

## First Patient Treated in Phase I/II Rett Syndrome Clinical Trial

**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 first patient has been enrolled and treated in the Company's Phase I/II clinical trial investigating the use of NTI164 in female Rett Syndrome patients.

**Dr Thomas Duthy, Executive Director of Neurotech International said** "On behalf of Neurotech we warmly congratulate our Principal Investigator Associate Professor Carolyn Ellaway, on commencing this important trial in Rett Syndrome which seeks to provide initial evidence on the safety and efficacy of NTI164 in this patient population. Following on from our successful presentation at the 2023 International Rett Syndrome Scientific Meeting in Tennessee, there is a need for safer and more effective therapies that target the persistent neuroinflammation associated with this rare neurological disorder. Recent corporate activity in the Rett Syndrome therapeutic space highlights to us the significant opportunity ahead for the Company in developing NTI164 for this patient population."

The Phase 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 preliminary (top-line) results of the trial are anticipated in Q1 CY2024.

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.<sup>1</sup> The market is estimated at over US\$2 billion annually.<sup>2</sup>

### 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. 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 commenced Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in Q4 CY2022. Neurotech is also conducting additional Phase I/II trials in Paediatric Autoimmune

<sup>1</sup> <https://reverserett.org/about-rett-syndrome/>

<sup>2</sup> <https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside>

Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with Rett Syndrome and Cerebral Palsy during CY2023. Neurotech is also commercialising Mente, the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

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 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 trial will be an open-label, exploratory study, over 16 weeks of treatment with NTI164 at the maximum tolerated dose or 20mg/kg/day. 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.

If successful, the Company will follow with a 14-week double-blind, randomised, placebo-controlled Phase II in 34 participants to determine further efficacy and safety, which will be subject to a second HREC filing and approval. The Phase II clinical trial has been registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) under registration number: **ACTRN 12623000563662**.