ASX Announcement

17 March 2026

Neurotech initiates first clinical site for Phase 3 "Beyond Harmony" trial

- First clinical site initiated and open for recruitment
- Phase 3, multi-centre, randomised, placebo-controlled design
- Evaluating NTI164 in paediatric patients with Autism Spectrum Disorder (ASD)
- Targeting core symptoms and underlying neuroinflammatory mechanisms
- Additional sites expected to initiate in the coming months

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce the initiation of the first clinical site for its Phase 3 "Beyond Harmony" trial evaluating NTI164 in paediatric patients with Autism Spectrum Disorder (ASD).

The first site to be activated is Monash Children's Hospital, one of Australia's leading paediatric medical and research facilities. The site is now open for patient screening and recruitment following receipt of all required regulatory approvals.

The Phase 3 Beyond Harmony trial is a multi-centre, randomised, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and tolerability of NTI164 in children diagnosed with ASD. The study will assess key behavioural and functional endpoints aligned with regulatory guidance, with a focus on addressing core symptoms of ASD and associated neuroinflammatory pathways.

One hundred and fifty patients are planned for enrolment under the adaptive trial design. The design permits pre-specified modifications based on interim analyses while maintaining scientific and regulatory integrity. The trial is appropriately statistically powered and conducted in accordance with applicable regulatory guidelines and requirements.

In advancing this pivotal Phase 3 program, the Company is working closely with a group of international clinical and regulatory experts to support study expansion, global alignment and execution of its broader development strategy. Additional clinical sites are expected to be initiated in the coming months as the study progresses.

The initiation of Monash Children's Hospital represents a significant milestone in Neurotech's clinical development program and an important step toward potential regulatory registration and potential commercialisation of NTI164.

Anthony Filippis, CEO and Managing Director, commented:

"The initiation of our first Phase 3 site is a major milestone for the Company and for families affected by ASD. Beyond Harmony is designed to rigorously evaluate NTI164 in a well-controlled setting, and we look forward to progressing recruitment across multiple centres."

The initiation of the first site comes following Neurotech's recent announcement (2 February 2026) of HREC approval to commence the Beyond Harmony Phase 3 study.

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 III Clinical Study in ASD.

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

Forward Looking Statements

This announcement includes forward-looking statements, including forward-looking statements relating to the future operation of the Company. These forward-looking statements are based on the Company's expectations and beliefs concerning future events. Forward-looking statements are necessarily subject to risks, uncertainties and other factors, many of which are outside the control of the Company, which could cause actual results to differ materially from such statements. The Company makes no undertaking to subsequently update or revise the forward-looking statements made in this announcement to reflect the circumstances or events after the date of this announcement. There is no guarantee that the Phase 3 study will be successful or that NTI164 will receive regulatory approval. You are strongly cautioned not to place undue reliance on forward-looking statements.