PANS Clinical & Mechanistic Data Published in Leading Scientific Journal

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce the publication of clinical and mechanistic data for its proprietary drug NTI164 in the peer-reviewed journal *Neurotherapeutics*, the official journal of the American Society for Experimental NeuroTherapeutics.

The publication, titled "Medicinal cannabis plant extract (NTI164) modifies epigenetic, ribosomal, and immune pathways in paediatric acute-onset neuropsychiatric syndrome", is based on the results for a sub-cohort of patients within the Company's Phase I/II open-label clinical trial in Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)[1], together with a comprehensive multi-omics analysis of immune and epigenetic pathways[2].

Publication of NTI164 data in Neurotherapeutics, a high Impact Factor (6.9) peer reviewed scientific journal, further supports the scientific credibility of Neurotech's broader development program and the therapeutic potential of NTI164.

PANS is a severe, relapsing neuroimmune disorder characterised by abrupt-onset obsessive-compulsive disorder, anxiety, tics, cognitive decline and behavioural regression, often triggered by infection. There are currently no approved treatments.

The study evaluated NTI164 administered orally at 20 mg/kg/day over 12 weeks in 14 children with chronic, relapsing PANS. NTI164 was well tolerated, with no serious adverse events and only mild, self-limiting gastrointestinal or fatigue-related effects reported.

Clinically, NTI164 produced statistically significant improvements across all major disease domains for the sub-cohort of patients, including:

- Overall disease severity, with Clinical Global Impression – Severity (CGI-S) improving from 4.8 to 3.3 ($p = 0.002$)
- Anxiety and emotional dysregulation (RCADS-P, $p < 0.0001$)
- Obsessive-compulsive symptoms (CY-BOCS-II, $p = 0.0001$)
- Tics (YGTSS, $p < 0.0001$)
- ADHD symptoms (Conners, $p = 0.028$)
- Quality of life (EQ-5D-Y, $p = 0.011$)

Using integrated bulk RNA sequencing, single-cell RNA sequencing, proteomics, phosphoproteomics and DNA methylation profiling, the investigators showed that children with PANS exhibit widespread dysregulation of:

- Epigenetic machinery (chromatin structure, DNA methylation, transcription factors)
- Ribosomal and translational pathways
- Immune and inflammatory signalling networks

Following NTI164 treatment, these same pathways were significantly normalised, including restoration of ribosomal and mitochondrial function and broad immune modulation affecting cytokine production and defence signalling.

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Neurotech's Managing Director and CEO, Dr Anthony Filippis, said:

"This publication represents another key piece of validation for Neurotech and NTI164. As previously disclosed, the results of the Phase I/II clinical trial in PANS not only demonstrates meaningful clinical improvements in children with PANS, but also provide detailed molecular evidence that NTI164 modulates key immune and epigenetic pathways implicated in the disease.

"Having both clinical outcomes and mechanistic data reported in a high-quality, peer-reviewed journal strengthens the scientific foundation of NTI164 and supports its continued development across PANS and other neuroinflammatory paediatric indications."

Authority

This announcement was authorised for release by Anthony Filippis, Managing Director and CEO of Neurotech International Limited.

For further information contact us via info@neurotechinternational.com

About Neurotech

Neurotech International Limited (ASX:NTI) is a clinical-stage biopharmaceutical development company focused predominantly 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.

[1] The Phase I/II clinical trial results in PANS were released to ASX on 6 October 2023.
[2] The results of this analysis were released to ASX on 9 September 2024 and 15 November 2024.

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