ASX Announcement

17 June 2024



Phase I/II Autism Patients Meet Two Year Daily NTI164 Treatment Milestone

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces that level II and level III Autism Spectrum Disorder (ASD) patients who participated in the Company's world-first Phase I/II clinical trial of the broad-spectrum cannabinoid drug therapy NTI164 have crossed over two (2) years of daily oral treatment. There were no reportable serious adverse events or adverse events recorded from 90 weeks¹ to the 2-year milestone. Importantly, no patient has dropped-out due to safety or reversal in their clinical improvements that would warrant withdrawal from treatment. The results continue to reinforce NTI164 as an attractive, long term therapy for autism.

Dr Thomas Duthy, Executive Director of Neurotech said "Today marks an important milestone for Neurotech with our 11 level II or level III ASD patients who originally participated in the Company's first clinical trial of NTI164 now having been on daily oral treatment with NTI164 for two years. We once again thank Professor Fahey and his team at Monash Medical Centre for their continued support of this ground-breaking clinical trial. The initial positive results of this trial have been the catalyst for further R&D investment by Neurotech which has now delivered strong clinical benefits in a further Phase II/III ASD study and additional clinical benefits in Phase I/II trials in PANDAS/PANS² and Rett Syndrome without compromising patient safety. All three of these neurological disorders lack safe and effective therapies and accordingly represent a significant commercial opportunity for Neurotech as we develop our core NTI164 asset."

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 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

¹ See ASX release dated 7 February 2024

² Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS



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 the Phase I/II ASD Clinical Trial

The clinical trial was a Phase I/II Open-Label Study to Evaluate the Safety and Efficacy of Orally Administered Full-Spectrum Medicinal Cannabis Plant Extract 0.08% THC (NTI164) in Children with Autism Spectrum Disorder (ASD).

For more information on the trial, please visit <u>www.clinicaltrials.gov</u> Identifier **NCT05516407** or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: **ACTRN12621000760875**.

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