

Approval for Additional Phase I/II ASD Trial Extension

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, is pleased to announce Human Research Ethics Committee (HREC) approval has been secured to extend the Phase I/II Autism Spectrum Disorder (ASD) clinical trial (NTIASD1) beyond the 54 weeks of daily oral treatment with NTI164 for an additional six months on a patient specific basis.

The additional submission was predicated on Neurotech's commitment to the paediatric patients who have been recruited into the study and the strong desire of the Paediatric Neurology Unit at Monash Medical Centre, the trial's Principal Investigator Professor Michael Fahey and the family/caregiver's request for a continuation of treatment. Based on the approved HREC extension, individual patients can continue to receive NTI164 for an additional six months over the 54 week treatment period. This represents a total of 80 weeks or 1.5 years of daily NTI164 treatment, which will generate a substantial amount of additional safety data for Neurotech and enhance future regulatory submissions for additional trials in ASD or alternative paediatric neurological disorders including PANDAS/PANS¹ and cerebral palsy.

Dr Thomas Duthy, Executive Director of Neurotech said "We have demonstrated an unwavering level of support for our patients through the continued supply of NTI164 well beyond the original 28 day clinical trial, due to the exceptional clinical and safety results observed to date. We anticipate the results of the full 54 weeks of treatment to be available late Q1 CY2023, which we hope will confirm the long term durability of the improvements we have seen across a range of clinically accepted doctor, caregiver and patient assessments in ASD, coupled with no long-term safety concerns. The support we have had for this trial from the hospital, doctors and patients/caregivers has been nothing short of impressive and on behalf of Neurotech we are certainly appreciative of their role in helping to bring much needed safe and effective therapies for ASD to market, through robust clinical design and execution."

Authority

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

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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 and 20 weeks of treatment with NTI164. The Company has commenced a

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¹ Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS



Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD during Q4 CY2022. Neurotech plans to conduct 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 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 please visit <u>http://www.neurotechinternational.com</u>.

About NTI164

NTI164 is a proprietary drug formulation derived from a unique cannabis strain with low THC (M<0.3%) and a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. NTI164 has been exclusively licenced for neurological applications globally. Pre-clinical studies have demonstrated a potent anti-proliferative, anti-oxidative, anti-inflammatory and neuro-protective effects in human neuronal and microglial cells. NTI164 is being developed as a therapeutic drug product for a range of neurological disorders in children where neuroinflammation is involved.

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 <u>www.clinicaltrials.gov</u> Identifier **NCT05516407** or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: **ACTRN12621000760875**.

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