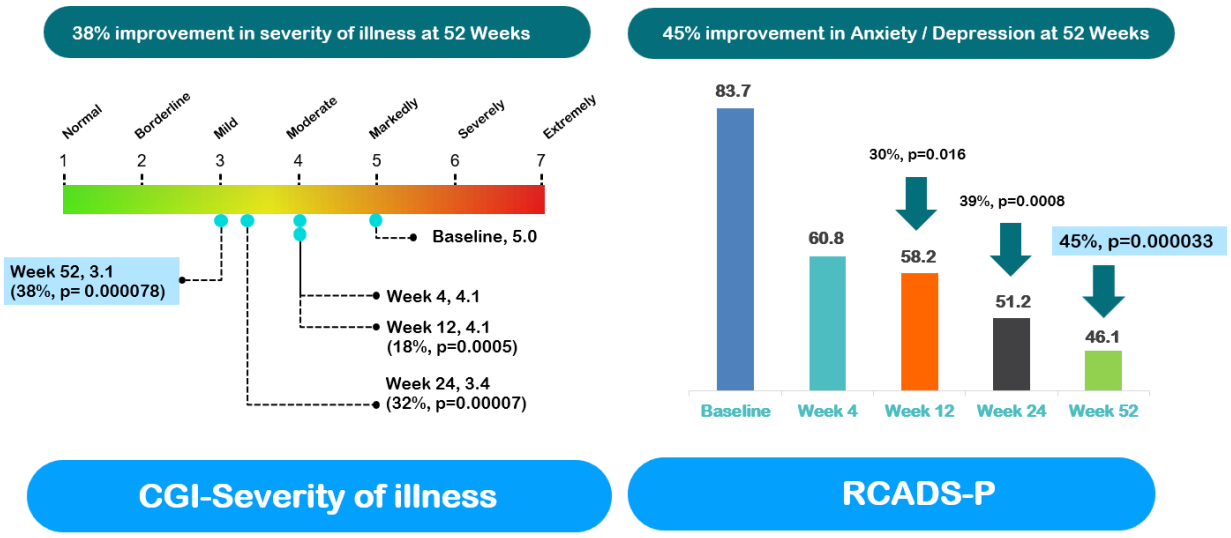
Neurotech Reports Continued Clinical Improvement in PANDAS/PANS Patients to 52 Weeks of NTI164 Treatment

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces a further clinical update on the open-label 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), which showed a continued improvements in patients' clinical symptoms to 52 weeks of daily oral treatment with NTI164.

PANDAS/PANS is a rare neurological disorder predominately in children characterised by an infection-triggered autoimmune response and associated neuroinflammation which results in a sudden, dramatic change in personality, displayed as obsessive-compulsive disorder (OCD), anxiety, tics or other abnormal movements and personality changes. There are no approved therapies for PANDAS/PANS, globally. Neurotech estimates the annual market for PANDAS/PANS is worth US$1.2 billion.[1]

Today, the Company is pleased to report that based on analysis undertaken of PANDAS/PANS patients who are currently being treated in the extension phase of the trial (representing 100% / 15 patients who commenced the trial), NTI164 daily use provided further significant improvements in the severity of their illness (**38% improvement** at 52 weeks versus baseline) and their anxiety and depression as measured by the Revised Child Anxiety and Depression Scale – Parent Version (RCADS-P; **45% improvement** at 52 weeks versus baseline). These results are highly significant and clinically meaningful, with children re-classified as mildly ill (versus markedly ill at baseline) with low severity of clinical anxiety/depression (versus high severity at baseline). Between the period of 24 weeks to 52 weeks, there was **no additional adverse events** recorded in any patients.

A caregiver of patient 008 said *"He is now building a miniature boat - this is something we could never even imagine. Prior to starting the treatment, he wasn't able to sit on his own for more than 10 mins. We are so grateful."*



A caregiver of patient 002 said *"We are so happy and grateful to be a part of this incredible program. She is able to focus throughout school. She is happy and content and so are we."*

Dr Thomas Duthy, Executive Director of Neurotech said *"The durable response we are seeing in our PANDAS/PANS patients is remarkable in the context of their baseline clinical symptoms immediately prior to commencing NTI164 therapy. When overlaid with the safety benefits, we believe NTI164 provides a therapeutic intervention well-suited in this patient population, where persistent or progressive neuroinflammation is consistently observed."*

Under an extension to the original Human Research Ethics Committee (HREC) clearance, the Company will be able to treat these patients for an additional 52 weeks (i.e. two years in total).

Clinical Global Impression (CGI)- is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders. CGI-S is a single-item, 7-point scale by clinicians designed to assess global impression of severity (1=normal, 7 = severely ill).

RCADS-P- is a 47-item parent-report questionnaire of youth anxiety and depression (a scale of anxiety, social phobia, panic disorder, OCD, and low mood, a score below 65 represents low severity, scores between 65-70 represent medium severity and are on the borderline clinical threshold, and scores above 70 represent high severity and are above the clinical threshold). This test is completed at the site.

Authority
This announcement has been authorised for release by the Board of Neurotech International Limited.

Further Information
Dr Thomas Duthy
Executive Director
td@neurotechinternational.com
+61 (0) 402 493 727

About Neurotech

Neurotech International Limited (ASX:NTI)) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders with a broad-spectrum oral cannabinoid drug therapy called NTI164. Neurotech has completed a Phase II/III randomised, double-blind, placebo-controlled clinical trial in Autism Spectrum Disorder (ASD) with clinically meaningful and statistically significant benefits reported across a number of clinically-validated measures and excellent safety. In addition, Neurotech has completed and reported statistically significant and clinically meaningful Phase I/II trials in ASD and Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS along with Rett Syndrome. Neurotech has received human ethics committee clearance for a Phase I/II clinical trial in spastic cerebral palsy.

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 was a single-arm, open-label, Phase I/II clinical trial that recruited 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 enrolled 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

[1] ASX Announcement 21 February 2024