Factsheet: PANS/PANDAS

PANS:

Paediatric Acute-onset Neuro-psychiatric Syndrome PANDAS:

Paediatric Autoimmune Neuro-psychiatric Disorder Associated with Streptococcal infections

BACKGROUND

Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS), collectively PANS/PANDAS, is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including Obsessive-Compulsive Disorder (OCD) and/or restrictive eating.

CAUSES

While the cause of PANS/PANDAS is unknown, suspected triggers are infections, metabolic disturbances and other inflammatory reactions. Experts believe PANDAS and PANS happen because of a problem with the immune system's response to an infection. Instead of attacking the germs, the immune system targets a part of the brain by mistake. This part of the brain is called the basal ganglia. It affects thoughts, feelings, movement, and other behaviours.



SYMPTOMS

Children with PANS or PANDAS can experience a sudden and rapid deterioration in their behaviour, personality, and overall abilities. They may exhibit repetitive tic movements, become moody, irritable/aggressive and anxious and have difficulty with schoolwork.

DIAGNOSIS

A clinical diagnosis is one made based on specific signs and symptoms observed by a medical provider rather than on lab tests or biomarkers.



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Both PANS and PANDAS are clinical diagnoses based on a set of specific criteria. They are also diagnoses of exclusion, meaning that a patient should be assessed for other known illnesses or diseases that could cause the observed symptoms.

TREATMENT

PANDAS/PANS is a rare (orphan) disease and there are currently no U.S Food & Drug Administration (FDA) or European Medicines Agency (EMA) approved treatments. If left untreated, symptoms of PANS and PANDAS may continue to worsen and can result in permanent cognitive damage.

OUR WORLD FIRST HUMAN CLINICAL STUDY TO TREAT PANS/PANDAS

Neurotech is conducting the world's first human clinical study to treat children with PANS/ PANDAS. NTIPAN1 is a single-arm, open-label, Phase I/II clinical trial that will recruit 15 paediatric patients with a clinical diagnosis of moderate to severe PANS/PANDAS to determine the efficacy and safety of orally administered NTI164 in these patients. NTI164 is a medicinal cannabis derived biopharmaceutical providing 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.

The trial is running at two centres within Australia - the Children's Hospital at Westmead, Sydney Australia and the Paediatric Neurology Unit at Monash Medical Centre, Melbourne Australia – and is being conducted under the guidance of Professor Russell Dale, a world expert on PANS/PANDAS.

Professor Dale is a Paediatric Neurologist and Clinical Academic at Sydney Children's Hospitals Network; Head of Clinical School and Head of Specialty of Child and Adolescent Health at the University of Sydney; and Clinical Director of Kids Neuroscience Centre, Sydney Children's Hospitals Network. He was one of the first doctors in the world to research PANS/PANDAS 20 years ago. Neurotech anticipates the top-line results of the NTIPANS1 trial in Quarter 3, 2023.



WHY NTI164?

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NTI164's unique combination of CBDA and other minor cannabinoids work together to create an 'entourage effect' that is more potent than CBD isolate, with only 0.3% THC. 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.



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FOR MORE INFORMATION

Visit <u>https://neurotechinternational.com/biopharmaceutical-trials</u> 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/PANDAS, Rett syndrome and cerebral palsy. NTI164 has been exclusively licenced by Neurotech International for neurological applications globally.

REFERENCES

- <u>https://aspire.care/treating-pans/treating-pans-pandas/</u>
- https://www.e-hospital.co.uk/wp-content/uploads/2019/04/PANDAS-Protocol-V1.6.pdf
- PANDAS Physicians Network: <u>https://www.pandasppn.org/...</u>
- Stanford PANS Clinic: <u>http://med.stanford.edu/pans.html</u>
- PANDAS Network: <u>http://pandasnetwork.org/</u>
- NIMH: https://www.nimh.nih.gov/.../public.../pandas/index.shtml...



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