Improving Lives

Neurotech International

PANDAS/PANS
Phase I/II Clinical Trial Results

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About PANDAS / PANS

What is it?

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS) – PANDAS is a subgroup of PANS

PANS and PANDAS are severe forms of obsessive-compulsive disorder (OCD) that appear suddenly (acute onset) in young children, accompanied by other confusing and distressing symptoms

World Health Organisation recognition within the International Classification of Diseases (ICD-11) for the first time (2022)

Source: PACE Foundation

Cause & Treatment

Postinfectious neuroinflammatory disease that involves the basal ganglia and patients have obsessive-compulsive disorder as a major manifestation[1]

Treatment interventions treating the symptoms, treating the source of inflammation, and treating disturbances of the immune system

Diagnosis is by exclusion (i.e., other medical issues ruled out first)

1. https://pubmed.ncbi.nlm.nih.gov/36740356/

Recognised Diagnostic & Treatment Guidelines

Diagnostic Criteria (2015)

The PANS/PANDAS Research Consortium, in conjunction with the NIMH, issued a consensus statement regarding diagnosing PANS/PANDAS in the 2015 edition of the *Journal of Child and Adolescent Psychopharmacology*

MILD CASE
Symptoms are significant and cause disruptions at home and/or school. They occupy a few hours a day.

MODERATE CASE
Symptoms are distressing and interfere with daily activities. They occupy 50%–70% of waking hours.

SEVERE CASE
Symptoms are incapacitating, life threatening, or occupy 71%–100% of waking hours.

Treatment (2017)

The PANS/PANDAS Research Consortium, consisting over 30 experts and the NIMH, published new treatment recommendations for PANS/PANDAS in the 2017 *Journal of Child and Adolescent Psychopharmacology*

MILD CASE
- Antibiotics
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)
- Steroids

MODERATE CASE
- Antibiotics (short/long term)
- Steroid burst or NSAIDS at immunomodulatory dose
- Intravenous Immunoglobulin (IVIG)
- CBT/ERP[1] and/or psychiatric care

SEVERE CASE
- Antibiotics (short/long term)
- Steroid burst or NSAIDS at immunomodulatory dose
- Intravenous Immunoglobulin (IVIG)
- CBT/ERP and/or psychiatric care

There are no FDA/EMA/TGA approved drug therapies for PANDAS/PANS

New Clinical Trials and Treatments Urgently Needed

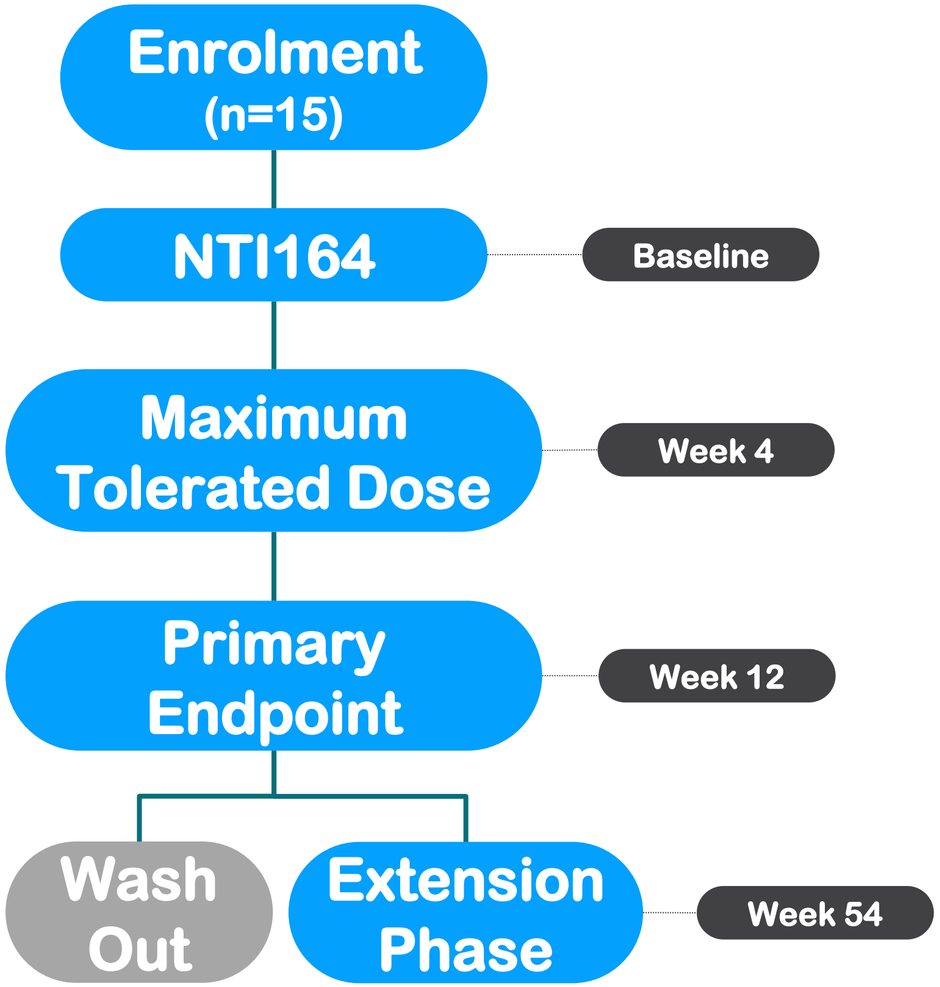
1. Cognitive Behavioural Therapy (CBT) / Exposure and Response Prevention (ERP)
   Source: https://www.pandasppn.org/guidelines/

PANDAS/PANS Phase I/II Trial

“We encourage clinicians, teachers, providers, extended family, and friends to understand the human aspects of PANDAS/PANS as symptoms are often so distressing, causing high levels of caregiver burden. [1]

1. https://aspire.care/what-is-pans/caregiver-experience/

NTI164 PANDAS/PANS Phase I/II – Trial Design



- Open-label, patients must fulfil PANS criteria
- Primary Endpoints
  - Revised Children's Anxiety and Depression Scale-Parent-rated (RCADS-P) score
  - Clinical Global Impression-Severity (CGI-S)
  - Clinical Global Impression- Improvement (CGI-I)
  - Clinical Global Impression – Therapeutic Effect

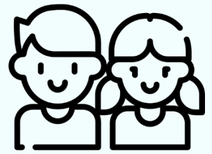
  Impression of Effect
- Secondary Endpoints
  - Yale Global Tic Severity Scale (YGTSS)
  - Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS)
  - Conners Scale (ADHD)
  - Unique blood transcriptomic and/or epigenetic signature
- Safety

Selecting NTI164 for PANDAS/PANS

- 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
- Neuroinflammation is hypothesised to be relevant to PANDAS/PANS (~80% cases)
- NTI164 exhibited excellent safety and tolerability in autism patients over 52 weeks of daily oral treatment
- Professor Dale (Co-PI) has ~30 PANDAS/PANS children under care: strong interest in clinical trials

Baseline Patient Characteristics

Characteristic		Number (%) / Mean
Age		11.9 years (mean)
Sex	Male	9 (60%)
	Female	6 (40%)
Diagnosis	PANDAS	0 (0%)
	PANS	15 (100%)
CGI-S[1]	Moderate	3 (20%)
	Marked	9 (60%)
	Severe	3 (20%)
RCADS-P[2]	>65	83.7 (mean)



A total of 15 patients with moderate-severe PANDAS/PANS recruited

1. Clinical Global Impression (CGI) – Severity is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders.
2. Revised Child Anxiety and Depression Scale – Parent Version (RCADS-P) - is a 47-item parent-report questionnaire of youth anxiety and depression (a scale of anxiety, social phobia, panic disorder, OCD, and low mood, a score below 65 represents low severity, scores between 65-70 represent medium severity and are on the borderline clinical threshold, and scores above 70 represent high severity and are above the clinical threshold)

Safety (12 week Data)

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NTI164 Exhibits Excellent Safety Over 12 Weeks

A total of 15 patients evaluable at 12 weeks

No serious adverse events recorded

Across all doses, across entire period (12 weeks)

Adverse events were tolerated and manageable

9 adverse events were recorded from three (3) participants.

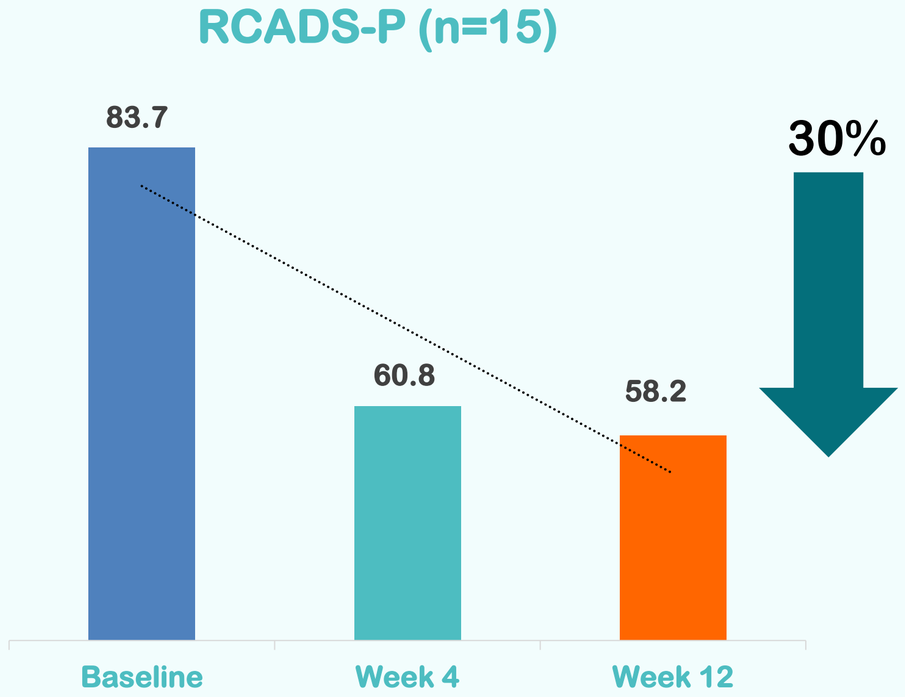
6 were possibly related to the study medication and included vomiting (4 events, 50%) and nausea (2 events, 22%).

The remaining 3 reactions were viral infections unrelated to the study drug (3 events, 33%)

Normal blood chemistry, normal kidney and liver function and vital signs

Conclusion: NTI164 exhibits an excellent safety profile and minimal patient-specific side-effects, consistent with long term data seen in paediatric autism patients over 52 weeks of daily treatment

Efficacy: RCADS-P (Primary Efficacy Endpoint)



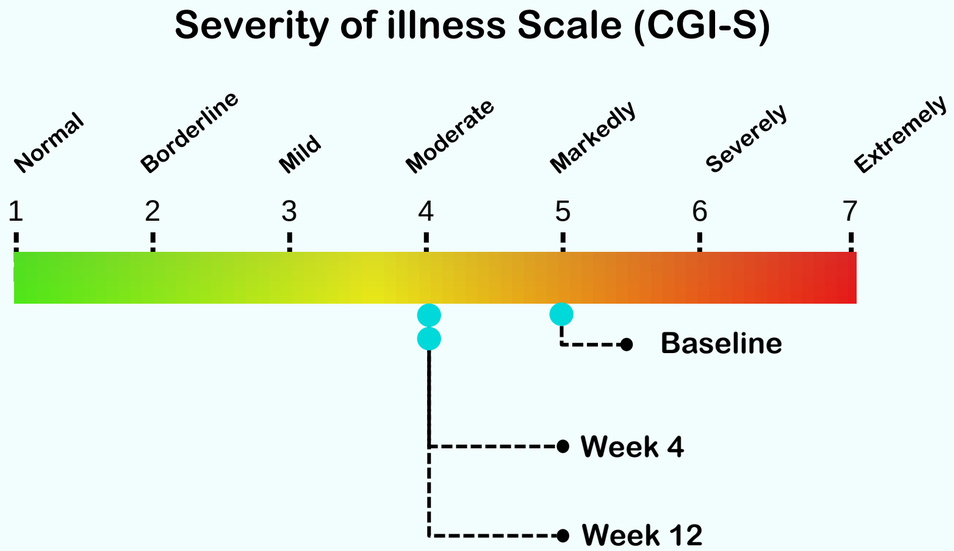
RCADS-P[1] (p = 0.016)

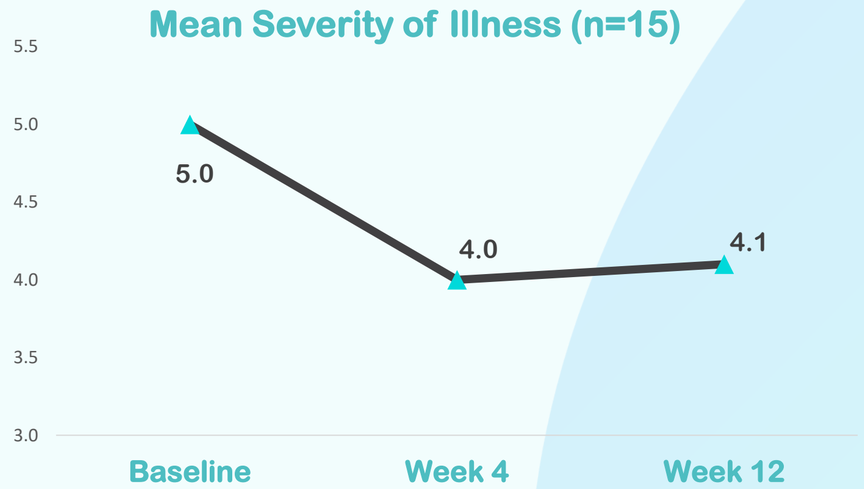
Clinical Interpretation

- Mean difference between baseline and 12 weeks was 25.5, representing a statistically significant, clinically meaningful improvement of 30% = LOW SEVERITY v HIGH SEVERITY at Day 0
- Upon commencement with NTI164, all sub-domains of RCADS-P relating to social phobia, panic disorder, major depression, separation anxiety, general anxiety and obsessive-compulsive behaviours all improved (decreased scores).
- Upon commencement with NTI164, the maximum increase across all measures was Nil (no worsening at all) except for a small increase score for major depression in one patient

1. Revised Child Anxiety and Depression Scale – Parent Version (RCADS-P) - is a 47-item parent-report questionnaire of youth anxiety and depression (a scale of anxiety, social phobia, panic disorder, OCD, and low mood, a score below 65 represents low severity, scores between 65-70 represent medium severity and are on the borderline clinical threshold, and scores above 70 represent high severity and are above the clinical threshold). This test is completed at the site.

Efficacy: CGI-S (Primary Efficacy Endpoint)





CGI-Severity of illness[1] (p = 0.0005)

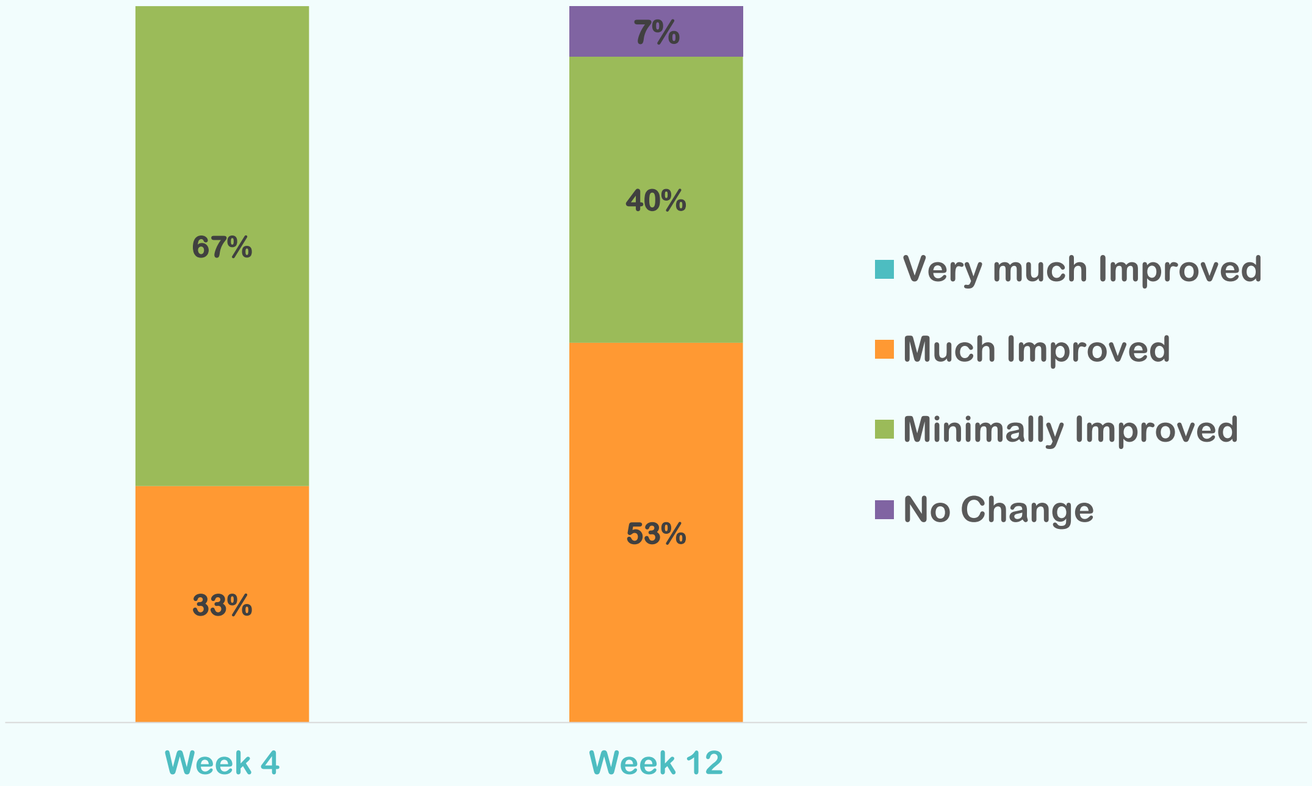
Clinical Interpretation

- NTI164 treatment is associated with a significant reduction in disease severity (0.9 scale change, 18% improvement)
- By week 12, patients were classified as mildly ill (20%), moderately ill (73%) and one patient (7%) was classified as markedly ill (pt. acquired infection)
- 20% of subjects severely ill at baseline – 0% at week 4 onwards

1. Clinical Global Impression (CGI)- is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.

Efficacy: CGI-I (Primary Endpoint)

CGI-Global improvement [1]



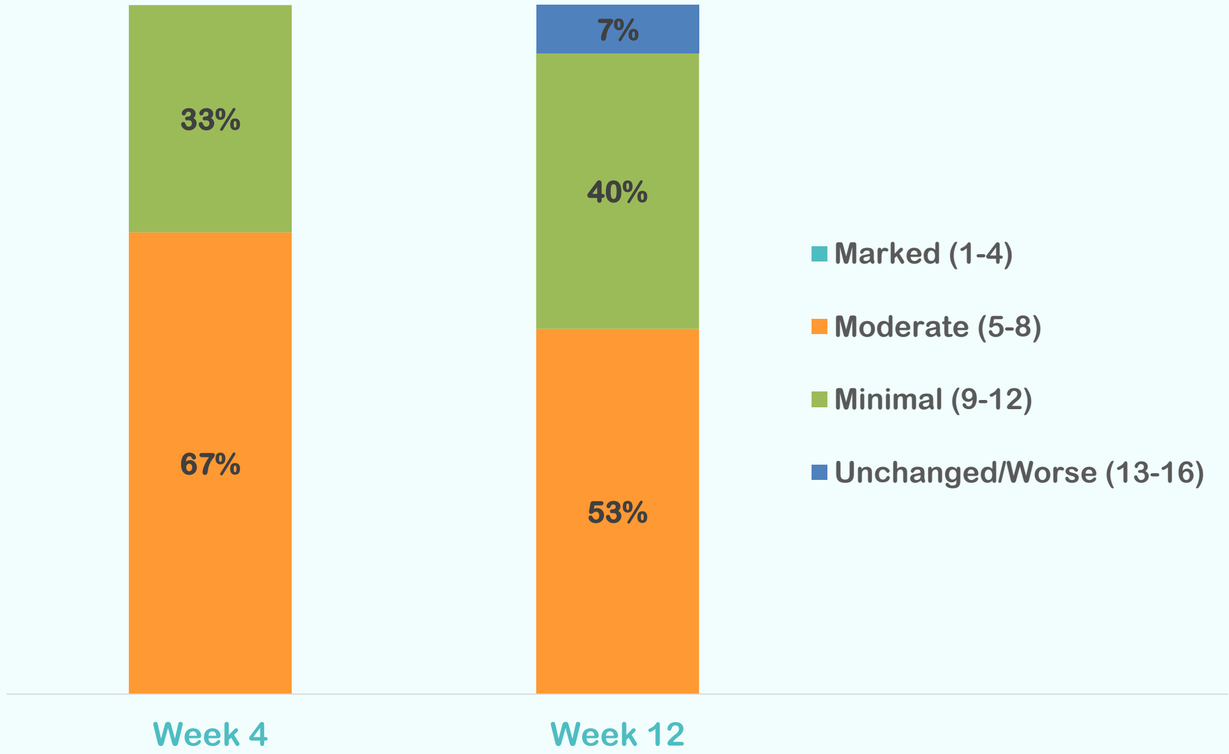
Clinical Interpretation

- After 4 weeks of treatment with NTI164, 33% of patients were much improved, 67% minimally improved
- After 12 weeks of daily treatment with NTI164, 53% of patients were much improved, 40% minimally improved and one patient (7%) had no change (pt acquired infection).

1. Clinical Global Impression (CGI) - is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect. CGI-I does not provide for statistical p values from the change (no improvement assumed at baseline)

Efficacy: CGI-Therapeutic Effect (Primary Endpoint)

CGI-Therapeutic Effect[1]



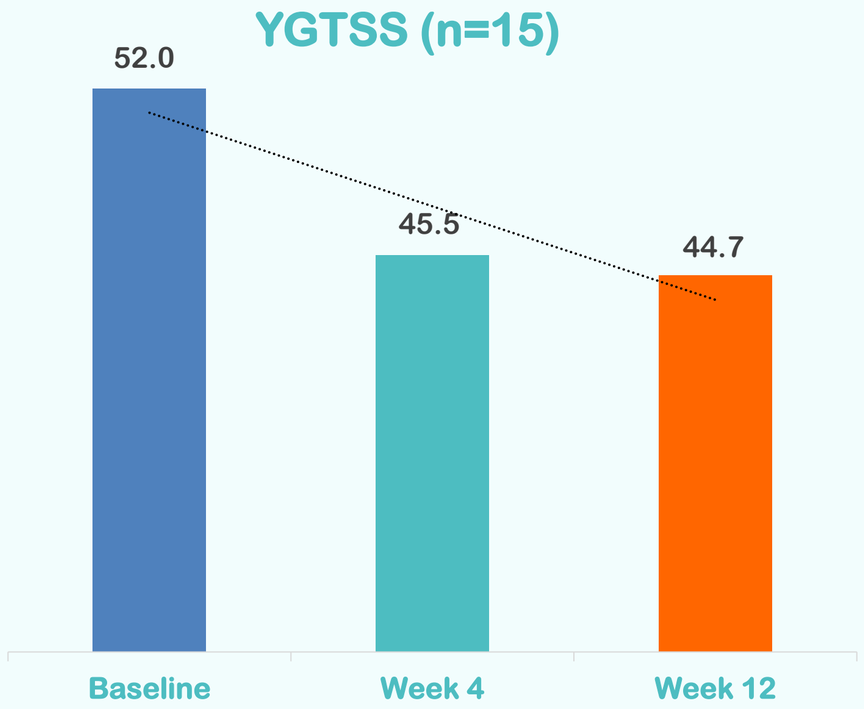
Marked - Vast improvement. Complete or nearly complete remission of all symptoms.
Moderate - Decided improvement. Partial remission of symptoms.
Minimal - Slight improvement. Doesn't alter status of care of patient.

Clinical Interpretation

- After 4 weeks of daily NTI164 treatment, 67% of patients demonstrated a Moderate improvement and 33% demonstrated a Minimal improvement
- After 12 weeks, 53% demonstrated a Moderate improvement, 40% Minimal and 7% (n=1) No Change

1. Clinical Global Impression (CGI) - is a physician/observer-rated scale synthesizing the clinician's impression of the global state of an individual & frequently employed in clinical trials for neuropsychiatric disorders. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect. CGI-Therapeutic Effect does not provide for statistical p values (no therapeutic effect assumed at baseline)

Efficacy: YGTSS (Tic Severity)(Secondary Endpoint)



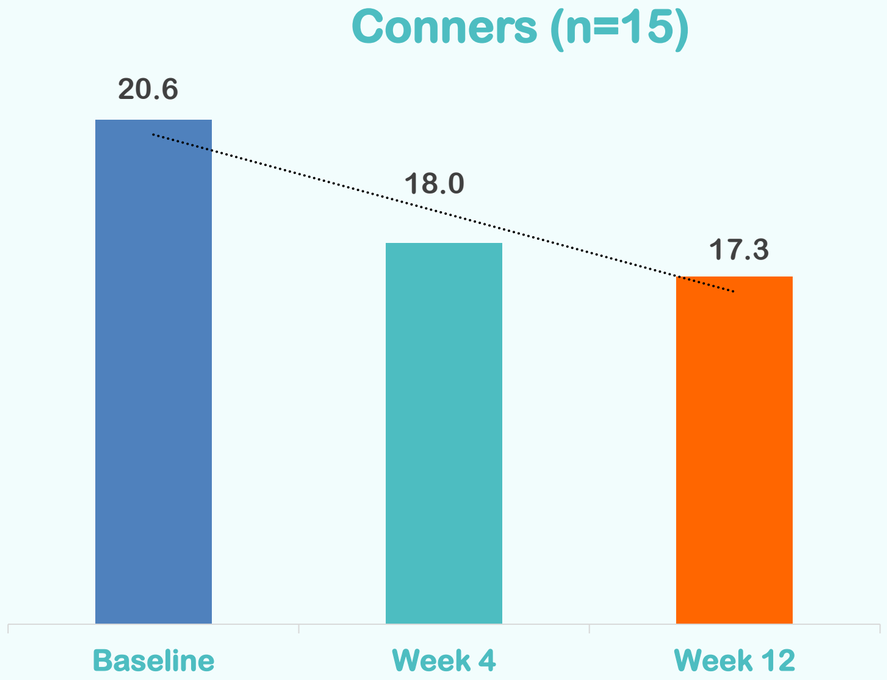
YGTSS Score[1] (p = 0.07)

Clinical Interpretation

- Mean difference of -7.3, representing an improvement of 14% over baseline
- Motor tic severity did not increase once patients commenced treatment with NTI164, and showed an overall 32% improvement versus baseline

1. The Yale Global Tic Severity Scale (YGTSS) is a clinician-rated instrument considered as the gold standard for assessing tics in patients with Tourette's Syndrome and other tic disorders. The YGTSS enables evaluations of number, frequency, intensity, complexity, and interference of motor and phonic tics. The tool gives ratings in 5 domains: Total Motor Tic Score, Total Verbal Tic Score, Total Tic Score (Motor + Verbal), Overall Impairment Rating, and Global Severity Score. The Global Severity Score has a range of 0- 100. A higher score on all scales suggests a more severe Tic, or a greater impact the Tic has on the person's life. 0–9 = borderline, 10–25 = mild, 26–55 = moderate, 56–81 = marked, 82–96 = severe.

Efficacy: Conners Scale (ADHD)(Secondary Endpoint)



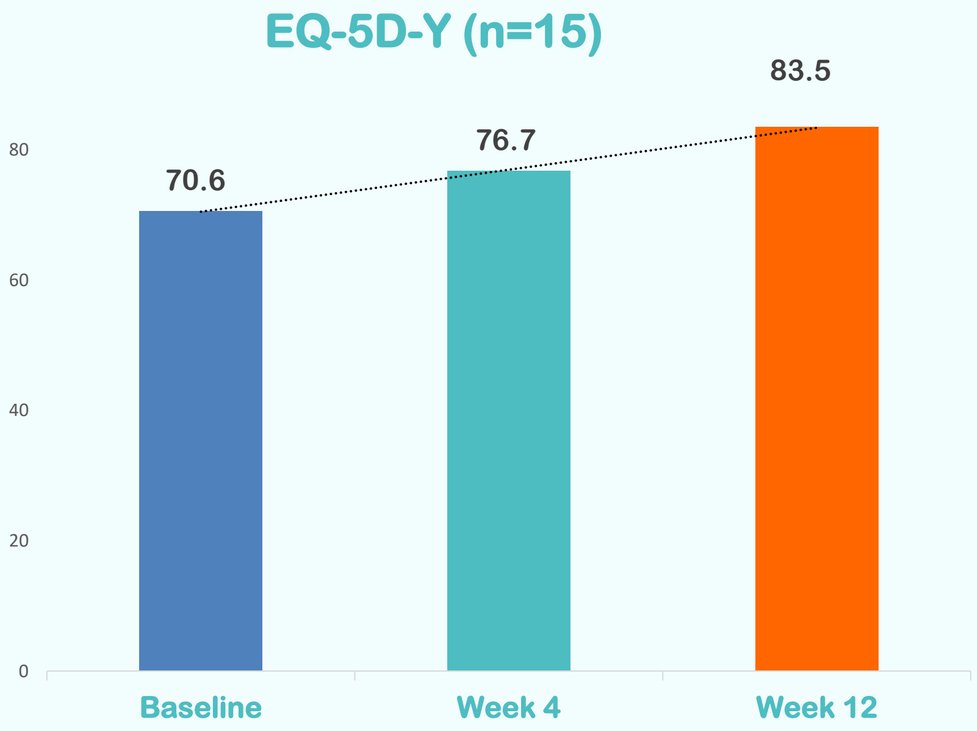
Conners Score[1] (p = 0.08)

Clinical Interpretation

- The mean total T-score for the 15 patients after 12 weeks of NTI164 treatment was 17.3 which is a significant improvement (16%) from baseline where it was 20.6 (mean difference of -3.3, p =0.08)
- Overall reduction in ADHD symptoms trending to a score of 15 or less, which is no suggestion of ADHD

1. The Conner's scale is an assessment tool used to obtain observations about a youth's behaviour. The instrument is designed to assess Attention Deficit/Hyperactivity Order (ADHD) and its most common co-morbid problems in children and adolescents aged 6 to 18 years old. A Total Score of 15 and above may be suggestive of ADHD.

Quality of Life: EQ-5D-Y (Secondary Endpoint)



EQ-5D-Y Score[1] (p = 0.05)

Clinical Interpretation

- Patient's quality of life as measured by the EQ-5D-Y assessment improved considerably between baseline and 12 weeks of treatment with NTI164
- The mean total T-score after 12 weeks of NTI164 treatment was 83.5, which is an 18% improvement from baseline where it was 70.6 (mean difference of 12.9, p value=0.05)

1. The EQ-5D-Y (youth) assessment includes the simplicity of the descriptive system which measures health across five dimensions and a general rating of health on a visual analogue scale (VAS) of 0 (worst health) to 100 (best health). The dimensions include Mobility (walking about), Self-Care (washing and dressing), doing Usual Activities (going to school, hobbies, sports, playing, doing things with family or friends), having Pain or Discomfort and feeling Worried, Sad or Unhappy.

Efficacy: CY-BOCS (Secondary Endpoint)

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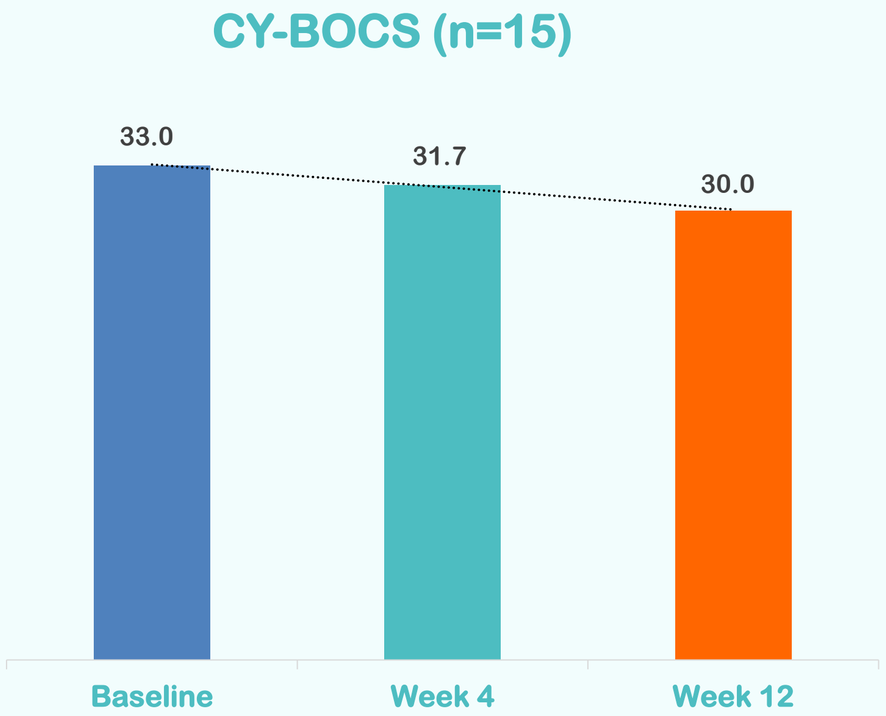

CY-BOCS Score[1] (p = 0.96)

Clinical Interpretation

- The mean total T-score for the 15 patients after 12 weeks of NTI164 treatment was 30.0 which was an improvement (10%) from baseline where it was 33.0 (mean difference of -3.0, p=0.96)
- The children were down-staged from extreme symptoms to severe symptoms based on this scale change

1. Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) is a semi-structured interview made up of 10 items rated on a 5-point Likert scale evaluating the severity of Obsessions and Compulsions across five dimensions, Frequency, Interference, Distress, Resistance, and Control, during the previous week and up to the time of interview. A score above 16 is generally considered indicative of the presence of OCD (0–7 indicating sub-clinical symptoms, 8–15 mild symptoms, 16–23 moderate symptoms, 24–31 severe symptoms and 32–40 extreme symptoms)

NTI164 PANDAS/PANS Phase I/II – Conclusions

- **NTI164 was safe and well tolerated in this patient population**
- **NTI164 provided significant evidence of effect over 12 weeks of daily oral treatment**
- **Met primary endpoints of RCADS-Y with 30% improvement in anxiety and depression, a major complication of PANDAS/PANS, and CGI- severity of illness with an 18% improvement**

Professor Russell Dale – Co-Lead Investigator

"I am very pleased with the clinical results reported to date and wish to thank all patients and their families for participating in this novel clinical trial. I have observed quite profound improvements in a number of my patients with NTI164, making it the first trial of its kind with a broad-spectrum cannabinoid therapy showing initial clinical utility like this with excellent safety. In addition, we await further evidence of genomic molecular changes from baseline measures and after 12 weeks of treatment to correlate this meaningful clinical response we have seen with biological evidence of effect. This would be a major step-forward for PANDAS/PANS patients and assist in in identifying relevant biomarkers of the disease."

Summary

- First ever broad-spectrum cannabinoid therapy to show a strong benefit in this population
- All psychometric endpoints studied exhibited showed clinical improvement over time with statistically significant and clinically meaningful improvements shown for the two key primary endpoints
- All patients have voluntarily elected to move to the extension phase of the trial to one year of treatment, several now being treated as adults (>18 years of age)
- Major market need for new safe and effective therapies
- Neurotech considering follow on clinical trial options in AU and US
- Orphan Drug Designation (ODD) applications in Europe and the US well-advanced

Neurotech International

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Appendix

Neurotech is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders

Neurotech International

- NTI164 exclusive worldwide licence for neurological disorders
- Patents Pending – Use, Composition
- Novel oral biopharmaceutical cannabinoid platform (NTI164)
- Focus on Paediatric Patients
- Multiple Phase I/II and Phase II/III Clinical Trials
- Mente device & therapy for ASD

Neurotech Four Core Strategies

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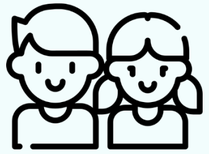
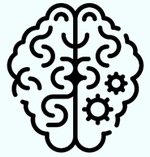
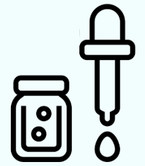


Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Drug Product Development