NTI164 demonstrates favourable long-term safety profile in GLP non-rodent study

- **Favourable safety findings:** 90-day GLP toxicology study showed NTI164 was well tolerated with no mortality or dose-limiting toxicities.
- **Supports long-term dosing potential:** Demonstrated tolerability across all dose levels, including the highest administered dose of 216mg/kg/day.
- **Supports ongoing regulatory preparation:** Data strengthens the IND/TGA-enabling safety package for future clinical and registration activities.
- **No clinically meaningful adverse events:** No meaningful impacts on body weight, blood markers, or general health; mild effects were reversible.
- **No CNS safety concerns identified:** Additional FDA-guided brain assessments found no neurological safety concerns.

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce positive results from a 90-day GLP repeat-dose oral toxicity study of its lead drug candidate NTI164, conducted in a non-rodent species (Beagle dogs).

The positive results support the long-term dosing potential of NTI164 and strengthen the Company's IND/TGA-enabling safety package, required to support further clinical and regulatory activities required under US FDA and Australian TGA registration guidelines. The study was conducted in accordance with US FDA Good Laboratory Practice (GLP) requirements.

The new toxicology results demonstrated a favourable safety and tolerability profile across all dose levels tested, with no mortality or dose-limiting toxicities observed at any stage of the study. NTI164 was well tolerated at the highest administered dose of 216 mg/kg/day – representing approximately ten times the highest prescribed human dose evaluated to date in completed studies – administered twice daily over a 90-day period.

Importantly, there were no clinically meaningful adverse effects on body weight, food consumption, hematology, coagulation parameters, or general clinical observations throughout the dosing phase.

Any treatment-related findings identified at higher dose levels were mild in nature and reversible, with full recovery observed following a 14-day non-dosing period. All animals completed the planned dosing schedule with no treatment-related early terminations, and no progressive, irreversible, or life-threatening toxicities were identified.

Following consultation with the US FDA, through Type C and Type D meeting interactions, additional central nervous system-focused safety assessments were incorporated into the study, including enhanced brain sectioning and detailed analysis. These expanded evaluations did not identify any safety concerns, further supporting the favourable safety profile of NTI164 and reinforcing confidence in its continued clinical development.

Dr Anthony Filippis, Managing Director and CEO of Neurotech said: "Demonstrating long-term safety is one of the most important milestones in drug development. These results provide additional non-clinical safety data for NTI164 and support its development as a potential chronic therapy for neurological and neurodevelopmental disorders. This study also strengthens our safety package for future regulatory interactions."

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Authority

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

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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.