

NTI164 HARMONY STUDY - Phase II/III Autism Data Accepted for Publication in Leading Scientific Journal *Neurotherapeutics*

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce that results from its Phase II/III clinical trial of NTI164 in children with Autism Spectrum Disorder¹ ("ASD") have been accepted for publication in the peer-reviewed journal *Neurotherapeutics*, the official journal of the American Society for Experimental Neurotherapeutics.

The manuscript, titled **"NTI164, a novel medicinal cannabis extract, improves core symptoms of autism spectrum disorder: Results from a double-blind, randomised, controlled trial (The Harmony Study)"**, reports the results of the Company's NTIASD2 clinical trial, a randomised, double-blind, placebo-controlled Phase II/III study evaluating the efficacy and safety of NTI164 in 54 children with ASD.

Acceptance by *Neurotherapeutics*, a high-impact, internationally recognised scientific journal, represents an important further validation of Neurotech's clinical development program. The manuscript has undergone independent peer review, providing external scientific scrutiny of the trial methodology, analysis and findings.

This publication adds to a growing body of peer-reviewed NTI164 data spanning multiple paediatric neurological indications, including clinical and mechanistic results from Neurotech's Phase I/II trial in Paediatric Acute-Onset Neuropsychiatric Syndrome ("PANS"), and earlier papers in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections ("PANDAS") and Rett Syndrome. Independent peer review across these programs continues to support the clinical outcomes and mechanistic rationale for NTI164.

The Harmony Study was a 54-patient randomised, double-blind, placebo-controlled Phase II/III clinical trial designed to evaluate the efficacy and safety of NTI164 in children aged two to 17 years with ASD.

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

"Acceptance of our Phase II/III autism data by Neurotherapeutics represents another important external validation of NTI164 and the quality of Neurotech's clinical development program."

"The Phase II/III study generated clinically meaningful and statistically significant results across a range of validated measures, supported by an excellent safety profile. Having these findings reviewed and accepted by a leading international scientific journal strengthens the evidence base for NTI164 and increases the visibility of our work among clinicians, researchers and potential partners."

Authority

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

For further information contact us via info@neurotechinternational.com

¹ Refer to ASX announcements dated 17 April 2024, 10 July 2024 and 18 July 2024 for further information on the results of the NTIASD2 clinical trials.

About NTI164

NTI164 is a proprietary, multi-constituent, GMP-grade standardised formulation containing CBDA-rich extracts and select minor cannabinoids. Preclinical and earlier clinical findings have demonstrated its potential to modulate neuroinflammatory signalling, immune dysregulation and upstream biological mechanisms implicated in neurodevelopmental disorders.

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, doubleblind, 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 III Clinical Study in ASD.

For more information about Neurotech please visit <http://www.neurotechinternational.com>.