All Phase I/II Rett Syndrome Patients to Receive NTI164 Treatment for a Total of 52 Weeks

Key Points:

- **All 14 Rett Syndrome patients (100% of trial participants) to receive NTI164 for a total of 52 weeks under the extension phase of the Phase I/II clinical trial (NTIRTT1)**
- **Neurotech has secured Human Research Ethics Committee (HREC) clearance for this extension**
- **Neurotech expects the results of the NTIRTT1 clinical trial in late Q1 to early Q2 CY2024**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today is pleased to announce the extension of the Company's Phase I/II clinical trial investigating the use of NTI164 in female Rett Syndrome patients and an additional HREC approval.

Dr Thomas Duthy, Executive Director of Neurotech International said *"The extension phase to 52 weeks of daily oral treatment with NTI164 was approved by Westmead's Human Research Ethics Committee under the clinical trial protocol. It is certainly pleasing that under the supervision and care of Associate Professor Carolyn Ellaway at The Children's Hospital at Westmead that all patients and their families have elected to continue treatment with NTI164 for a period of one year. We eagerly await the clinical findings from this world-first cannabinoid drug therapy trial in Rett Syndrome over the coming weeks."*

Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls, with incidence of one in 10,000 female live births. The prevalence is approximately 15,000 girls and women in the US and 350,000 globally.[1] The market is estimated at over US$2 billion annually.[2]

Authority
This announcement has been 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 predominately on paediatric neurological disorders. Neurotech has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days, 20 weeks and 52 weeks of treatment with NTI164. The Company has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD, and

[1] https://reverserett.org/about-rett-syndrome/
[2] https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside

completed a Phase I/II trial in Rett Syndrome and in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS. In addition, 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.

About Rett Syndrome

Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls compared to boys (mostly fatal within one year of birth), with incidence of approximately 1 in 10,000 female live births across all racial and ethnic groups worldwide. According to the Rett Syndrome Research Trust, the prevalence is approximately 15,000 girls and women in the US and 350,000 globally.

Rett syndrome is characterized by typical early normal development between 7-18 months after birth, followed by a slowing of development, loss of functional use of the hands, distinctive hand movements along with difficulty walking, communicating, irritability and seizures. There is currently no cure for Rett Syndrome and no approved therapies. Current treatments only address symptoms and provide support that may improve movement, communication and social participation into adulthood.

About NTIRTT1

The NTIRTT1 Phase I/II clinical trial will examine the effects of daily oral treatment of NTI164 and is targeting the recruitment of 14 Rett Syndrome patients initially. The primary endpoint at 12 weeks of treatment is the change in Clinical Global Impression Scale-Improvement (CGI-I). Key secondary endpoints include the Rett Syndrome: Symptom Index Score (RTT-SIS), Rett Syndrome Behaviour Questionnaire (RSBQ), RTT- Clinician Domain Specific Concerns – Visual Analog Scale (RTT-DSC-VAS), Communication and Symbolic Behaviour Scales Developmental Profile™ Infant-Toddler Checklist (CSBS-DP-IT Social), Impact of Childhood Neurological Disability Scale (ICND), RTT Caregiver Burden Inventory (RTT-CBI), Overall Quality of Life Rating of the Impact of Childhood Neurological Disability Scale (ICND-QoL) and improvement in the three domains of the Clinical Global Impression Scale – Severity (CGI-S), Severity of Illness, Global Improvement and Therapeutic Effect.

The Phase I/II clinical trial has been registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) under registration number: **ACTRN 12623000563662**.