ASX Announcement

19 January 2023

Neurotech Granted FDA Pre-IND Meeting for NTI164 in Autism Spectrum Disorder

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the US Food and Drug Administration (FDA) has approved the Company's request for a pre-Investigational New Drug Application (pre-IND) Type B meeting to be held on 15 March 2023 (US time).

The purpose of the meeting is to seek FDA feedback in relation to the Company's chemistry/manufacture/control (CMC) package, along with non-clinical requirements and the proposed clinical developmental program for NTI164 in Autism Spectrum Disorder (ASD). The outcome of the meeting is expected to better inform the Company's planned future IND submission to undertake a clinical trial of NTI164 in the US.

Dr Thomas Duthy, Executive Director of Neurotech said *"In collaboration with our advisors, the Company has spent considerable time and effort in optimising our regulatory package for the FDA meeting and we eagerly await their feedback on our development plans for NTI164. We believe the controls we have put in place for drug product manufacture and the strong evidence of safety and efficacy we have demonstrated in our ASD patients, which now extends beyond 50 weeks of daily treatment with NTI164, will be important considerations for our upcoming meeting. We are certainly pleased the FDA has approved the Company's pre-submission request and now afforded us this opportunity to meet with them in such a timely manner."*

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 will commence a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in 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 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.