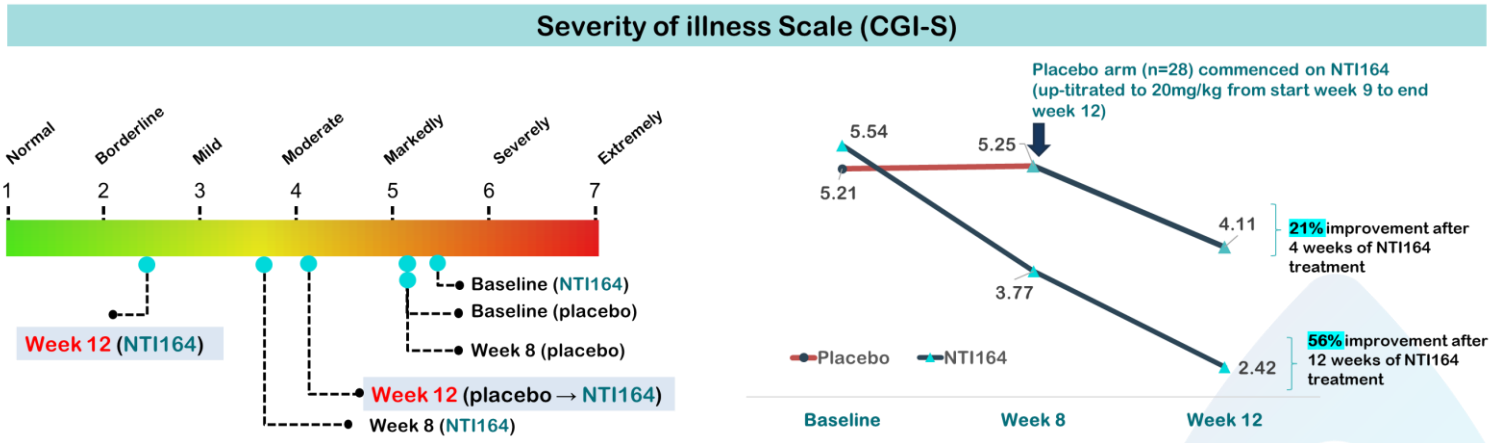
Significant further benefits for Phase II/III Autism patients after 12 weeks of NTI164 therapy

Highlights:

- **An analysis undertaken by Neurotech on Autism Spectrum Disorder (ASD) patients participating in the Phase II/III clinical trial demonstrates further beneficial improvements, as measured by the clinician via the Clinical Global Impression - Severity of Illness Scale (CGI-S)**
- **For patients receiving NTI164 (n=26) there was a 36% improvement from week 8 to week 12 and 56% improvement from baseline (Day 0) to week 12**
- **Overall, ASD symptoms present but barely noticeable at 12 weeks for recipients receiving NTI164 (borderline ill) versus significant impairments observed at baseline (markedly ill)**
- **Patients who initially received placebo (n=28) then received NTI164 after week 8 onwards and showed immediate positive clinical benefits (21% improvement) after just 4 weeks of treatment**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces that following strongly positive results for the double-blind, placebo-controlled Phase II/III NTIASD2 clinical trial for children with Autism Spectrum Disorder (ASD), a further analysis has been carried out on the effect of NTI164 in children who were receiving placebo for 8 weeks and then crossed-over to NTI164 from the end of week 8 (beginning of week 9) to week 12 per the trial protocol. In addition, CGI-S information was analysed at week 12 for those patients who were initially enrolled in the NTI164 arm of the trial.

Neurotech continues to see further significant improvements in ASD patients who received NTI164 following the primary endpoint analysis at 8 weeks as previously reported.[1] At 12 weeks, NTI164 patients showed a mean CGI-S score of 2.42, representing a 56% improvement from baseline (CGI-S: 5.54) with children re-classified under this scale as borderline ill (CGI-S score of 2.42). In general, for a CGI-S score of 2, ASD symptoms are present but only just noticeable and not significantly impairing for the child. This is a very significant improvement at 12 weeks for those patients on NTI164 relative to their baseline score of 5.54 (markedly ill), and versus 8 weeks (mildly ill, CGI-S 3.77). Markedly ill patients show significant impairments, needing substantial, consistent support to manage daily life.



For the placebo group, patients were unblinded at 8 weeks and commenced NTI164 therapy at the low dose being 5mg/kg per day in week 9, up to 20mg/kg or the maximum tolerated dose per day in week 12. Despite just four weeks on therapy commencing with a low dose of NTI164, these patients showed initial positive improvements in their clinical scores with CGI-S improving 21% to 4.11 (moderately ill) from 5.21 (markedly ill). These results are very encouraging.

Dr Thomas Duthy, Executive Director of Neurotech *said "We were curious to understand the immediacy of the benefits conferred by NTI164 in the context of an unblinded clinical trial where patients previously receiving placebo were crossed-over to receive progressively higher amounts of NTI164 over 4 additional weeks prior to entering the 52 week extension part of the trial. The results once again confirm the benefits conferred are drug-related with a rapid clinical onset of improvement. Moreover, patients who have received NTI164 for 12 weeks in total continued to improved following the primary analysis at 8 weeks, so much so their symptoms are barely noticeable. In general this means substantial lifestyle improvements for the patient and their caregivers, which makes us very proud to be supporting these clinical trials in autism."*

There was no serious adverse events or adverse events related to NTI164 observed from the commencement of week 9 through to week 12 in all 54 children. Five participants did record adverse events relating to headache, viral infections and a single urinary tract infection (not deemed NTI164 related).

NTIASD2 was a randomised, double-blind, placebo-controlled, Phase II/III clinical trial that recruited 54 patients with ASD to determine the efficacy and safety of NTI164 versus placebo. The study comprised an 8-week treatment period followed by an 8-week open-label maintenance period followed by a 2-week wash-out period. Participants who choose to continue receiving NTI164 beyond the duration of the study may do so for an additional 38 weeks. They will undergo the 2-week down-titration phase at the end of their extension phase. A diagram of the trial design is shown in **Appendix 1**.

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

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 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.

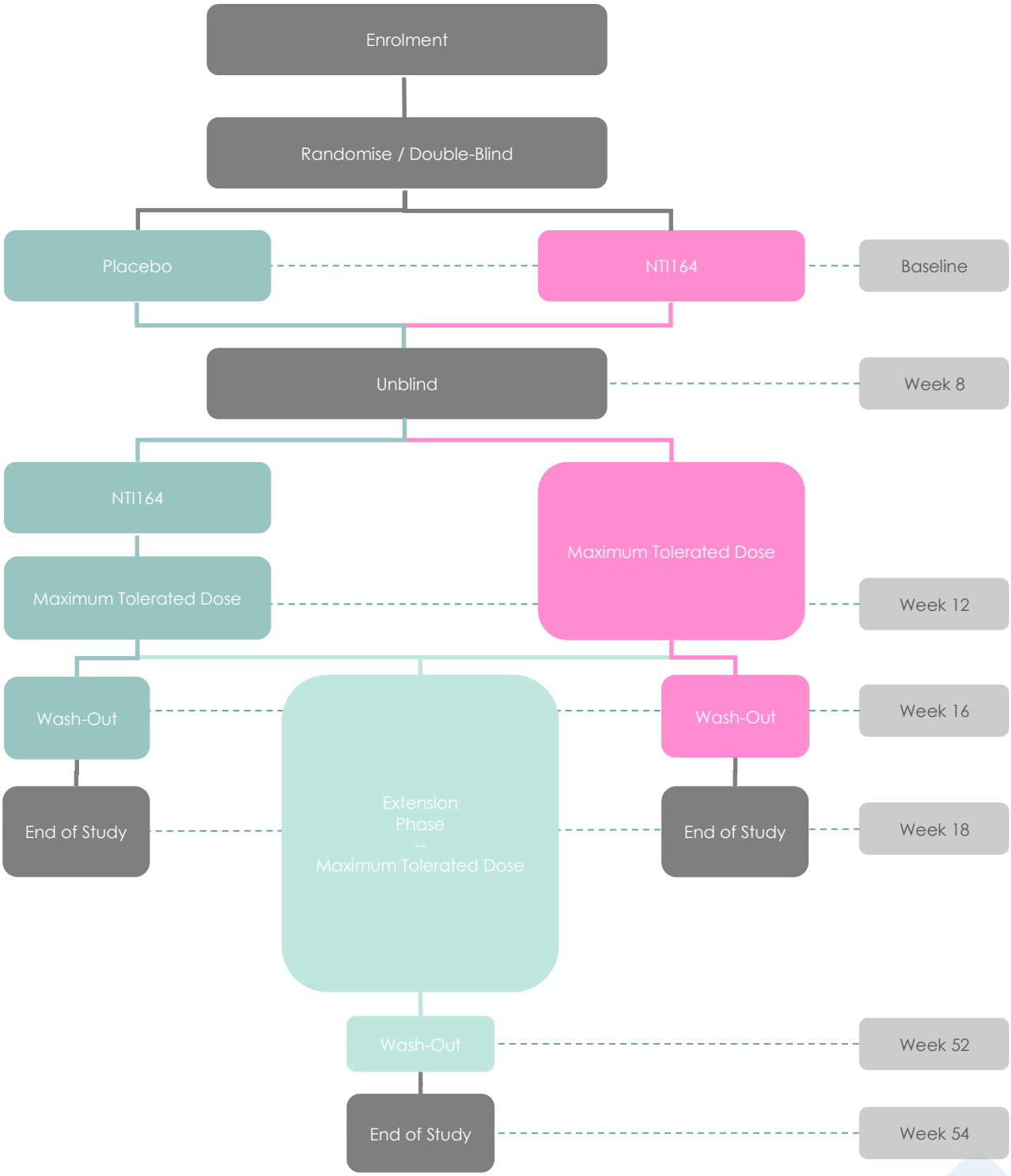
About NTI164

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 the ASD Phase II/III Clinical Trial

NTIASD2 was a Phase II/III Double-Blind, Randomised and Controlled-to-Open-Label Study to assess the efficacy of NTI164 up to 20mg/kg/day on the severity of spectrum disorder (ASD) in 54 patients aged 2-17 years (inclusive). The primary endpoint of the trial was Clinical Global Impression-Severity (CGI-S), which reflects clinician's impression of severity of illness on a 7-point scale ranging from 1=not at all to 7=among the most extremely ill [Timeframe: Baseline, Week 12]. This endpoint was met, and a number of key secondary endpoints. For more information on the trial, please visit the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number **ACTRN12622001398796** at: https://www.anzctr.org.au

Appendix 1 - NTIASD2 Clinical Trial Design



[1] [1] See ASX announcement dated 17 April 2024