# Phase II/III Autism Clinical Trial Shows Significant Improvements in Anxiety and Depression at 8 Weeks

**Highlights:**

- **Important secondary endpoint from Phase II/III autism spectrum disorder (ASD) clinical trial at 8 weeks was the child's change in Anxiety, Depression and Mood Scale (ADAMS)**
- **Statistically significant and clinically meaningful treatment effect in ADAMS total score shown, with children showing significant improvement from day 0 to week 8 (p<0.001)**
- **Approximately 40-50% of children with autism experience clinically significant levels of anxiety.[1] The prevalence of depression in autistic children has been estimated at 10-20%.[2]**
- **Children receiving NTI164 showed significant clinical improvements on top of existing anxiety/depression medications (62% of NTI164 pts were on such treatments at enrolment)**

**Neurotech International Limited (ASX: NTI)** ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces additional secondary endpoint data analysis following the release of clinically meaningful and statistically significant results from the 54-patient randomised, double-blind, placebo-controlled Phase II/III NTIASD2 clinical trial for children with Autism Spectrum Disorder (ASD).

On 17 April 2024 Neurotech reported the results of the NTIASD2 trial which met the primary endpoint of severity of illness improvement versus placebo, along with improvements in key secondary endpoints relating to clinical improvement, adaptive behaviours and socialisation.

The Company is pleased to report today the results of analysis from the eight (8) week measure relating to the child's change in Anxiety, Depression and Mood Scale (ADAMS) for the NTI164 arm versus placebo. ADAMS was a secondary endpoint of the trial. ADAMS is a caregiver-led scale that is designed to assess mood and anxiety symptoms and is particularly valuable in the autism population.

ADAMS produces a total score and 5 subscale scores: manic/hyperactive behaviour, depressed mood, social avoidance, general anxiety, and obsessive/compulsive behaviour. The ADAMS scale is useful for identifying mood and anxiety disorders in children with autism, who may have difficulty communicating their emotional states and is used in both clinical and research settings to track changes in symptoms over time and to evaluate the effectiveness of therapies like NTI164.

There was a marked treatment effect of NTI164 versus placebo to week 8 representing a -19.01 score improvement in the ADAMS scale, which is a clinically meaningful difference and statistically significant (**p<0.001, 95% confidence interval -25.0, -13.0**). In addition, NTI164 treatment resulted in improvements within the depressed mood (**p=0.004**), social avoidance (**p=0.008**), general anxiety (**p<0.001**) and obsessive/compulsive behaviour (**p=0.001**) subscales. There was no treatment effect of NTI164 on manic/hyperactive behaviour noted (**p=0.154**).

At commencement of the Phase II/III ASD trial, 62% of patients in the NTI164 arm were receiving treatment for their anxiety/depression and 43% of patients in the placebo arm. Between day 0 and the end of week 8, patients in the placebo arm saw a deterioration of 24% in their ADAMS result (+7.50) and for NTI164, there was a 39% improvement (-19.9) from baseline to the end of week 8.

***Dr Thomas Duthy, Executive Director of Neurotech*** *said "Significant improvements seen in these children's anxiety, mood and depression as measured by ADAMS is consistent with our previous findings in autism and reinforces our confidence in the utility of NTI164 as a chronically administered therapy in autism, where safe and effective therapies are urgently needed."*

NTIASD2 was a randomised, double-blind, placebo-controlled, Phase II/III clinical trial that recruited 54 patients with ASD to determine the efficacy and safety of NTI164 versus placebo. The study comprised 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.

**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 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 the ASD Phase II/III Clinical Trial**

NTIASD2 was 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 54 patients aged

2-17 years (inclusive). The primary endpoint of the trial was 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]. This endpoint was met, and a number of key secondary endpoints. 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

[1] White, S. W., Oswald, D., Ollendick, T., & Scahill, L. (2009). Anxiety in children and adolescents with autism spectrum disorders. Clinical Psychology Review, 29(3), 216-229.

[2] Lai, M.-C., Kassee, C., Besney, R., Bonato, S., Hull, L., Mandy, W., ... & Ameis, S. H. (2019). Prevalence of co-occurring mental health diagnoses in the autism population: a systematic review and meta-analysis. The Lancet Psychiatry, 6(10), 819-829.