Improving Lives

Neurotech International

Investor Presentation

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17 June 2024

Disclaimer

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Corporate / Capital Summary

$0.061
Share price
(as at 14 Jun 2024)

$62.0M
Market capitalisation

$13.6M
Pro-Forma Cash 31 March ’24*

~2,450
No. of shareholders

1016.7M
Share on issue

176.5M
Options^

$6.5M
FY23 R&D Exp.
(up from $2.6M in FY22)

45.4%
Top 20 Holders

- 31 March cash balance of $4.2 million + Equity Placement (net of fees of $9.4m)
- ^Inc Listed, Unlisted Investor Options, Executive, Director options at various strike prices between $0.06 to $0.16 as at 3 June 2024

Neurotech Four Core Strategies

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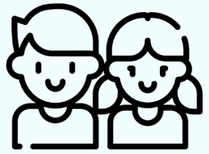
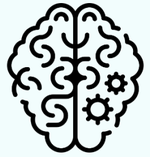
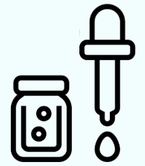


Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Drug Product Development

Clinical Pipeline – 2024

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Pre-Clinical	Phase I/II	Phase II/III
Other Licensed Strains	NTI164 Cerebral Palsy	NTI164 ASD
Synthetic Cannabinoid(s) combinations	NTI164 PANDAS / PANS[1]	
	NTI164 ASD[2] (90 week+ open label extension)	
	NTI164 Rett Syndrome	

Data reported (all with statistically significant primary endpoint results)

1. Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)
2. Autism Spectrum Disorder

Intellectual Property – 2024

Strong Patent Position

Neurotech has three patent families to underpin future worldwide commercialisation in neurological applications of NTI164. Two families have now entered the national phase and one family has entered the international (PCT) phase.

Composition

Uniqueness of the NTI-164 strain – composition profile with low THC (<0.3%) and a unique combination of 'rarer' cannabinoids: CBDA, CBC, CBDP, CBDB & CBN

Lodged Oct 2021

Combination

The application, formulation and use of NTI164

Lodged Oct 2021

Methods

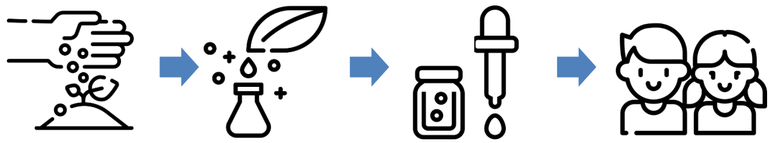
The application, formulation and use of NTI164 in paediatric patients

Lodged Oct 2022

Other IP & Barriers to Entry

Vertically Integrated: Seed to Patient Controlled

(Trade Secret: continuity of production to SOP, extraction(s))



Orphan Drug Designation(s)

10 Years	Market Exclusivity from Approval – Europe
7 Years	Market Exclusivity from Approval – United States

PANDAS/PANS **Rett Syndrome**

1. Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)
2. Autism Spectrum Disorder

Therapeutic Agent: NTI164

High potency, Broad Spectrum Cannabinoid Formulation in Oil, *C. sativa L.* (Plant Derived)

- THC < 0.3%
- Major constituent Cannabidiolic acid (CBDA)
- Minor constituents include other cannabinoids: CBD, CBG, CBGA, other + terpenes

Convenient 1x or 2x (split dose) oral formulation in oil, ideal format for pediatric patients 20mg/kg (CBDA)

NTI164 is not a low dose CBD oil to be sold over-the-counter

Entourage Effect

Neuroprotective

Anti- Neuroinflammatory

Our Target Markets

Lack of effective therapies, significant unmet medical need

Annual Drug Therapy Market opportunity

Autism Spectrum Disorder (ASD)	Rett Syndrome	PANDAS/PANS	Cerebral Palsy (CP)
US$2 billion*	US$2 billion	US$1.4 billion[1]	US$4.3 billion
ndis	Orphan	Orphan	
$6.1 Billion – Implied annual cost of ASD to NDIS based on average ASD funding of $32,800 per annum e.g. physio, psychology, speech therapy, support workers			
• Prevalence of ~2.0M <18 yr. patients in the US • 2 Approved Drugs (* limited use) • Risperidone, Aripiprazole	• Prevalence of ~15,000 patients in the US • 1 Approved Drug • Trofinetide	• Incidence of ~6,000 patients <18 yr. in the US[1] • No FDA/EMA Approved Drug	• Incidence of ~500,000 <18 yr. patients in the US • 2 Approved Drugs for spastic CP • Baclofen, Botox

1. Neurotech Estimate based on: Wald ER, et al. Estimate of the incidence of PANDAS and PANS in 3 primary care populations. Front Pediatr. 2023 Sep 21; EU/UK: 8,000 pts / US: 6,000 pts <18 years based on annual intravenous immunoglobulin (IVIG) cost of ~US$100k (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8019941/)

Autism Spectrum Disorder (ASD)

“The goals of treatment for ASD are to improve core deficits in social communication and social interactions and minimize the impact of restricted behaviours, with an overarching goal to help children develop greater functional skills and independence.” [1]

1. Weitlauf AS, McPheeters ML, Peters B, et al. Therapies for Children With Autism Spectrum Disorder: Behavioural Interventions Update. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Aug. (Comparative Effectiveness Review, No. 137.) Introduction.

Phase I/II ASD Results to Date (NTIASD1)

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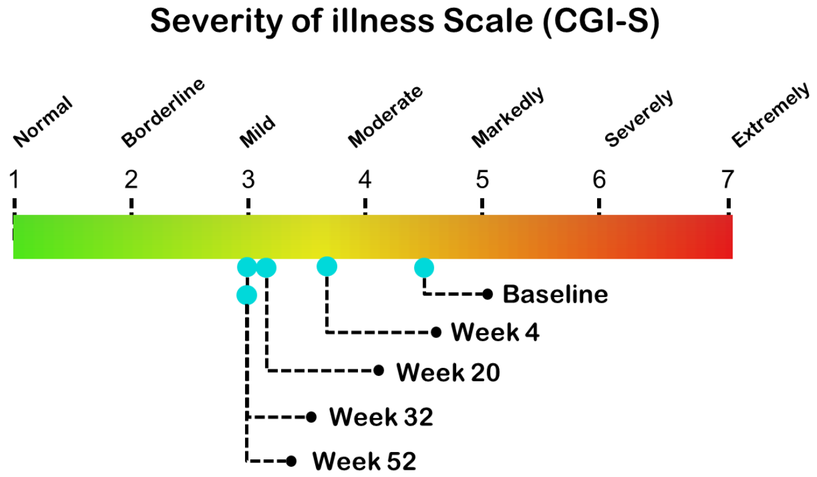
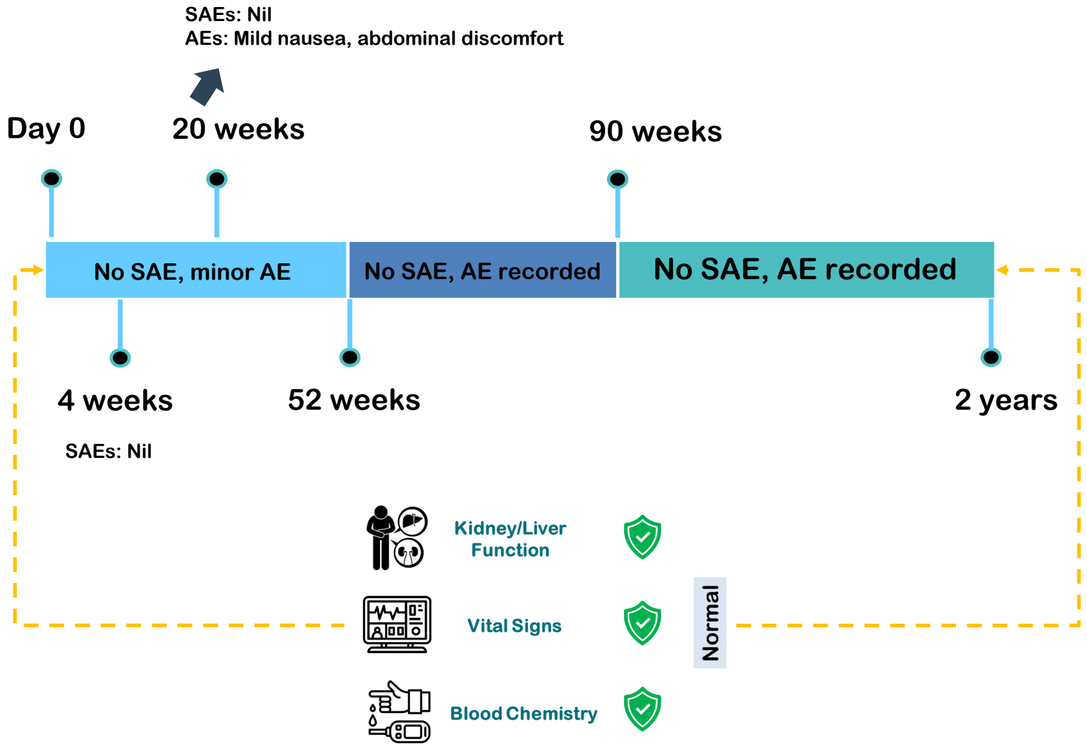
Efficacy



CGI-Severity of illness[1] (p = 0.03)

Safety

AE- adverse event
SAE – serious adverse event



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.

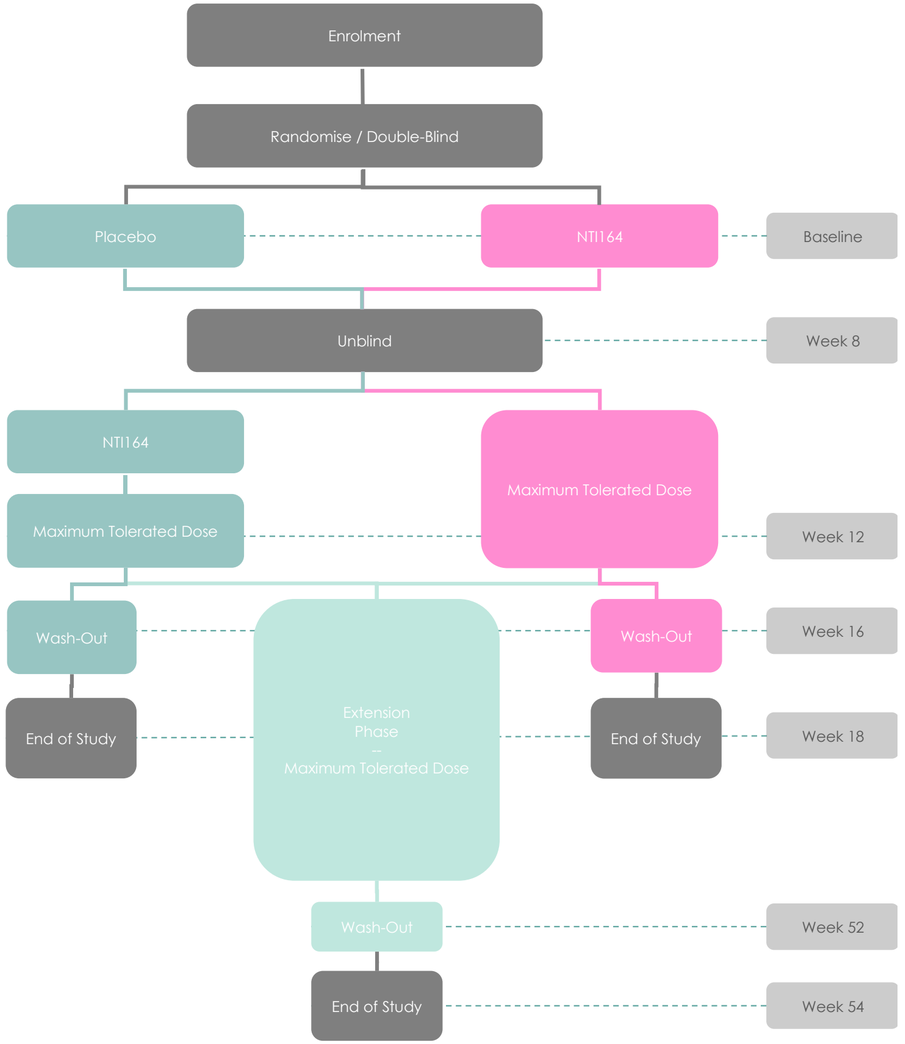
Phase II/III ASD Trial Design (NTIASD2)

Primary Endpoint

- Clinical Global Impression – Severity of illness (CGI-S)

Secondary Endpoints

- Vineland™-3 (adaptive behaviours measure)
- Clinical Global Impression – Improvement (CGI-I)
- Social Responsiveness Scale, 2nd Edition (SRS-2),
- Safety
- Change in Anxiety, Depression and Mood Scale (ADAMS)[2]



8 Week Safety Data

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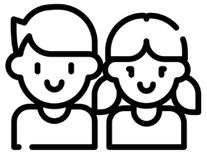
NTI164 Exhibits Excellent Safety Over 8 Weeks

A total of 54 patients evaluable at 8 weeks



No serious adverse events (SAEs) recorded for NTI164 & placebo, across entire period (8 weeks)

Adverse Events (AEs) were tolerated and manageable (total of 11 AEs across 7 patients for both arms)

Nausea/Vomiting

- 2 pts (8%) (NTI164)
- 3 pts (11%) (Placebo)

Diarrhoea

- 0 pts (0%) (NTI164)
- 2 pts (8%) (Placebo)

Kidney/Liver Function

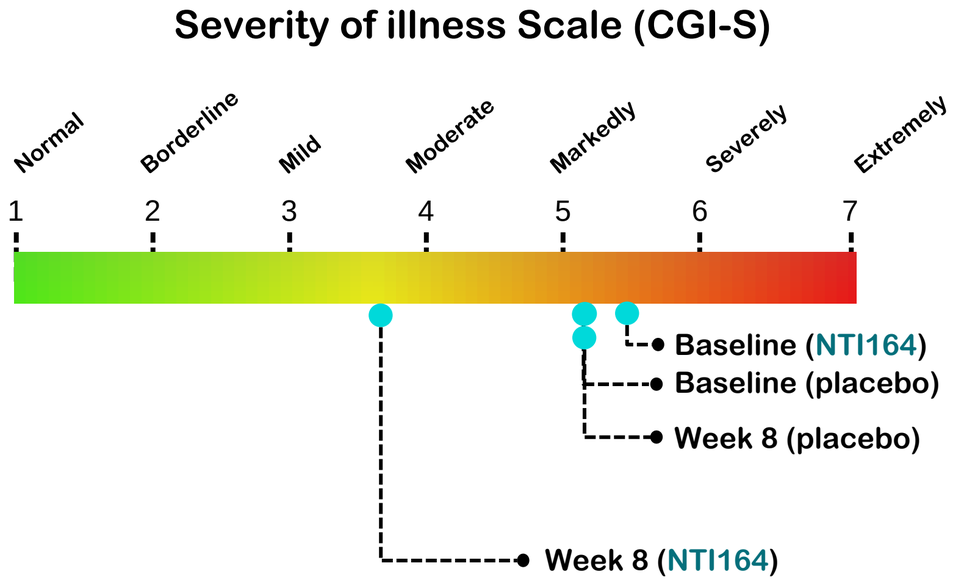
Vital Signs

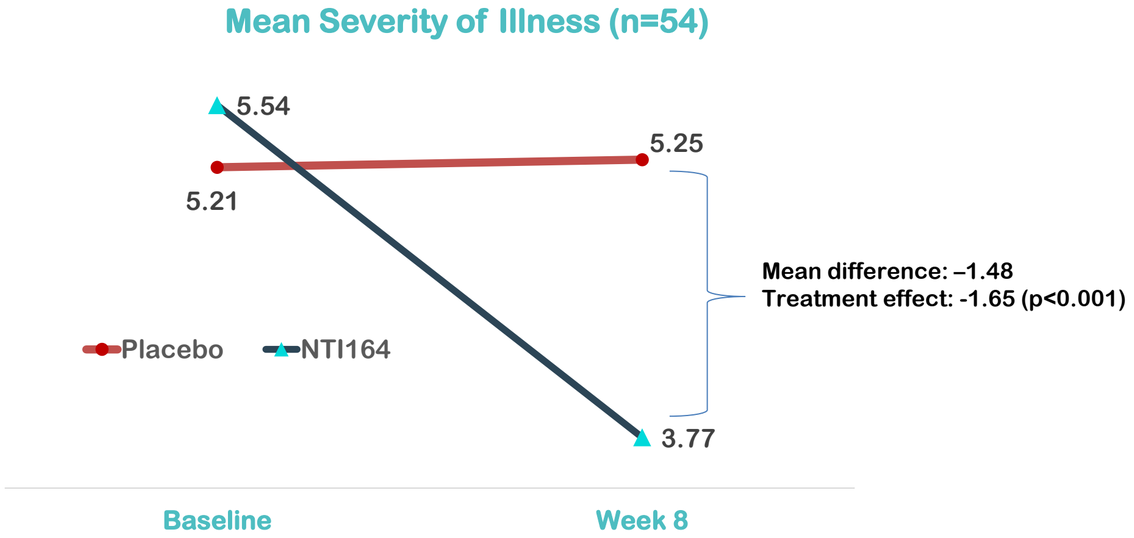
Blood Chemistry

Normal

Conclusion: NTI164 exhibits an excellent safety profile and minimal patient-specific side-effects

Primary Endpoint: CGI-S





CGI-Severity of illness versus placebo at 8 weeks[1] (p <0.001)

Clinical Interpretation

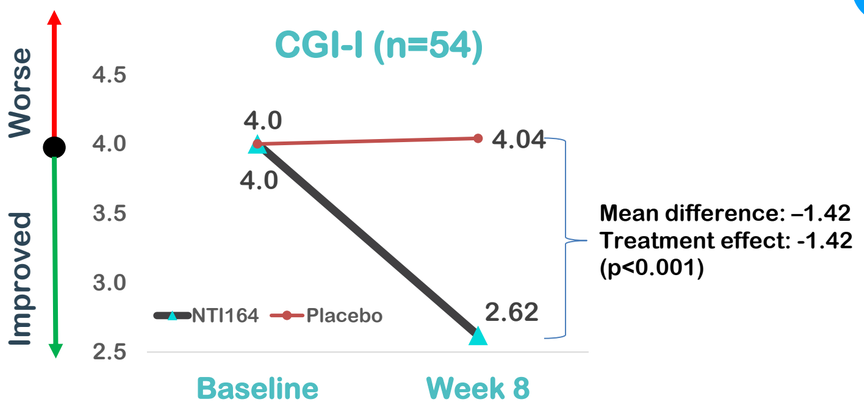
- Placebo group showed no improvement at week 8 (1.8% worse)
- 28% improvement for NTI164 v placebo at 8 weeks, 32% v baseline
- Significant down-staging of patient's illness severity – 88% pts markedly/severely ill at baseline in the NTI164 arm

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. CGI-S reflects the clinician's impression of severity of illness on a 7-point scale ranging from 1=Normal to 7=among the most extremely ill.

Secondary Endpoint: CGI-I

Clinical Global Impression – Improvement (CGI-I) is a 7−point scale that reflects experts' clinical judgment of the patient based on the clinician's total experience with the ASD population graded from 1 (very much improved) to 7 (very much worse). A decrease in CGI-I score indicates improvement.

	Very Much Improved	Much Improved	Minimally Improved	No Change	Minimally Worse	Much Worse	Very Much Worse
Scale	1	2	3	4	5	6	7
Placebo (week 8)	-	1(4%)	11 (39%)	8 (29%)	4 (14%)	2 (7%)	2 (7%)
NTI164 (week 8)	2 (8%)	10 (38%)	10 (38%)	4 (15%)	-	-	-



CGI-I at 8 weeks (p<0.001)

Clinical Interpretation

- 1.42 mean improvement between NTI164 and placebo at 8 weeks (36%)
- 46% of NTI164 patients very much or much improved v 4% for placebo

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. Clinical Global Impression – Improvement (CGI-I) is a 7−point scale that reflects experts' clinical judgment of the patient based on the clinician's total experience with the ASD population graded from 1 (very much improved) to 7 (very much worse). A decrease in CGI-I score indicates improvement.

Secondary Endpoint: Vineland™-3

Vineland™-3[1]

Standardised measure of adaptive behaviour

Norm-based: adaptive functioning compared to others of same age

Excellent test, re-test reliability & between rater (clinician, parent)

Vineland-3 Domain 8 week measure	Treatment Effect	P-value
Adaptive behaviour composite	**3.23**	**0.0240**
Communication	2.92	0.0467
Daily living skills	3.56	0.0213
Socialisation	3.47	0.0475

Clinical Interpretation

- No Secondary endpoints were statistically powered for this trial
- Adaptive behaviour improvement is a treatment goal in ASD
- Statistical significance reached for adaptive behaviour composite **and** all three sub-domains

1. Vineland™-3 is internationally recognised as a leading instrument for supporting the diagnosis of intellectual and developmental disabilities in ASD; specifically adaptive behaviour. Adaptive functioning, which are skills people need to function independently at home, at school and in the community is an important factor in predicting long-term outcomes for people with ASD. Improving adaptive abilities in patients is therefore a desirable treatment goal. The adaptive behaviour composite consists of (a) communication, (b) daily living skills & (c) socialisation.

Data Comparison & Context - Risperidone

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	RISPERIDONE	NTI164 Phase I/II (n=11)	NTI164 Phase II/III (n=54)
CGI-Severity of illness	• (n=96): -1.0 from baseline at 12 months[1] • (n=38): -0.7 from baseline at 48 weeks[2]	• -1.1 change at 20 weeks (p=0.005), 26% improvement • -1.3 change at 52 weeks (p=0.032) • ~40% of subjects markedly or severely ill at baseline – 0% from week 4 onwards • At 20 weeks, mean result: 100% mildly ill	• -1.48 change v placebo at 8 weeks, 28% improvement • Treatment effect of -1.6 (p<0.001) • 88% of subjects markedly or severely ill at baseline – 27% at 8 weeks • 19% borderline ill at 8 weeks

CGI- Improvement	• (n=15): CGI-I changes after 8 weeks from baseline[3]
	  • 27% - very much improved
	  • 47% - much improved
	  • 20% - minimal improved
	  • 6.6% - no change
		• 100% of active patients showed improvement after 20 weeks of daily treatment with NTI164
		• 100% patients much Improved at 20 weeks
		• 90% of patients much Improved at 52 weeks 10% very much improved)
			• 86% of patients showed improvement at 8 weeks of daily treatment with NTI164 v 43% placebo
			• 46% of NTI164 patients very much or much improved v 4% for placebo

Vineland™-3	• Near absence of RCTs examining Vineland noted in the medical literature • No impact on social interaction and communication[4]	• Adaptive behaviour mean difference of 3.8 (p=0.0005) at 20 weeks and mean difference 6.4 at 52 weeks (p=0.028) • Highly significant improvement • Highly significant improvements also in domains of communication, daily living, socialisation at 20 weeks and 52 weeks (ex-socialisation)	• Adaptive behaviour treatment effect 3.23 v placebo (p=0.024) • Highly significant improvement • Highly significant improvements also in domains of communication, daily living, socialisation by 8 weeks
Safety	• Significant weight gain Increase in BMI by 0.62[1] • Weight gain[2] • Increase in appetite, sedation[3]	• No change to weight • No change to appetite • Mild nausea, stomach pain	• Nausea / Vomiting (8% pts) • No diarrhoea

"The goals of treatment for ASD are to improve core deficits in social communication and social interactions and minimize the impact of restricted behaviours, with an overarching goal to help children develop greater functional skills and independence."

RCT- randomised controlled trial; BMI – Body Mass index

1. Kent, et al. Risperidone Dosing in Children and Adolescents with Autistic Disorder: A Double-Blind, Placebo-Controlled Study. Journal of autism and developmental disorders. 2012. 43. 10.1007
2. A Study to Evaluate the Efficacy and Safety of Risperidone (R064766) in Children and Adolescents With Irritability Associated With Autistic Disorder, 2015
3. Ghaeli P et al. Effects of risperidone on core symptoms of autistic disorder based on childhood autism rating scale: an open label study. Indian J Psychol Med. 2014 Jan;36(1):66-70.
4. McDougle CJ, et al.. Risperidone for the core symptom domains of autism: results from the study by the autism network of the research units on pediatric psychopharmacology. Am J Psychiatry. 2005 Jun;162(6):1142-8

Rett Syndrome

“Caregivers of children with RTT experience the illness as being like an “obstacle course”, where they must continuously overcome hurdles. These include hindrances for finding responses to their symptoms and achieving a diagnosis, for managing the treatment and daily care, and for finding the essential financial resources to meet all the expenses generated by the illness.”[1]

1. Palacios-Ceña D, Famoso-Pérez P, Salom-Moreno J, Carrasco-Garrido P, Pérez-Corrales J, Paras-Bravo P, Güeita-Rodriguez J. “Living an Obstacle Course”: A Qualitative Study Examining the Experiences of Caregivers of Children with Rett Syndrome. International Journal of Environmental Research and Public Health. 2019; 16(1):41

Rett Syndrome Market Dynamics

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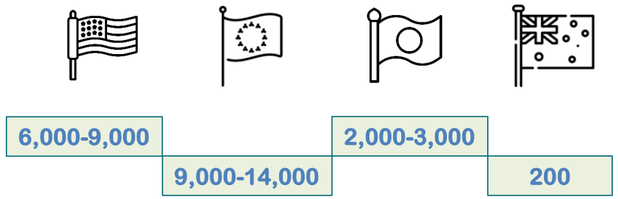
Significant Market



- 17-26k patients in USA, Europe, Japan, Australia
- Est. US$2 billion annual market opportunity
- Narrow range of Rett specialist clinicians: focused prescriber group
- Concentrated market dynamics: 18 Rett Centres of Excellence in the US (3 in AU)
- No approved Rett drugs in Europe, Japan and Australia (USA:1)

Single Approved Therapy

Daybue™ (trofinetide)

- First FDA approved therapy (March 2023)
- Est. drug cost to patient ~US$1,000 per day. US$87 million in Q4 CY2023 (US$177m in CY2023) net sales
- Q3: 800 patient starts (4,500 registered with Rett, ~18% penetration) – strong demand highlights urgent market need
- CY2024 sales est. US$370m – US$420m

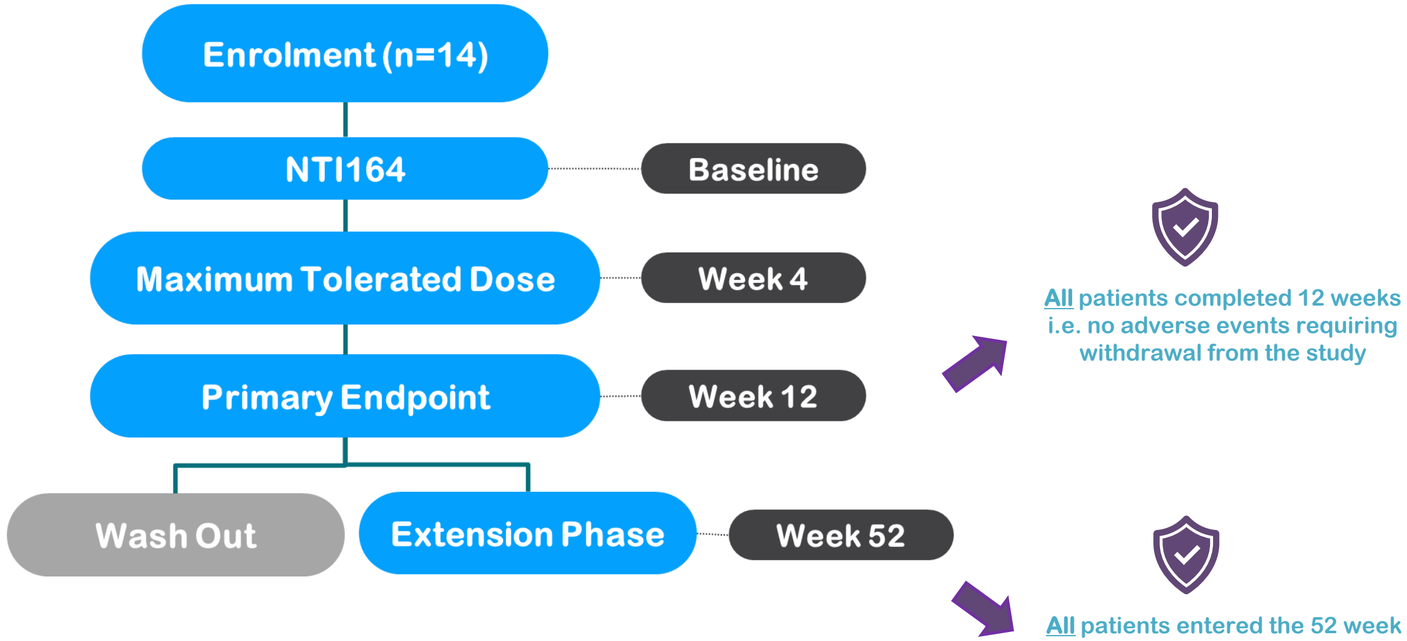
Valuation/Pricing Benchmarks

ACADIA™ neuren pharmaceuticals

- Neuren (ASX:NEU) license deal with Acadia (NASDAQ:ACAD) close to US$1 billion for trofinetide (*inc other indications)
- 80% covered lives for DAYBUE™ from US payers within 6 months – rapid reimbursement adoption
- Market approval via single Phase 3 clinical trial v placebo (“Lavender” – 187 pts), with open-label extension (“Lilac” – 154 pts)

Source: Acadia Pharmaceuticals, Neuren Pharmaceuticals Nov 2023 Investor Presentation, International Rett Syndrome Foundation, Rett Syndrome Association of Australia, Livewire Markets, Company Analysis

Rett Syndrome Trial Design (NTIRTT1)



Primary Endpoint

- Clinical Global Impression – Improvement (CGI-I)

Secondary Endpoints

- Rett Syndrome Behaviour Questionnaire (RSBQ)
- CGI-severity of illness (CGI-S)
- RTT- Clinician Domain Specific Concerns – Visual Analog Scale (RTT-DSC-VAS)
- Impact of Childhood Neurological Disability Scale (ICNDS)
- Overall Quality of Life Rating of the Impact of Childhood Neurological Disability Scale (ICNDS-QoL)
- Rett Syndrome: Symptom Index Score (RTT-SIS)
- RTT Caregiver Burden Inventory (RTT-CBI)
- Safety
- Communication and Symbolic Behaviour Scales Developmental Profile™ Infant-Toddler Checklist (CSBS-DP-IT Social)

* No participants received DAYBUE™ (trofinetide)[1]

1. DAYBUE is a trademark of Acadia Pharmaceuticals Inc

12 Week Safety Data

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NTI164 Exhibits Excellent Safety Over 12 Weeks

A total of 14 patients evaluable at 12 weeks

One serious adverse event (SAE) recorded (Urticaria-hives) Across all doses, across entire period (12 weeks)

Adverse events (AEs) were tolerated and manageable 11 AEs*, 4 patients

Weight Loss/Gain

- No change from baseline

Vomiting^

- 2 pts (14%)

Diarrhoea

- 0 pts (0%)

	Weight Loss/Gain	Vomiting^	Diarrhoea
DAYBUE™	12% with >7% weight lost	29%	82%

Kidney/Liver Function

Vital Signs

Blood Chemistry

Normal

Conclusion: NTI164 exhibits an excellent safety profile and minimal patient-specific side-effects
(consistent with autism and PANDAS/PANS clinical data)

*Other AEs were common cold, viral infection, pharyngitis , chest infection.
^None of these adverse events were serious and were not considered to interfere with the patient's functioning. No additional treatment was required (i.e. administration of anti-vomiting medications). DAYBUE data, source: Acadia Pharma.

Summary of Efficacy Measures

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Primary Endpoint

- **CGI-I**

Improvement of 10% from Baseline at 12 weeks (p=0.009) – 9 exploratory Rett-Specific Anchors
Improvement of 23% from Baseline at 12 weeks (p=0.001) – 4 core Rett Anchors (further development)

FDA APPROVED

- **CGI-I**
- **RSBQ**

→ Co-primary endpoints used for FDA approval in trofinetide Phase 3 trial

Secondary Endpoints

- **RSBQ** — Patients receiving NTI164 showed a **13.4** score decrease in average RSBQ total score versus baseline (30% improvement, p<0.001)
- **CGI-S** — Patients receiving NTI164 showed a **0.4** decrease in CGI-S versus baseline (8.7% improvement, p=0.009)
- **ICNDS** — Patients receiving NTI164 showed an **8.5** score decrease versus baseline (13% improvement, p=0.004)
- **ICNDS-QoL** — Patients receiving NTI164 showed a **1.5** score increase versus baseline (60% improvement, p<0.001)
- **RTT-CBI** — Patients receiving NTI164 showed a **5.0** score decrease versus baseline (16% improvement, p=0.025)
- **RTT-DSC-VAS** — Patients receiving NTI164 showed a 0.6 score decrease in verbal communication (13% improvement, p=0.014) but no improvement in ambulation (p=0.374), communication choices (p=0.374) and hand function showed no change (NM)
- **RTT-SIS** — No significant change (p=0.146) in total score

CSBS-DP-IT — Not Measured

Rett Syndrome Behavioural Questionnaire RSBQ is a caregiver-completed scale assessing a wide range of neurological and behavioural symptoms in RTT (maximum score 90). RTT Symptom Index Score RTT-SIS developed by A/Prof Ellaway examines 16 Rett-specific symptoms. RTT-Clinician Domain Specific Concerns-Visual Analog Scale RTT-DSC-VAS is a clinician-completed VAS assessing the severity of concerns in: (1) hand use; (2) ambulation; (3) seizures; (4) autonomic features; (5) behaviour; (6) attentiveness; (7) social interaction; and (8) language/communication. CGI-S is a single-item, 7-point scale by clinicians designed to assess global impression of severity (1=normal, 7 = severely ill). Impact of Childhood Neurologic Disability Scale ICNDS measures the impact that a child's condition has on the child's and the family's everyday life at the time of assessment and during the previous 3 months. It is an accurate, quick measurement tool reflecting the impact of behaviour, cognitive learning ability, physical/neurologic disability, and epilepsy on children and their families (0 = no impact, 132 = severe impact). ICNDS-QoL measures the overall quality of life of the affected individual (1 – poor, 6 –excellent). RTT-Caregiver Burden Inventory RTT-CBI is a syndrome-specific, caregiver-completed questionnaire that is based on the CBI designed for Alzheimer's disease (0= never, 5 = nearly always). N/M – not measured as no difference

CGI-I: Specific Rett Anchor Analysis

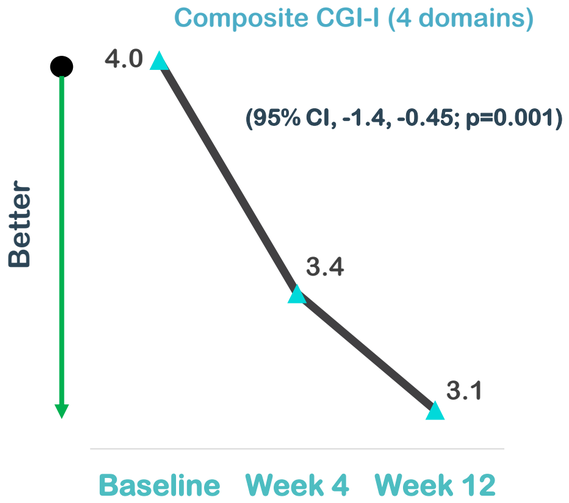
- As a first in human trial of NTI164 in Rett patients, Neurotech examined nine (9) anchors/sub-domains to further understand what domain benefits NTI164 could target for registration-directed trials
- Only 2-3 sub-domains are typically examined in Phase 3 trials for CGI-I: composite results for four (4) domains consistently cited by doctors, caregivers as important and where NTI164 showed strong improvements are shown

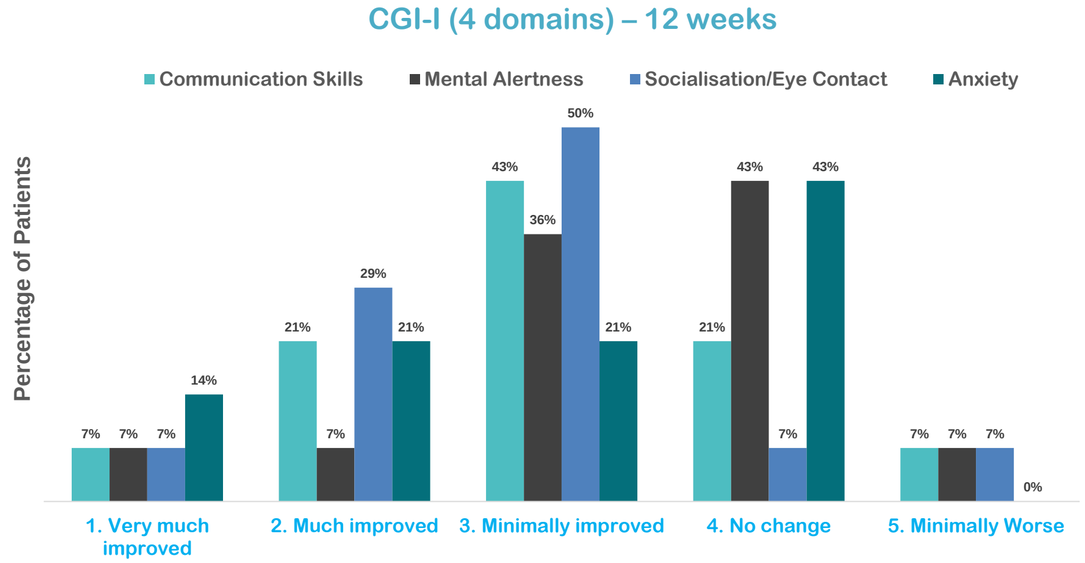
Communication Skills

Mental Alertness

Socialisation / Eye Contact

Anxiety





	Very Much Improved	Much Improved	Minimally Improved	No Change	Minimally Worse	Much Worse	Very Much Worse
Scale	1	2	3	4	5	6	7
NTI164 (week 12)	1 (7%)	4 (29%)	8 (57%)	1 (7%)	0 (0%)	0 (0%)	0 (0%)

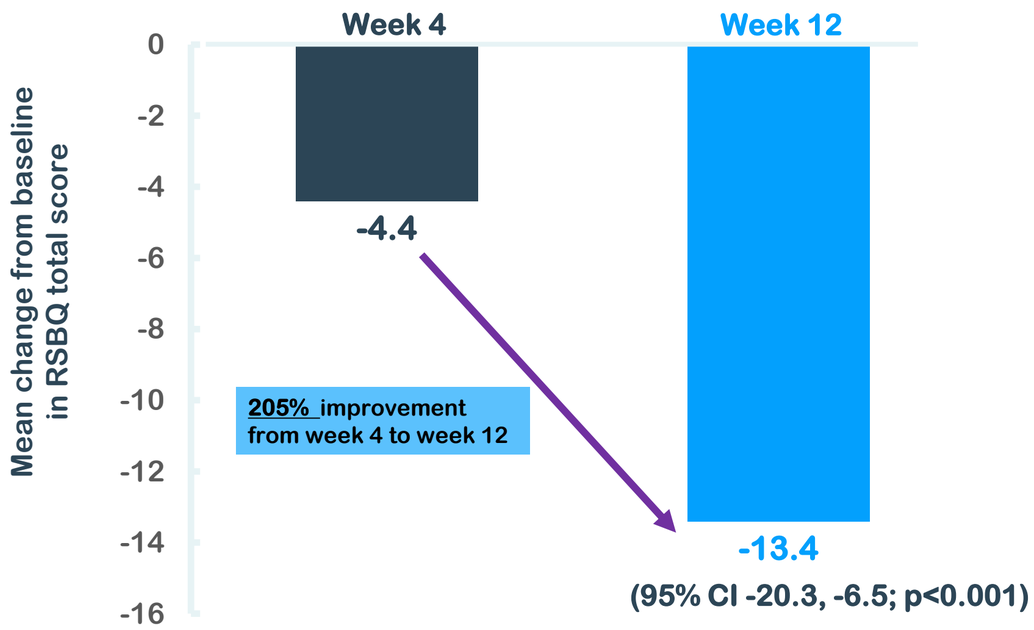
CGI-I (4 core domains) improved 23% at 12 weeks (p=0.001). 93% of patients improved

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.

Secondary Endpoint: RSBQ

The Rett Syndrome Behaviour Questionnaire (RSBQ) assesses the severity of neurobehavioral problems from the perspective of the caregiver and is one of the most widely used measures due to the specificity of its psychometric profile to the core features of Rett and is accepted by the United States Food and Drug Administration (FDA) for use in Rett Syndrome studies

Change from Baseline RSBQ Scores[1]



Total RSBQ Scores[1]

Baseline	4 weeks	12 weeks	P value
44.6	40.2	31.2	<0.001
Improvement (v baseline) mean diff.	4.4 (10%)	13.4 (30%)	

A lower score reflects lesser severity in signs and symptoms of Rett

RSBQ Sub Domain Scores[1]

Measure	12 weeks mean diff.	P value
Mood	-4.6	0.001
Breathing	-0.4	0.233
Hands	-2.0	<0.001
Face	-0.8	0.009
Body Rocking	-2.0	0.042
Nighttime	-1.0	0.161
Fear/Anxiety	-1.8	0.02
Walk/Stand	-0.8	0.104

12 week RSBQ score improved 30% v baseline (p <0.001)

Clinical Interpretation

- Substantial 205% improvement from week 4 to week 12
- The change in RSBQ was aligned with CGI-I, implying that improvement in behavioural components may be related to overall clinical status

1. RSBQ was first shown to discriminate RTT from other intellectual disorders with good inter-rater and test–retest reliability scores. RSBQ consists of 45 items, rated as 0 = 'not true',1 = 'somewhat or sometimes true' or 2 = 'very true', that can be grouped into eight symptom domain subscales graded on a scale of 0–90 (maximum severity). 8 domains/subscales that reflect the core features of Rett examined: General Mood; Breathing Problems; Hand Behaviours; Repetitive Face Movements; Body Rocking and Expressionless Face; Nighttime Behaviours; Fear/Anxiety; and Walking/Standing. Moderate to high internal consistency has been reported for the total score and the 8 subscales, with good inter-rater and test–retest reliability scores, and significantly higher scores in a Rett population versus those with intellectual disability, thus validating its use as a diagnostic tool.

PANDAS/PANS

“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/

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

Neurotech International

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

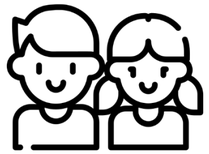
There are no FDA/EMA/TGA approved drug therapies for PANDAS/PANS

New Clinical Trials and Treatments Urgently Needed

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

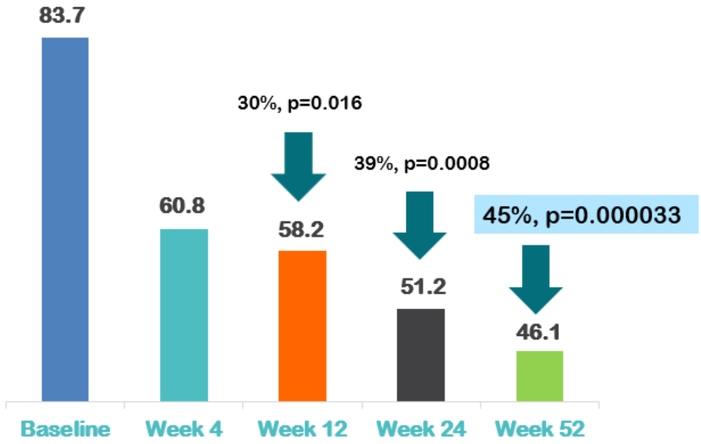
PANDAS/PANS

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



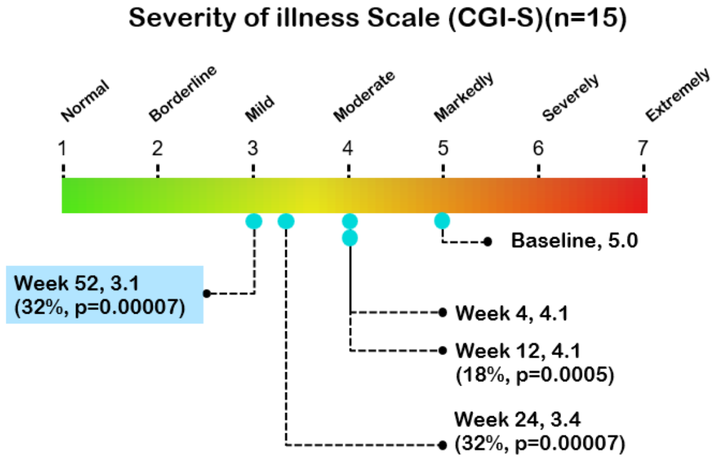
Phase I/II reported: 15 patients with moderate-severe PANDAS/PANS recruited,12-week data (Oct 23), 24-week data (Feb 24), 52-week data (June 24)

45% Improvement in anxiety / depression at 52 weeks



RCADS-P[1]

32% Improvement in Disease Severity at 52 weeks



CGI-Severity of illness[1]

Attractive Clinical and Market Dynamics

- Rare, paediatric onset with **NO** Approved treatments
- Diagnostic and Treatment Criteria now accepted
- Strong correlation to brain inflammation
- World first trial of broad-spectrum cannabinoid therapy
- All patients continue treatment > 12 weeks, some now adults. No serious adverse events recorded
- Seeking orphan drug designations (ODDs) in US, EU

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. 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.

Key Milestones – NTI164

1H CY2024

- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial
- 24-week PANDAS/PANS Phase I/II Clinical Trial Data
- Rett Syndrome Phase I/II (14 girls) 52-week Extension HREC Approval
- Results of ASD Phase II/III Clinical Trial
- Top-line Rett Syndrome Phase I/II Clinical Trial data
- Results of Rett Syndrome Phase I/II Clinical Trial – full data
- Meeting outcome – TGA[1] Regulatory Advice
- Publications for ASD Phase I/II + pre-clinical NTI164 results
- Metabologenomic data from Phase I/II PANDAS/PANS Clinical Trial

2H CY2024

- Orphan Drug Designation USA – Rett Syndrome
- Orphan Drug Designation USA – PANDAS/PANS
- Orphan Drug Designation Europe – Rett Syndrome
- Orphan Drug Designation Europe – PANDAS/PANS
- Presentation of Phase I/II Rett Syndrome data at international Rett meeting
- FDA IND / EMA[2] toxicology
- Commence Phase I/II Cerebral Palsy Clinical Trial

Timing controlled by Journal(s) not Neurotech, likely to be 2H

1. Therapeutic Goods Administration (TGA)
2. Food and Drug Administration (FDA), European Medicines Agency (EMA)

Outlook

- **Completed $10.0 million capital raise, $13.6 million in available pro-forma funds: well-funded to accelerate development activities in Australia and US, EU**
- **Continued safety/efficacy data releases across 3 indications (ASD, PANDAS/PANS, Rett) as patients enter or are maintained in open-label extensions**
- **Clinical, regulatory, commercial strategies in development – anticipate finalisation early Q3 CY2024**
- **Strong focus on expedited path(s) to market given NTI164 efficacy and safety in very serious neurological disorders in children lacking effective therapies**

Neurotech International

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*This presentation has been authorised by the Board of Neurotech International Limited

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