. 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