

## Neurotech Receives Additional HREC Approval in Autism

**Neurotech International Limited (ASX: NTI)** ('Neurotech', 'NTI' or 'the Company') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces Human Research Ethics Committee (HREC) approval to extend the Phase I/II clinical trial in autism spectrum disorder (ASD) by another 52 weeks in total.

This additional 52 week HREC extension for this trial was based on requests from the Company's Lead Investigator, patients and their caregivers, to continue to extend the duration of treatment for these patients.

**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 *"This second long-term extension to our core clinical program which commenced in mid-2022 and reported 52 week safety and efficacy data in March 2023 reflects the significant progress my patients have made, and their caregivers strong desire to continue treatment over the long term. The lack of side-effects with NTI164 and the significant clinical improvements we've observed in these patients necessitates a long-term treatment plan. We thank Neurotech for their continued support of our early study patients and we look forward to the results of our larger double-blind, placebo-controlled Phase II/III clinical trial in ASD."*

**Dr Thomas Duthy, Executive Director of Neurotech** said *"We thank the Monash HREC for this extension, which provides comfort to our Phase I/II trial participants that they are able to receive NTI164 therapy for an additional 52 weeks above existing approvals. We continue to focus our resources on completing the current Phase II/III ASD trial and remain on track to report the results of our Phase II/III ASD trial in late Q1 CY2024 to early Q2 CY2024."*

### 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**.