Neurotech Completes Patient Recruitment in the Phase II/III ASD Clinical Trial

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today is pleased to announce the completion of patient recruitment of the Phase II/III NTIASD2 clinical trial for children with Autism Spectrum Disorder (ASD). The trial has recruited a total of 56 patients with Level 2 (requiring substantial support) and Level 3 (requiring very substantial support) autism. All patients were enrolled at the Paediatric Neurology Unit at Monash Medical Centre, through the trial's Principal Investigator Professor Michael Fahey, Head of the Paediatric Neurology Unit and Director of Neurogenetics.

Dr Thomas Duthy, Executive Director of Neurotech *said "We are delighted to have completed recruitment in this world first clinical trial, which seeks to confirm the therapeutic effects of our broad-spectrum cannabinoid therapy NTI164 as shown in a previous clinical trial, with this much larger randomised, double blind, placebo-controlled Phase II/III study. With the explosion in autism-associated costs under the Australian National Disability Insurance Scheme, there is an urgent need for new enabling treatments like NTI164, which has been shown to significantly improve adaptive behaviours and socialisation and improve these children's quality of life while reducing caregiver burden. The results of this trial will inform our discussions with the Therapeutic Goods Administration to understand our pathway to market approval in Australia as our first market opportunity, where the prevalence of autism is estimated at 1 in 50 across the population, representing a 40 fold increase in the last 20 years."*

The results of the NTIASD2 clinical trial are expected in Q1 CY2024 (Q3 FY24).

NTIASD2 is a randomised, double-blind, placebo-controlled, Phase II/III clinical trial that will recruit up to 54 patients with ASD to determine the efficacy and safety of NTI164 versus placebo. The study comprises an 8-week treatment period followed by an 8-week open-label maintenance period followed by a 2-week wash-out period. Participants who choose to continue receiving NTI164 beyond the duration of the study may do so for an additional 38 weeks. They will undergo the 2-week down-titration phase at the end of their extension phase.

The primary endpoint of the trial is Clinical Global Impression-Severity (CGI-S), which reflects a 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. Key Secondary Endpoints include Change in Vineland Adaptive Behaviour Scales, Third Edition (Vineland™-3), Change in Social Responsiveness Scale, 2nd Edition (SRS-2), Change in Clinical Global Impression Scale -Improvement (CGI-I), Change in Anxiety, Depression and Mood Scale (ADAMS) and safety as measured by full blood, liver and kidney analyses at defined time points.

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, 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