ASX Announcement

31 May 2023

Neurotech Granted Two Year Extension of NTI164 Treatment for Autism Trial Participants to Facilitate Commencement of Compassionate Use

Highlights:

- **Human Research Ethics Committee (HREC) clearance for an additional two years of daily oral treatment of NTI164 for Autism Spectrum Disorder (ASD) patients who participated in the Neurotech Phase I/II trial over 54 weeks + 6 months extension**
- **HREC approval until Q3 CY2025**
- **11 ASD patients will transition to compassionate use (SAS-B) program from Q3 CY2023**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces Human Research Ethics Committee (HREC) clearance that will allow 11 Autism Spectrum Disorder (ASD) patients who have continued daily oral NTI164 treatment beyond 1.5 years to remain on treatment for an additional two years. The extension will now facilitate clinical trial patients to be transitioned to a compassionate use program, specifically Special Access Scheme (SAS) Category B (SAS B) through Monash Medical Centre, with Neurotech continuing to collect periodic safety information under the HREC approval, providing further valuable long term data to Neurotech.

SAS B is an application pathway through which a registered health practitioner may apply to the Therapeutic Goods Administration (TGA) for approval to prescribe an unapproved drug product for a patient under their care. The applicant must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the Australian Register of Therapeutic Goods (ARTG) are not suitable for treatment of the patient. The SAS B program will apply specifically to NTI164 and only for those 11 ASD patients under the auspices of the treating clinician, notably 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.

Dr Thomas Duthy, Executive Director of Neurotech *said "We have previously reported the 52 week clinical results for NTIASD1 for our ASD study which showed outstanding clinical efficacy and safety for our oral formulation of NTI164. All 11 patients have requested to continue treatment with NTI164 for the foreseeable future, given the significant improvements seen in their clinical symptoms and excellent safety profile of our treatment over time. Neurotech will continue to make NTI164 available for these patients, while also collecting further safety information under our approved HREC extension. In addition, the Company will receive reductions on certain charges associated with pharmacy, clinician, and pathology costs from Monash Medical Centre under SAS B equating to a significant reduction in the overall cost of monthly drug product supply to these patients into the future."*

Dr Duthy continued *"We certainly thank Monash Medical Centre for the extended HREC approval and for their participation in this important initiative for our ASD patients who have seen their quality of life transformed by our clinical trial. In addition, we continue to recruit patients into our 54 patient Phase II/III ASD trial, also at Monash Medical Centre and remain committed to the continued clinical development of NTI164 in paediatric patients across a range of neurological disorders."*

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

Further Information
Dr Thomas Duthy
Executive Director
td@neurotechinternational.com
+61 (0)402 493 727

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 please visit http://www.neurotechinternational.com.

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