Neurotech to Launch Phase II Clinical Trial in Rett Syndrome

Highlights:

- **New Phase II clinical trial of daily oral NTI164 in females aged 5-20 with Rett Syndrome at two prestigious centres within Australia**
- **Submission to HREC for study protocol expected prior to the end of Q1 CY2023**
- **Rett Syndrome is an orphan disease with no cure and an annual market opportunity estimated at over US$2 billion[1]**
- **Strong clinician interest in this new application of NTI164**
- **Aligns with Neurotech's strategic focus on rare paediatric neurological disorders characterised by persistent neuroinflammation**
- **Second Phase II clinical trial launched in a rare paediatric neurological disorder in last six months; deepening pipeline and value**
- **HREC/TGA approval anticipated in Q2 CY2023, trial commencement 2H CY2023 and initial results in 1H CY2024**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the launch of a new clinical program in Rett Syndrome, comprising an upcoming filing for Human Research Ethics Committee (HREC) approval and thereafter, the commencement of a Phase II clinical trial investigating the use of NTI164 in female patients. The trial will be conducted across two centres in Australia with Co-Principal Investigators Dr Giuliana Antolovich, Department of Neurodevelopment & Disability, Royal Children's Hospital and Professor Michael Fahey, Head of the Paediatric Neurology Unit at Monash Medical Centre, Director of Neurogenetics.

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.[2]

Dr Thomas Duthy, Executive Director of Neurotech International said *"We have carefully examined the design and subsequent results of several late-stage Phase III clinical trial results in Rett Syndrome[3], which has provided invaluable information relating to important regulatory endpoints that have now been proven as acceptable to global regulators, notably the US Food and Drug Administration, with the very recent approval of DAYBUE™ (trofinetide). This drug was developed by Neuren Pharmaceuticals and Acadia Pharmaceuticals. We believe the neuroprotection shown by NTI164 with improvements in neuronal function and strong anti-inflammatory effects in brain-derived neuronal and microglial cells could translate to improved clinical outcomes in Rett Syndrome patients. When overlaid with NTI164's excellent safety profile, this new clinical focus in Rett Syndrome*

[1] https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside
[2] https://reverserett.org/about-rett-syndrome/
[3] Neuren Pharmaceuticals (ASX:NEU), Anavex Life Sciences Corporation (NASDAQ: AVXL)

where only one recently approved therapy now exists and the global market potentially worth over US$2 billion annually, will allow Neurotech to further diversify its clinical pipeline and drive shareholder value."

The proposed Phase II clinical trial (which may be subject to change by HREC) will examine the effects of daily oral treatment of NTI164 and is targeting the recruitment of approximately 15 Rett Syndrome patients initially. The proposed primary endpoints at 12 weeks of treatment are the Rett Syndrome Behaviour Questionnaire (RSBQ), Clinical Global Impression Scale-Improvement (CGI-I) and CGI-severity of illness (CGI-S). Key secondary endpoints include safety, adverse events and measures associated with hand function, motor skills, communication and quality of life. In addition, the trial will analyse the effects of NTI164 on a range of biomarkers associated with neuronal function and neuroinflammation in Rett Syndrome. If successful, the Company will follow (under the same HREC approval), with a 14-week double-blind, randomised, placebo-controlled Phase II in 34 participants to determine further efficacy and safety.

Neurotech anticipates HREC approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence the Phase II trial during Q2 CY2023, with patient recruitment to commence in 2H CY2023. The preliminary results of the trial (n=15) are anticipated in 1H CY2024.

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 and 20 weeks of treatment with NTI164. The Company has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD during Q4 CY2022. Neurotech plans to conduct additional Phase I/II trials in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with cerebral palsy and Rett Syndrome 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.