ASX Announcement

19 December 2022

Commencement of Phase II/III ASD Clinical Trial and Patient Randomisation

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 commencement of patient randomisation and the first patient successfully treated under the new Phase II/III NTIASD2 clinical trial for children with Autism Spectrum Disorder (ASD).

Dr Thomas Duthy, Executive Director of Neurotech *said "We are very pleased to have met this milestone so soon after receiving Human Research Ethics Committee (HREC) approval. The level of interest in this important clinical trial, under the supervision of Principal Investigator Professor Michael Fahey, has been overwhelming. NTIASD2 seeks to confirm the safety and efficacy of NTI164 in a larger patient population under a double-blind, placebo-controlled clinical trial design; the results of which are expected to confirm our earlier clinical trial, where patients continue to show improvement in their severity of illness after 32 weeks of daily oral treatment with NTI164, with minimal side-effects."*

Recruitment is anticipated to complete in 2H CY23. The trial will be enrolling children at the Paediatric Neurology Unit at Monash Medical Centre. The Company received HREC approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) on 17 November 2022.

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 and 20 weeks of treatment with NTI164. The Company will commence a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in 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 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

NTIADS2 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