ASX Announcement

15 September 2022

Autism Spectrum Disorder Phase I/II Clinical Trial Update

Highlights:

- **ASD patients continue to receive daily doses of NTI164, up to a maximum 54 weeks with further safety and efficacy data analysis conducted after 20 weeks of daily treatment with NTI164**
- **20 week results expected in late Q3 to early Q4 CY2022**
- **20 week data to include additional longer term assessments, including Vineland™-3 – a leading outcome measure for ASD clinical trials**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today provides an update on the open-label extension of the Phase I/II clinical trial in children with Autism Spectrum Disorder (ASD), conducted under the guidance of Professor Michael Fahey, Head of Paediatric Neurology at Monash Children's Hospital in Melbourne.

As announced to ASX on 8 July 2022[1], after 28 days of treatment with NTI164, 93% of patients (n=14) showed symptom improvement relating to the severity of illness with a statistically significant and clinically meaningful change in a gold-standard assessment tool, Clinical Global Impression of Severity of Illness (CGI-S) shown (p=0.027). In addition, NTI164 was well-tolerated with no serious adverse events recorded across all doses tested (5, 10, 15 and 20 mg/kg/day) and no changes were noted in blood analysis or liver function tests.

The lack of any safety issues coupled with positive therapeutic effects of NTI164 across a range of behaviour, focus and related cognitive parameters using validated neuro-psychological tools resulted in the study being granted Human Research Ethics Committee (HREC) approval to continue for a further 54 weeks with additional safety and efficacy assessments over that time.

Neurotech anticipates the results of the 20 week data analysis to be available in late Q3 to early Q4 CY2022. In addition, Neurotech expects to report additional analysis between 28 days and 20 weeks on patients using the Vineland™-3 outcome measure, which was a secondary endpoint of the study. Vineland™-3 is internationally recognised as a leading instrument for supporting the diagnosis of intellectual and developmental disabilities in ASD; specifically adaptive behaviour. Adaptive functioning, which are skills people need to function independently at home, at school and in the community is an important factor in predicting long-term outcomes for people with ASD. Improving adaptive abilities in patients is therefore a desirable treatment goal.

Dr Thomas Duthy, Executive Director of Neurotech said *"We are eagerly anticipating the consolidated results at 20 weeks for those patients who continued to receive daily treatment with NTI164 and remain part of the open-label extension of this important Phase I/II clinical trial. This data will provide deeper clinical insights into longer term treatment with NTI164, where patients are receiving their individualised maximum tolerated dose for a significantly longer period than the sequential weekly treatments of escalating concentrations of NTI164 to the primary outcome measures established at just 28 days of treatment. Such data will be a key module in our future submissions with government regulators including the Therapeutic Drug Administration in Australia and the US Food and Drug Administration to potentially undertake a trial in the US under an Investigational New Drug application."*

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 is currently conducting a world-first clinical trial to assess the potential application of NTI164 for the treatment of Autism Spectrum Disorder (ASD). Results of the Phase I/II clinical trial indicated that 93% of participants had notable improvements relating to the severity of illness with no serious side effects. The next step will be initiation of a Phase II/III clinical trial to further assess the long-term safety and efficacy of NTI164, with the potential to lead to drug registration. 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 from Dolce Cann Global (Ltd), 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 neuroinflammatory orphan diseases in children.

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 www.clinicaltrials.gov Identifier **NCT05516407** or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: **ACTRN12621000760875P**.

[1] https://www.investi.com.au/api/announcements/nti/e770be5c-85e.pdf