US FDA clears IND for NTI164, advancing global registration and commercialisation strategy

Highlights

- US FDA clears Neurotech's Investigational New Drug (IND) application for NTI164
- IND clearance provides Neurotech with the opportunity to initiate its US clinical development program
- Establishes a formal US clinical development pathway to support potential future FDA registration
- The potential US clinical program is designed to complement Neurotech's pivotal Australian Phase 3 "Beyond Harmony" trial, creating an integrated global registration strategy
- Supports Neurotech's global commercialisation strategy and strategic partnering opportunities

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 US Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) submission for NTI164.

The IND clearance authorises Neurotech to commence its proposed clinical development program for NTI164 in the United States and represents a major regulatory milestone for the Company. The IND submission included the Company's chemistry, manufacturing and controls (CMC), non-clinical and clinical information supporting the proposed clinical and development program.

Should the Company elect to commence clinical development in the United States, the study to be conducted under the FDA-cleared IND will be a comprehensive population pharmacokinetic (PopPK) program. The program has been strategically designed to complement the Company's Australian Phase 3 "Beyond Harmony" trial, which is intended to generate pivotal efficacy and safety data for NTI164 in paediatric patients with ASD. The Phase 3 results are expected to form an important component of the global clinical evidence package supporting future regulatory submissions, while the US PopPK study would generate vital pharmacokinetic data to support dose characterisation and product registration initiatives. The Australian Phase 3 trial and the proposed US IND program are expected to generate an integrated efficacy, safety, pharmacokinetic and regulatory data package to support Neurotech's global development, registration and commercialisation strategy for NTI164.

Separately, Neurotech continues to engage proactively with the Australian Therapeutic Goods Administration (TGA) to ensure alignment of its Australian and US regulatory strategies. The Company is using its interactions with both the FDA and TGA to progress the global development pathway for NTI164 and the potential use of clinical data across multiple regulatory jurisdictions.

The Australian Phase 3 clinical trial, the proposed US IND program and ongoing regulatory engagement with both the FDA and TGA are expected to generate a comprehensive and integrated efficacy, safety, pharmacokinetic and regulatory evidence package, supporting Neurotech's global development, registration and commercialisation strategy for NTI164.

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Beyond its regulatory significance, the IND clearance represents an important milestone in the development of NTI164 and supports the Company's broader commercialisation strategy. Combined with the Company's recently strengthened US intellectual property portfolio, including the Notices of Allowance for key US patent applications[1], Neurotech is continuing to build a differentiated and well-protected asset with increasing strategic value. These milestones support the Company as it continues discussions with potential strategic partners and progresses its development, regulatory and commercialisation strategy.

Neurotech CEO and Managing Director, Anthony Filippis, commented:

"FDA clearance of our IND application is a major milestone for Neurotech and marks the formal establishment of our US clinical development pathway for NTI164.

This clearance represents an important regulatory milestone for Neurotech and reflects the progress and maturity of our overall development program. Importantly, the FDA has completed its review of our CMC-, non-clinical and clinical data package in relation to the IND.

This clearance enables us to commence clinical development activities in the United States. Together with our ongoing Australian Phase 3 trial, the data generated under the FDA-cleared IND is expected to create an integrated clinical and regulatory evidence package for NTI164, supporting the Company's global development, registration and commercialisation strategy."

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.

[1] Refer to ASX announcement released on 2 July 2026.

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.