Expert PANDAS/PANS Advisory Group Established Following Productive TGA Meeting

Highlights:

- **TGA meeting provided guidance on Neurotech's PANDAS/PANS orphan development program following strong clinical results to 52 weeks, with non-binding advice also sought on a provisional registration pathway in Australia for NTI164**
- **A provisional registration application, if submitted and ultimately approved, could save up to two years of development for NTI164, with the overall process taking ~12-18 months**
- **TGA provisional registration application criteria and pathway for NTI164 is under active development and represents an accelerated registration option for NTI164 in Australia**
- **Neurotech expects to formalise its preferred clinical development plan and which neurological disorder it selects for a provisional application pathway (PANDAS/PANS, Rett, autism) following further key discussions with its regulatory and clinical advisors in early Q3 CY2024**
- **Following the productive TGA meeting, Neurotech has now established an international panel of leading PANDAS/PANS clinicians to build expert global consensus and drive awareness of this rare neurological disorder where effective treatments are desperately needed**

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**') a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the establishment of an internationally recognised expert advisory group to provide strategic advice to the Company for children diagnosed with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS).

The advisory group establishment follows initial feedback from the Australian Therapeutic Goods Administration (TGA) on the potential regulatory pathway(s), including provisional registration, available for Neurotech to consider in Australia for NTI164 in PANDAS/PANS, following strong initial Phase I/II clinical trial results observed at 12 weeks (primary endpoint) along with 24- and 52-week data in 15 paediatric patients.

Professor Russell Dale, Professor of Paediatric Neurology, University of Sydney and Children's Hospital at Westmead and Co-Principal investigator of the Neurotech PANDAS/PANS clinical trial will coordinate a team of global PANDAS/PANS experts, namely:

- **Professor Jennifer Frankovich**, Department of Pediatrics - Division of Allergy, Immunology & Rheumatology, Stanford Medicine. The Stanford Immune Behavioral Health Clinic was established in 2012 and is the first multi-disciplinary PANS clinic in the world.

- **Adj Assoc Prof Terrence Thomas**, Head Neurology Service & Senior Consultant Head at KK's Women's and Children's Hospital and Singapore General Hospital, Singapore.

The group of PANDAS/PANS experts will commence a Delphi process, which is widely used to achieve expert consensus during the development of rare or orphan drugs and includes input into regulatory processes including clinical trials and guidelines for decision making in clinical practice. The advisory group is expected to expand to include a leading European-based Key Opinion Leader in PANDAS/PANS in due course.

The establishment of the advisory group follows on from a productive pre-submission meeting with the TGA, where Neurotech requested and received non-binding guidance on the Company's planned clinical and regulatory development for NTI164 in PANDAS/PANS from the TGA. This included further insights into potential provisional application criteria for rare/orphan paediatric disorders such as PANDAS/PANS, along with clinical and non-clinical requirements. Professor Dale provided expert input into the diagnostic and treatment criteria for PANDAS/PANS to the TGA as part of the meeting.

A provisional approval pathway allows sponsors to apply for time-limited provisional registration on the Australian Register of Therapeutic Goods (ARTG). It provides access to certain promising new medicines where the TGA has made an assessment that early availability of the treatment outweighs the risk inherent in the fact that additional data are still required. The pathway provides a formal and transparent mechanism for expediting registration of promising new medicines in Australia with preliminary clinical data for sponsors and TGA business areas.

If granted, a provisional registration can save up to two years of development and a provisionally registered prescription medicine may be able to receive reimbursement via the Pharmaceutical Benefits Scheme (PBS) through a Category 1 filing and based on a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC).

PANDAS/PANS is a rare neurological disorder predominately in children characterised by an infection-triggered autoimmune response and associated neuroinflammation which results in a sudden, dramatic change in personality, displayed as obsessive-compulsive disorder (OCD), anxiety, tics or other abnormal movements and personality changes. There are no approved therapies for PANDAS/PANS, globally. Neurotech estimates the annual market for PANDAS/PANS is worth US$1.2 billion.[1]

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 PANDAS/PANS

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including Obsessive-Compulsive Disorder (OCD) and/or restrictive eating. Children may exhibit repetitive tic movements, become moody, irritable/aggressive and anxious and have difficulty with schoolwork. The cause of PANS is unknown in the majority of cases; however, the disorder is hypothesised to be triggered by infections, metabolic disturbances, and other inflammatory reactions. PANDAS is considered a subset of PANS.

[1] ASX Announcement 21 February 2024