ASX Announcement

24 September 2024

Upcoming Presentation of Rett Syndrome Phase I/II Clinical Data at the 9th World Rett Syndrome Congress

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces an upcoming presentation by Professor Carolyn Ellaway, Principal Investigator of the Neurotech Phase I/II Rett Syndrome Clinical Trial, Senior Staff Specialist, The Children's Hospital at Westmead, Sydney Children's Hospital Network at the 9th World Rett Syndrome Congress on the Gold Coast, 2-5 October 2024.

The presentation titled "*A novel full-spectrum medicinal cannabis-derived clinical trial in Rett syndrome*" will be held on **Friday, 4 October at 8:50 am AEST** followed by a discussion of emerging therapies in Rett Syndrome.

For more information and to register for the conference, visit: rettworldcongress.org

Neurotech is anticipating a response from the US Food and Drug Administration (FDA) on the Company's filed Orphan Drug Designation request for NTI164 in Rett Syndrome before December 2024.

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 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.

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 one approved therapy in the United States. 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 examined the effects of daily oral treatment of NTI164 with 14 Rett Syndrome patients initially. The trial was 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 Behaviour Questionnaire (RSBQ), Rett Syndrome: Symptom Index Score (RTT-SIS), 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 Clinical Global Impression Scale – Severity (CGI-S).

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