Positive Human PK Study Results for NTI164

Highlights:

- **Comprehensive human pharmacokinetic (PK) study confirms rapid and predictable absorption of NTI164, with CBDA as the dominant circulating cannabinoid.**
- **Minimal THC exposure confirms NTI164's non-intoxicating profile, suitable for paediatric use.**
- **Repeat-dose studies show no significant cannabinoid accumulation, supporting a safe, twice-daily dosing regimen.**
- **Demonstrated minimal in vivo conversion of CBDA to CBD, confirming NTI164's targeted therapeutic mechanism.**
- **Findings validated by recent independent publication from Johns Hopkins University, reinforcing the therapeutic potential of CBDA[1].**
- **Results support consistent and reliable symptom management in children with chronic neurological conditions, giving families confidence in daily care.**
- **Results reinforce NTI164's potential as a long-term treatment option that balances effectiveness and safety — essential for paediatric use.**
- **Neurotech to continue advancement of dual-track regulatory strategy for registration of NTI164 with US FDA and Australian TGA.**

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 first-in-human pharmacokinetic (PK) study evaluating NTI164, a proprietary CBDA-rich, standardised formulation.

About the Study

This pharmacokinetic study was conducted in healthy adult volunteers to evaluate the absorption, cannabinoid ratios, and systemic exposure profile of NTI164. The study was conducted in two parts.

Part A assessed single-dose pharmacokinetics in four participants (3 male, 1 female) who received 20mg/kg/day of NTI164, administered in two divided doses over a single day.

Part B examined a repeat-dose pharmacokinetics and sex-based dose-exposure dynamics in eight participants (4 male, 4 female) dosed twice daily over seven consecutive days. Males received 20mg/kg/day, while females received 10mg/kg/day to characterise pharmacokinetic variability and inform future dosing strategies.

Blood and urine samples were collected at defined intervals to evaluate CBDA exposure, time to steady-state, accumulation, and cannabinoid stability.

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Key findings include:

- **Rapid, Predictable Absorption:** CBDA reached peak plasma levels up to 3,801 ng/mL within 2-4 hours, demonstrating rapid and predictable systemic absorption.
- **Negligible THC Levels:** THC exposure remained consistently minimal (≤ 9.5 ng/mL), even at steady-state conditions, affirming NTI164's non-intoxicating safety profile.
- **Stable Cannabinoid Profile:** No significant cannabinoid accumulation was observed, with steady-state conditions achieved by Day 3 and only a modest increase (~17%) seen after multiple doses, indicating no accelerated build-up of cannabinoids in the body. This is a key finding from both a safety and patient dosing perspective, as it suggests a low risk of long-term accumulation and supports predictable, consistent dosing without the need for complex titration.
- **Consistent Dosing Regimen:** Twice-daily (BID) dosing provided effective 24-hour therapeutic coverage, ideal for paediatric management.
- **Chemical and Metabolic Stability:** NTI164 showed a stable CBDA:CBD plasma ratio of around 16:1, indicating minimal conversion of CBDA into CBD in the body. This confirms that CBDA stays in its original form, supporting both the chemical stability of NTI164 and its intended therapeutic effect.

These results form a robust PK data package that justifies dose selection and strengthens the product's benefit-risk profile — all essential for achieving positive regulatory outcomes.

The results, along with a recent independent study from Johns Hopkins University[1], support Neurotech's view that CBDA and other cannabinoids work as active therapies — not just as precursors to CBD. CBDA acts directly on the body, especially by targeting inflammation in the brain.

NTI164, a pharmaceutically standardised formulation, exhibits distinct neuroprotective and anti-inflammatory activity mediated via TRPV1 and 5-HT1A receptors, unlike CBD alone.

Consistent with previous preclinical GLP-compliant toxicology studies in rats and dogs, NTI164 displayed excellent tolerability with no systemic or organ-specific toxicities or serious adverse events (SAEs), supporting NTI164's favourable safety profile for chronic paediatric administration.

These positive results reduce the risk in NTI164's clinical development and support its progression into future registration trials under both FDA and TGA guidelines. The pharmacokinetic (PK) study data will form a component of the regulatory submissions and safety packages being prepared for both agencies. Neurotech is advancing parallel approval pathways in the US and Australia to accelerate global access to NTI164 as a standardised, pharmaceutical-grade treatment for children with neurological and inflammatory brain disorders.

Dr Anthony Filippis, CEO and Managing Director of Neurotech, commented: "The results of our first-in-human PK study represent another important clinical milestone for NTI164. The clear validation of systemic stability, safety and targeted therapeutic action highlights NTI164's potential as a disease-modifying therapy. We are eager to advance NTI164 rapidly into the next stages of its development and regulatory progress, while actively pursuing commercial opportunities."

[1] The Pharmacokinetics and Pharmacodynamics of a Hemp-Derived "Full-Spectrum" Oral Cannabinoid Product with a 1:1 Ratio of Cannabidiol to Cannabidiolic Acid and Delta-9-Tetrahydrocannabinol to Delta-9-Tetrahydrocannabinolic Acid: A Double-Blind, Placebo-Controlled, Within-Subjects Human Laboratory Study

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

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.