ASX Announcement

4 December 2023



Neurotech Receives HREC Approval to Extend Phase II/III ASD Trial to Adults

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) approval to extend the current Phase II/III clinical trial in Autism Spectrum Disorder (ASD) patients to allow for patients who turn 18 years of age to remain on treatment with NTI164 during the extension phase of the trial for up to 54 weeks of total treatment. The current HREC approval covers treatment with NTI164 in a paediatric population of ASD.

Dr Thomas Duthy, Executive Director of Neurotech International said "We are pleased to secure this additional HREC approval for NTI164 in this patient population. I am delighted with the progress of this large double-blind, placebo controlled clinical trial and we remain steadfastly committed to developing NTI164 as a first-line treatment for Level 2-3 patients with autism where the market need for new therapies remains significant. Importantly, with recruitment into the trial to complete during the current quarter, we are on track to report results during the first quarter of calendar year 2024 (Q3 FY24)."

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 has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD and 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 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 ASD Phase II/III Clinical Trial

NTIASD2 is a Phase II/III Double-Blind, Randomised and Controlled-to-Open-Label Study to assess the efficacy of NTI164 up to 20mg/kg/day on the severity of spectrum disorder (ASD) in up to 54 patients aged 2-17 years (inclusive). The primary endpoint of the trial is Clinical Global Impression-Severity (CGI-S), which reflects clinician's impression of severity of illness on a 7-point scale ranging from 1=not at all to 7=among the most extremely ill [Timeframe: Baseline, Week 12].

For more information on the trial, please visit the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number **ACTRN12622001398796** at: https://www.anzctr.org.au

T: +61 (8) 9389 3130 E: info@neurotechinternational.com W: neurotechinternational.com **ABN:** 73 610 205 402

ASX: NTI