ASX Announcement

29 January 2024

Neurotech Receives HREC Approval to Commence Phase I/II Cerebral Palsy Trial

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence a Phase I/II clinical trial investigating the use of NTI164 in paediatric patients with Spastic Diplegia Cerebral Palsy (Spastic CP) the most common form of CP, representing up to 80% of cases.

CP is the leading cause of childhood disability. Approximately 750,000 children and adults in the United States have CP. In Australia, there are approximately 34,000 persons living with CP. The market is estimated to grow to US$4.3 billion annually by 2030[1].

The Phase I/II trial is proposed to be a single-arm, open-label clinical trial that will recruit up to 14 paediatric patients with a clinical diagnosis of Gross Motor Function Classification System (GMFCS) severity of 2-3, non-ambulant Spastic CP patients to determine the efficacy and safety of NTI164 in these patients from baseline to twelve (12) weeks of treatment with NTI164. The trial intends to enrol patients at Monash Medical Centre. The primary endpoint of the trial is the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD©) Questionnaire, which evaluates caregivers' perceptions of health-related quality of life (HRQOL) and caregiver impact in children with CP. Secondary endpoints include safety and the effect of Nti164 on pain, sleep, seizure frequency, dystonia (involuntary muscle contraction) and spasticity.

The Lead Investigator of the trial is Professor Michael Fahey, Head of the Paediatric Neurology Unit and Director of Neurogenetics at Monash Medical Centre, Victoria, Australia. Professor Fahey has significant experience with NTI164 having led both Neurotech's Phase I/II and Phase II/III clinical trials in autism.

Dr Thomas Duthy, Executive Director of Neurotech International said *"We are pleased to have received HREC clearance for this important clinical trial of NTI164 in children with spastic CP. Although there are a variety of drug therapies used in the treatment of spastic CP, they are often associated with sedation, confusion, memory loss, and attention deficits. For first-line treatment with oral Baclofen the actual evidence of efficacy remains somewhat subjective and not necessarily supportive of widespread use in spastic CP.[1] Accordingly, we see NTI164 as potentially a new breakthrough treatment as part of the clinical armamentarium to treat CP spasticity more effectively noting improvements in gross motor function, increased participation at a social level and comfort are considered important treatment goals to improve the overall quality of life of the individual."*

The Phase I/II clinical trial will be registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) under registration number in due course.

The Company anticipates commencing the Phase I/II trial in 1H CY2024.

Authority

This announcement has been authorised for release by the Board of Neurotech International Limited.

[1] https://www.emergenresearch.com/industry-report/cerebral-palsy-treatment-market

Neurotech International Ltd
Suite 5 CPC, 145 Stirling Highway
Nedlands, Western Australia 6009

T: +61 (8) 9389 3130
E: info@neurotechinternational.com
W: neurotechinternational.com

ABN: 73 610 205 402
ASX: NTI

Further Information
Dr Thomas Duthy
Executive Director
td@neurotechinternational.com
+61 (0)402 493 727

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 and 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 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 Cerebral Palsy

According to the Centers for Disease Control and Protection, Cerebral palsy (CP) is a group of disorders that affect a person's ability to move and maintain balance and posture. CP is the most common motor disability in childhood. CP is caused by abnormal brain development or damage to the developing brain that affects a person's ability to control his or her muscles. There are four main types of CP: Spastic CP (80% of cases), Dyskinetic CP (6% of cases), Ataxic CP (6% of cases) and Mixed CP (balance of cases). Common classes of medicines used to treat Spastic CP include Muscle Relaxants (Antispasmodics) including Baclofen/Dantrolene and Benzodiazepines (Diazepam).

[1] Navarrete-Opazo AA, Gonzalez W, Nahuelhual P. Effectiveness of Oral Baclofen in the Treatment of Spasticity in Children and Adolescents With Cerebral Palsy. Arch Phys Med Rehabil. 2016 Apr;97(4):604-618. doi: 10.1016/j.apmr.2015.08.417. Epub 2015 Aug 28. PMID: 26321489.