



Factsheet: NTI164

Neurotech International is conducting clinical studies to assess the neuro-protective, anti-inflammatory and neuro-modulatory activities of our proprietary NTI cannabis strains. We have the exclusive worldwide licence for NTI164 for the treatment of neurological disorders. Our primary clinical focus is the development of NTI164 for rare paediatric neurological disorders.

BACKGROUND

During the last two decades there has been a surge in clinical trials of Cannabidiol (CBD) owing to the absence of psychoactive effects and its confirmed favourable safety profile in humans for treatment of several neurological and psychiatric disorders. Neurotech International has derived NTI164, a unique strain of medicinal cannabis which naturally contains high levels of cannabidiolic acid (CBDA) and other minor cannabinoids whilst containing less than 0.3% Tetrahydrocannabinol (THC), which is the substance primarily responsible for the “high” effect on a person's mental state.

WHAT IS NTI164?

NTI164 is a medicinal cannabis derived biopharmaceutical. It provides all the beneficial properties and components of ‘full-spectrum’ cannabis (not CBD) without Tetrahydrocannabinol (THC), the substance primarily responsible for the “high” effect on a person's mental state.

NTI164 has multi-functional modes of action: neuro-protection, neuro-modulation and neuro-regulation. Grown in Australia under strict horticultural conditions that ensure its integrity, NTI164 has a high level of cannabidiolic acid (CBDA) and an assortment of other minor cannabinoids such as CBG, CBN and CBDP. NTI164's unique combination works differently to CBD and has powerful effects on inflammatory pathways.

Preclinical and clinical studies to date have shown that NTI164 is a powerful neuro-anti-inflammatory modulator, can suppress a wide range of inflammatory cytokines, and improves neuronal cell viability and overall health.





WHY IS NTI164 NEEDED?

There is a strong market need for an effective therapeutic intervention such as NTI164 to improve symptoms of paediatric neurological disorders such as autism spectrum disorder (ASD), PANS/PANDAS¹, Rett syndrome and cerebral palsy to reduce healthcare costs. It also has the potential to reduce the burden on government-funded schemes, like Australia's National Disability Insurance Scheme (NDIS).

HOW DOES NTI164 WORK?

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WHAT CAN NTI164 TREAT?

NTI164 is being developed as a therapeutic drug product for a range of neurological disorders in children where neuroinflammation is involved. Early clinical data in paediatric neurological disorders such as ASD demonstrate that treatment with NTI164 is associated with statistically significant and clinically meaningful symptom improvement relating to severity of illness, social behaviour and communication.



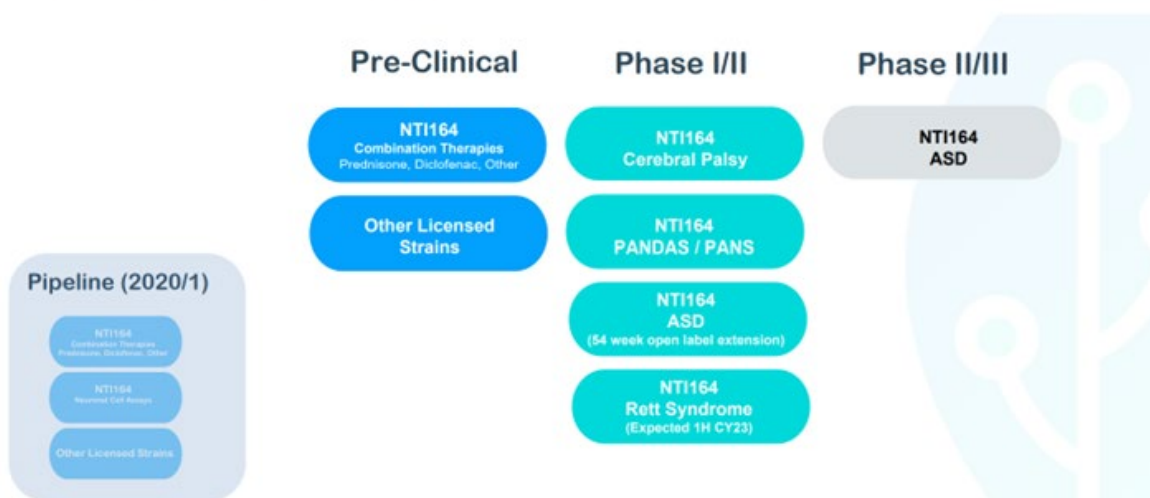
Data shows children taking NTI164 daily experienced marked improvement with socialisation, attendance at school, and classroom behaviour. These children also experienced improvement to their levels of anxiety, irritability and hyperactivity.

¹ Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)



Neurotech is furthering clinical trials with NTI164 by conducting a Phase II/III ASD trial along with a Phase I/II PANDAS/PANS trial which is currently underway at the Children's Hospital at Westmead, Sydney and the Monash Medical Centre's paediatric neurology unit, Melbourne. In addition, Neurotech is expected to commence a Phase I/II clinical trial in Rett syndrome and cerebral palsy in 2023.

Clinical Pipeline – 2023



NTI164 SAFE?

In clinical studies for ASD, NTI164 demonstrated excellent safety and efficacy results and was shown to be well-tolerated, with no reports of serious adverse events across all doses. No changes were observed in the blood analyses of cells and various biochemistries, such as liver function tests.

WHERE CAN I GET MORE INFORMATION ABOUT NTI164?

Visit <https://neurotechinternational.com/biopharmaceutical-trials> for up to date information about NTI164 and associated clinical trials focused on the treatment of rare paediatric neurological disorders including Autism spectrum disorder (ASD), PANS/PANDAS¹, Rett syndrome and cerebral palsy.

REFERENCES

- <https://neurotechinternational.com/biopharmaceutical-trials/>
- <https://neurotechinternational.com/asx-announcements/>
- <https://www.afr.com/policy/economy/the-number-of-people-in-the-ndis-is-rising-rapidly-smashing-forecasts-20230522-p5da5a>
- <https://www.theaustralian.com.au/weekend-australian-magazine/autism-will-cost-the-budget-825bn-via-the-ndis-will-the-safety-net-break/news-story/30431ced5d93b62f8c353407896606f8>