Neurotech Receives Ethics Approval to Commence Human PK Study

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, is pleased to announce the receipt of Human Research Ethics Committee (HREC) approval for the Company's planned pharmacokinetic (PK) study in healthy human adult participants to be conducted at CMAX Clinical Research, Adelaide, South Australia.

Dr Thomas Duthy, Executive Director of Neurotech said *"We are pleased to secure this important HREC approval, which now allows us to commence this PK study of NTI164. Although we have demonstrated long term safety and efficacy of NTI164 in paediatric patients across three separate neurological disorders, a PK study is a requirement for global health regulators, including the US Food and Drug Administration as part of an Investigational New Drug (IND) approval and the Australian Therapeutic Goods Administration as part of the necessary documentation to fulfill the requirements under an accelerated provisional application pathway. The study is expected to commence during the current quarter with results in Q1 CY2025. In parallel, we are currently conducting repeat-dose toxicity studies across two animal species, which we also expect to complete during Q1 CY2025 and also represents an important requirement for regulators."*

The PK study will generate important clinical data on the metabolism and excretion of NTI164 in an adult human population. This study will use two biological matrices (blood (plasma) and urine), collected at various time points. This study will be split into 2 parts, Part A and Part B. In both Parts, NTI164 will be delivered orally, twice daily, at a dose of 20mg/kg/day. In both Parts, blood and urine samples will be collected before the first dose of NTI164. Four participants will receive a 20mg/kg of NTI164 split into two doses of NTI164 approximately 12 hours apart (Part A), followed by eight participants who will receive NTI164 for seven consecutive days (Part B) using the same regimen as Part A.

Authority
This announcement has been authorised for release by the Board of Neurotech International Limited.

Further Information
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About Neurotech

Neurotech International Limited (ASX:NTI)) is a clinical-stage biopharmaceutical development company focused predominately 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.

About NTI164

NTI164 is a proprietary drug formulation derived from a unique cannabis strain with low THC (M<0.3%) and a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. NTI164 has been exclusively licenced for neurological applications globally. Pre-clinical studies have demonstrated a potent anti-proliferative, anti-oxidative, anti-inflammatory and neuro-protective effects in human neuronal and microglial cells. NTI164 is being developed as a therapeutic drug product for a range of neurological disorders in children where neuroinflammation is involved.