

Last Patient Completes Treatment in Neurotech Phase I/II PANDAS/PANS Clinical Trial

Key Points:

- Last patient last visit (LPLV) successfully completed at the Children's Hospital at Westmead under auspices of Professor Russell Dale
- All 15 patients who have now completed 12 weeks of treatment under the trial protocol have elected to continue to receive daily oral treatment with NTI164
- 3 patients have now turned 18 years of age and continue to receive NTI164 under revised HREC approval granted 30 May 2023
- Clinical trial results anticipated in Mid to Late September 2023

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the successful completion of the LPLV 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 successfully completed daily oral treatment with NTI164 over the initial 12 weeks of the trial with 100% of patients continuing to receive treatment under the extension phase (54 weeks) of the trial protocol. Results of the clinical trial are expected in Mid to Late September 2023.

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."

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 PANDAS/PANS

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>