ASX Announcement

3 May 2023

Neurotech Completes Recruitment in Phase I/II PANDAS/PANS Clinical Trial

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the completion of patient recruitment for the Phase I/II clinical trial of NTI164 in children diagnosed with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS). A total of 15 paediatric patients have now commenced treatment with NTI164.

Dr Thomas Duthy, Executive Director of Neurotech said *"We warmly congratulate the Co-Principal Investigators Professor Russell Dale and Professor Michael Fahey and their respective clinical teams on the very rapid enrollment into this important clinical trial in PANDAS/PANS patients. It is testament to the clinical interest in NTI164 as a treatment for certain paediatric neurological disorders characterised by persistent neuroinflammation and the evidence of benefit we have shown in our reported autism spectrum disorder trial. Neuroinflammation is well characterised in PANDAS/PANS, where approved drug therapies are lacking and clinical trials are desperately needed. We look forward to reporting the clinical efficacy and safety of NTI164 in these patients over the twelve week study period."*

Professor Russell Dale, Professor of Paediatric Neurology, University of Sydney and Children's Hospital at Westmead and Co-Principal investigator of the NTIPANS1 trial said, *"We are excited to be involved in this important clinical trial assessing the safety and efficacy of daily oral treatment of NTI164 in children with PANDAS/PANS, where treatment options are currently very limited and new therapies are urgently required. Our clinic has witnessed firsthand the devastating effects of this neurological disorder on patients and caregivers alike, and accordingly we believe the evidence supporting NTI164 in dampening neuroinflammation pathways in vitro, coupled with the safety and efficacy recently established in paediatric autism patients may translate to significant improvements in the clinical symptoms of PANDAS/PANS patients as part of this novel study. We now eagerly await this safety and efficacy data, given the rapid recruitment we have observed."*

As a result of the completion of recruitment, Neurotech now anticipates the top-line results of the NTIPANS1 trial will be available in Q3 CY2023.

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 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 PANS/PANDAS

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including Obsessive-Compulsive Disorder (OCD) and/or restrictive eating. Children may exhibit repetitive tic movements, become moody, irritable/aggressive and anxious and have difficulty with schoolwork. The cause of PANS is unknown in the majority of cases; however, the disorder is hypothesised to be triggered by infections, metabolic disturbances, and other inflammatory reactions. PANDAS is considered a subset of PANS.

About Neurotech PANDAS/PANS Phase I/II Clinical Trial

NTIPANS1 is a single-arm, open-label, Phase I/II clinical trial that will recruit 15 paediatric patients with a clinical diagnosis of moderate to severe PANDAS/PANS to determine the efficacy and safety of orally administered NTI164 in these patients. The primary endpoints of the trial are the change from baseline at twelve (12) weeks for the Revised Children's Anxiety and Depression Scale-Parent-rated (RCADS-P) score and Clinical Global Impression (CGI) of severity (CGI-S) and improvement (CGI-I). Secondary clinical endpoints include other gold-standard, validated assessment tools: Yale Global Tic Severity Scale (YGTSS), Children's Yale-Brown Obsessive-Compulsive Scale, Conners Scale and EQ-5D-Y. Other secondary endpoints will examine the Safety and Tolerability of orally administered NTI164 (at 5,10,15 and 20 mg/kg/day). The trial intends to enrol children at two centres within Australia; the Children's Hospital at Westmead and the Paediatric Neurology Unit at Monash Medical Centre. The Phase I/II clinical trial has been registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) under registration number: ACTRN12622001419752 or visit: https://www.anzctr.org.au