NTI164 shows excellent tolerability in key preclinical toxicology studies

Highlights:

- **NTI164 demonstrated excellent tolerability and no safety concerns in 28-day GLP repeat-dose studies in rats and dogs**
- **No test article-related adverse effects were observed across clinical observations, ophthalmic exams, neurological assessments, or clinical pathology**
- **Findings establish the nonclinical safety foundation for progression to longer-term toxicology studies and support regulatory submissions to the FDA, TGA and EMA**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical company focused on paediatric neurological disorders, is pleased to announce positive results from its recently completed 28-day Good Laboratory Practice (GLP) oral toxicology studies evaluating NTI164, the Company's proprietary lead drug formulation.

To support the regulatory development of NTI164, 28-day GLP-compliant repeat-dose toxicity studies were conducted in both Sprague-Dawley rats (total n=116) and Beagle dogs (total n=42) in accordance with ICH guidelines. Animals received twice-daily oral dosing across low, mid, and high dose levels, followed by a 14-day recovery period.

NTI164 was well tolerated in both species, with no systemic or organ-specific toxicities attributed to the test article. The absence of adverse findings across clinical pathology, histopathology, and neurobehavioral assessments highlights the formulation's favourable safety profile. Importantly, all incidental observations resolved during the recovery phase, confirming a strong therapeutic margin.

These data establish the nonclinical safety foundation required for IND submissions and support global regulatory filings with the FDA, TGA, and EMA. The study's GLP design and use of two regulatory-relevant species ensure broad acceptability across jurisdictions. The Company notes that the toxicology studies will be subject to review by the FDA, TGA and EMA, as part of the Company's submissions/safety package to these regulatory organisations.

Crucially, these findings significantly de-risk NTI164 for repeat-dose use in clinical trials and strengthen its positioning for future commercialisation in chronic-use indications, particularly in paediatric and neurological settings. These developments are fully aligned with both FDA and TGA regulatory guidance.

Dr Anthony Filippis, CEO and Managing Director of Neurotech, stated: "We are extremely encouraged by these robust safety findings, which mark a crucial step in our regulatory and clinical development pathway. The positive outcomes of this toxicology study provide a solid foundation for advancing NTI164 into longer-term toxicity studies, as required by the FDA and TGA. We look forward to progressing NTI164 rapidly into the next stages of clinical development and regulatory submissions, while continuing our focus on commercial opportunities for the business."

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Neurotech remains committed to achieving harmonised global regulatory submissions, leveraging these foundational safety results to support international development and commercialisation of NTI164.

For further information contact us via info@neurotechinternational.com

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 unique cannabis strains with a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. 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.