Neurotech Doses First Patient in Phase 3 "Beyond Harmony" Autism Study

- **All sites initiated and first patient dosed in Neurotech's pivotal Phase 3 Beyond Harmony clinical study of NTI164 in Autism Spectrum Disorder (ASD)**
- **Multi-centre, randomised, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and tolerability of NTI164 in children with ASD**
- **Up to 200 patients planned for enrolment under an adaptive trial design**
- **Beyond Harmony builds on encouraging clinical evidence generated in Neurotech's earlier HARMONY Phase II/III study**
- **Significant unmet need for ASD sufferers with no existing medications available for the core behavioural symptoms**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce that the first patient has been dosed in its pivotal Phase 3 Beyond Harmony clinical study evaluating NTI164 in paediatric patients with Autism Spectrum Disorder ("ASD").

The dosing of the first patient formally commences Beyond Harmony and advances NTI164 into pivotal Phase 3 clinical development, marking a significant milestone toward the Company's objective of regulatory registration and commercialisation of NTI164 as a potential treatment for the core symptoms of ASD.

The Beyond Harmony study is a national multi-centre randomised, double-blind, placebo-controlled Phase 3 clinical study, with six sites across Australia (*Victoria, Queensland, New South Wales, Tasmania and Western Australia*). The study is statistically powered to evaluate the efficacy, safety and tolerability of NTI164 in children diagnosed with Autism Spectrum Disorder (ASD). The study will assess key behavioural and functional outcomes aligned with regulatory guidance, with a focus on addressing the core symptoms of ASD and the underlying neuroinflammatory pathways associated with the disorder.

A total of up to 200 patients are planned for enrolment under Beyond Harmony's adaptive trial design, positioning it as a substantial Phase 3 clinical study in children with Autism Spectrum Disorder (ASD). The study combines a large, appropriately powered patient population with a rigorous multicentre, randomised, double-blind, placebo-controlled design. The adaptive design allows for pre-specified modifications based on interim analyses, while maintaining the scientific and statistical integrity of the study.

Following recent media coverage of the upcoming trial (refer to the Company's website: https://neurotechinternational.com/news-and-media/), the Company has received significant interest from the community, with more than 300 enquiries from parents and caregivers seeking information about potential participation.

This strong level of interest provides the Company with confidence in its ability to recruit the required number of participants within the planned recruitment timeframe.

Beyond Harmony builds on the clinical evidence generated from Neurotech's earlier HARMONY Phase II/III study, a 54-patient, randomised, double-blind, placebo-controlled trial evaluating the efficacy, safety and tolerability of NTI164 in children aged two to 17 years with ASD.

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The Phase II/III HARMONY study generated clinically meaningful and statistically significant results across a range of validated measures, supported by an excellent safety profile. These data formed part of the clinical evidence presented in Neurotech's recently cleared Investigational New Drug (IND) application with the US FDA, and have been published in *Neurotherapeutics*[1], the official journal of the American Society for Experimental Neurotherapeutics, following independent peer review of the study methodology, analysis and findings.

Neurotech's Executive Chairman, Mark Davies, said:

"Dosing the first patient in Beyond Harmony is a significant milestone for Neurotech and marks the commencement of what is an important pivotal study for NTI164 in autism.

"We enter this Phase 3 program with a strong clinical foundation established through our previous HARMONY study, which demonstrated clinically meaningful and statistically significant benefits across multiple validated measures, together with an excellent safety profile.

"With the HARMONY clinical trial now published following independent peer review, we are pleased to advance NTI164 into Phase 3. Our focus is on successfully executing Beyond Harmony and progressing NTI164 toward regulatory registration as a new treatment option for children with ASD. Autism sufferers have a significant unmet therapeutic need with no established medication available that effectively treats autism's core behavioural symptoms."

Anyone who wishes to receive more information about participation in the trial should contact the company on **info@neurotechinternational.com**

Authority

This announcement was authorised for release by the Board of Neurotech International Limited.

For further information contact us via info@neurotechinternational.com

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, 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] https://doi.org/10.1016/j.neurot.2026.e01033

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