ASX Announcement

2 February 2026

Neurotech International

Approval received for NTI164 Phase 3 Clinical Study in ASD

- **Human Research Ethics Committee approval secured to commence Neurotech's Beyond Harmony Phase 3 clinical study of NTI164 in ASD Levels 2 and 3.**
- **Study is designed to support regulatory submissions for NTI164 in Australia (TGA) and the United States (FDA).**
- **The Phase 3 design is informed by Neurotech's prior ASD studies showing statistically significant, clinically meaningful improvements across multiple symptom domains and caregiver-reported quality-of-life benefits[1], published in a peer-reviewed journal[2].**
- **Trial to be led by Professor Michael Fahey with a network of satellite clinical sites.**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce that it has received approval from a Human Research Ethics Committee (HREC) to commence its Beyond Harmony Phase 3 clinical study, evaluating NTI164 in individuals with autism spectrum disorder (ASD) Levels 2 and 3.

The HREC approval represents a critical regulatory and strategic milestone for Neurotech, enabling the initiation of clinical activities for the pivotal Beyond Harmony Registration Study, including site activation and participant recruitment. This study is a cornerstone of Neurotech's clinical and commercial strategy, designed to generate the high-quality data required to support regulatory submissions for NTI164 in both Australia and the United States. A successful execution of this study is expected to advance NTI164 toward a market authorisation pathway, underpinning Neurotech's long-term commercialisation objectives and global market entry strategy in ASD.

The Phase 3 study has been rigorously designed based on robust data generated from Neurotech's prior clinical studies of NTI164 in ASD. These earlier studies demonstrated statistically significant and clinically meaningful improvements across multiple core ASD symptom domains, alongside consistent improvements in caregiver-reported quality-of-life measures. The study design has been carefully informed by these outcomes to ensure clinical relevance, methodological robustness, and regulatory alignment.

Neurotech is now advancing NTI164 into a pivotal registration pathway to support potential submissions to the Therapeutic Goods Administration (TGA) in Australia and the US Food and Drug Administration (FDA).

The Beyond Harmony Phase 3 study will be conducted under the leadership of Professor Michael Fahey, Principal Investigator, a leading expert in paediatric neurology and neurodevelopmental disorders. Professor Fahey will be supported by a group of Co-Principal Investigators, with a network of satellite clinical sites to be activated across Australia and progressively into the USA.

The study will be conducted in accordance with Good Clinical Practice (GCP) guidelines and all applicable regulatory and ethical requirements for both TGA and FDA product registration.

Neurotech expects to commence study initiation activities, with further updates to be provided to the market as the Company continues to expand across Australia and USA.

Dr Anthony Filippis, Managing Director and CEO of Neurotech said: "This HREC approval is a major regulatory milestone for Neurotech and the penultimate step in advancing NTI164 into a pivotal, Phase 3 clinical program for ASD Levels 2 and 3. Building on the strong and clinically meaningful outcomes demonstrated in our earlier studies, it is most noteworthy that Beyond Harmony has been designed to support future regulatory submissions in both Australia and the United States. We now look forward to

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commencing study initiation activities as we progress site activation and participant recruitment across our Australian clinical network."

Authority

This announcement was authorised for release by the Board 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] Refer to Neurotech's ASX releases dated 10 July 2024, 18 July 2024, 17 March 2023, 22 July 2022, and 8 July 2022.
[2] Refer to Neurotech's ASX release dated 24 March 2025.

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