

## Autism Phase I/II Patients Exceed NTI164 Treatment Beyond 90 Weeks

### Highlights:

- 11 paediatric autism spectrum disorder (ASD) patients initially enrolled in Neurotech's Phase I/II clinical trial have now completed 90 weeks of daily oral treatment with NTI164
- NTI164 continues to exhibit an exceptional safety and tolerability profile, with all patients showing stable blood chemistries and normal liver and kidney function
- Although no further quantitative efficacy analysis has been collected since week 52, caregiver and clinician reports remain positive with symptomatic improvement maintained at 90 weeks
- Longest ever study in ASD examining the safety of a broad spectrum cannabinoid drug treatment, NTI164.
- Data will inform future regulatory interactions and filings in ASD to ensure timely NTI164 development
- Neurotech on track to report Phase II/III ASD clinical trial data in late Q1 to early Q2 CY2024

**Neurotech International Limited (ASX: NTI)** ('Neurotech', 'NTI' or 'the Company') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, is pleased to provide an update on the progress of the 11 autism spectrum disorder (ASD) patients who were part of the Company's world-first Phase I/II clinical trial examining the daily use of Neurotech's proprietary broad spectrum cannabinoid drug therapy, NTI164 out to 52 weeks of treatments, as initially announced in March 2023.

All patients have now crossed 90 weeks of daily oral therapy with NTI164. Neurotech is pleased to report that NTI164 continues to exhibit an exceptional safety and tolerability profile, with all patients showing stable blood chemistries and normal liver and kidney function over 90 weeks. The Company has received qualitative feedback from parents/caregivers on their child's ASD, as quoted below.

**A parent of one paediatric participant who has continued treatment past 90 weeks** said "We are so privileged to be a part of a revolutionary study that has enabled our child to participate in everyday activities which would have been very stressful and almost impossible to do in the past. To be able to participate in school sports and camp is something we never imagined we could achieve. We are very grateful."

**A second parent of a patient on the extension study commented** "The impact of our son's autism has had a profound impact on our family unit. We have had to cut back on our career's, our social events, holidays and basic everyday activities. To be able to participate in a study that has not only enhanced our son's quality of life but has also improved our lives as a family unit is remarkable in every sense."

**Professor Michael Fahey, Head of the Paediatric Neurology Unit at Monash Medical Centre, Director of Neurogenetics and Chief Investigator of the NTI164 Phase I/II Trial** said "I am delighted with the progress of my patients under this long term extension to our original Phase I/II clinical trial, which sought to examine the safety and efficacy of NTI164 following 30 days of daily oral therapy. To have 11 patients still on treatment past 90 weeks is testament to the durable responses we have seen in our patients coupled with a remarkable safety profile of this intervention in Level 2 and 3 autism patients. We therefore eagerly await the results of the double-blind, placebo-controlled Phase II/III clinical trial to confirm these earlier clinical findings."

**Dr Thomas Duthy, Executive Director of Neurotech said** *"This landmark clinical trial continues to demonstrate the excellent durability of NTI164 and importantly no significant safety concerns have arisen beyond the original 52 week analysis undertaken and reported by Neurotech. In our view, this updated safety analysis underscores the potential for NTI164 as a long term, chronically administered therapeutic agent in the treatment of ASD without the safety and side effects observed in approved therapies that restrict certain behaviours, particularly aggression and irritability in paediatric patients. NTI164 has demonstrated in a statistical manner clinically significant improvements in standardised ASD scales relating to global improvement, severity of illness, socialisation and adaptive behaviour out to 52 weeks of treatment."*

#### **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 (ASX:NTI)** is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. Neurotech has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days, 20 weeks and 52 weeks of treatment with NTI164. The Company commenced Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in Q4 CY2022. Neurotech is also conducting additional Phase I/II trials in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with Rett Syndrome and Cerebral Palsy during CY2023. 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 [www.neurotechinternational.com](http://www.neurotechinternational.com).

#### **About the Phase I/II ASD Clinical Trial**

The clinical trial was a Phase I/II Open-Label Study to Evaluate the Safety and Efficacy of Orally Administered Full-Spectrum Medicinal Cannabis Plant Extract 0.08% THC (NTI164) in Children with Autism Spectrum Disorder (ASD).

For more information on the trial, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) Identifier **NCT05516407** or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: **ACTRN12621000760875**.