ASX Announcement

16 February 2023

First Patient Treated 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, has today been informed that the first patient has received treatment in 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).

Dr Thomas Duthy, Executive Director of Neurotech said *"We warmly congratulate Professor Dale and his clinical team at the Children's Hospital at Westmead for their involvement in this important new clinical trial of NTI164 in PANDAS/PANS. It is testament to the interest this novel clinical trial has generated that the first patient of our planned 15 patients has received treatment so soon after receiving human ethics approval. We continue to believe NTI164 has the potential to reduce the neuroinflammation associated with PANDAS/PANS, which is postulated to play a role in the pathogenesis in the majority of cases and noting neuroinflammation is one of the main triggers for neurodegeneration."*

Recruitment of the 15 patients is now anticipated to complete during Q1 CY2023, with results of the trial anticipated in 2H CY2023. The trial is now open for enrollment 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.

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