



# Improving Lives



## Phase I/II ASD 52 Week Results Investor Presentation

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Executive Director

17 March 2023

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# Presentation Contents

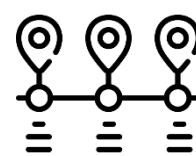
ASD 52 Week  
Phase I/II Results



Neurotech  
Strategies



Clinical Focus,  
Pipeline & Milestones



Summary &  
Outlook





# Autism Spectrum Disorder (ASD) Goals

*“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.”<sup>1</sup>*





# Autism Spectrum Disorder (ASD)

PREVALENCE OF ASD  
~1 in 44 children  
in the US<sup>1</sup>

## Market

ASD is a serious neuro inflammatory developmental disorder that impairs the ability to communicate & interact

Common symptoms; behavioural issues, agitation, repetitive movements, inability to focus & compulsive neurological patterns

TREATMENT  
MARKET SIZE  
US\$1.85b<sup>2</sup>



**RISPERIDONE**  
Approved 2006  
(irritability label claim)

## Current Treatment

Huge unmet medical need - patients need better treatment

Current drugs have numerous side effects; weight gain, breast tissue development, nausea, dry mouth, anxiety, irritability, insomnia, stomach pain & movement disorders



## Clinical Trial

Initial Focus of NTI164 – A full spectrum, oral cannabinoid biopharmaceutical product



# ASD and the NDIS



The National Disability Insurance Scheme (NDIS) provides assistance to people with a disability, as well as their families and carers

**\$35.5 Billion**

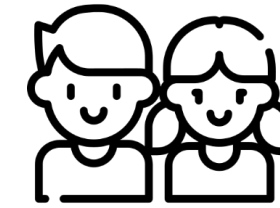
Cost of NDIS in 2022, to increase to \$52 billion by 2026, \$100 billion by 2033<sup>1</sup>

**34% ASD**

34% of the 550,000 NDIS participants have ASD, 40% ≤ 14 years old (860,000 by 2030)<sup>2</sup>

**\$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<sup>3</sup>



- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years<sup>5</sup>

TREATMENT  
MARKET SIZE  
**US\$1.85b<sup>4</sup>**



**RISPERIDONE**  
Approved 2006  
(irritability label claim)

Current Treatment



*There is a strong market need for an effective therapeutic intervention such as NTI164 to improve ASD symptoms & reduce healthcare costs*

1. The Australian, 25 October, 2022- <https://www.afr.com/politics/federal/how-the-ndis-will-blow-out-to-50b-in-four-charts-20221019-p5br1c>  
2. <https://www.uwa.edu.au/news/Article/2022/August/An-autism-minister-may-boost-support-and-coordination-But-governments-that-follow-SAs-lead-should-be-cautious>  
3. <https://disabilityplanservices.com.au/blog/how-much-is-ndis-funding-for-autism/#:~:text=At%20Disability%20Plan%20Services%2C%20we,per%20year%20under%20the%20NDIS.>  
4. <https://www.fortunebusinessinsights.com/industry-reports/autism-spectrum-disorder-therapeutics-market-101207-CAGR-of-7-4.html>  
5. Australian Bureau of Statistics. (2018). Autism in Australia. Retrieved from <https://www.abs.gov.au/ausstats/abs@.nsf/mf/4428.0>

# NTI164 ASD Phase I/II - Trial Design

## The Program

### First in human Phase I/II ASD paediatric study

Commenced in May 2021 at Monash Children's Hospital led by A/Prof. Michael Fahey

#### Open label – single group

14 patients from 8 to 17yo, Level II and III Autism Spectrum Disorder

#### Dose regime assessments

5mg/kg, 10mg/kg, 15mg/kg and 20mg/kg of NTI164 (initial 4 weeks)

#### Maximum tolerated dose daily through to 52 weeks

~7,000 Assessment points over 52 weeks, daily oral treatment

28 Day Data  
Released  
8 July 2022

20 Week Data  
Released  
26 October 2022

52 Week Data  
Released  
17 March 2023

# NTI164 ASD Phase I/II – Safety (52 week Data)

## NTI164 Safety Effects Maintained Over 52 Weeks

### No serious adverse events recorded

Across all doses

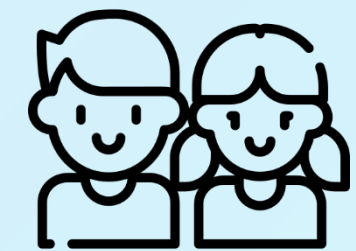
Only 1 patient on Risperidone at enrollment (not considered a pref. standard of care)

### Adverse events were tolerated and manageable

mild nausea, abdominal pain

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

**Conclusion:** NTI164 longer term (chronic) administration now established with an excellent safety profile and minimal patient-specific side-effects: safety data will be collected beyond 52 weeks for at least six additional months



**A total of 11 patients  
evaluative at 52 weeks**  
(12 pts. at 20 weeks)



# NTI164 ASD Phase I/II – Efficacy (52 week Data)

## Summary Outcome Measures

Sub-Domain	Scale	20 Weeks P-value (Paired T-Test)	52 Weeks P-value (Paired T-Test)
Severity of illness	CGI-S	0.005	0.032
Global improvement	CGI-S	n/a*	n/a*
Therapeutic effect	CGI-S	n/a*	n/a*
Adaptive behaviour composite (Total)	Vineland-3	0.0005	0.028
Communication	Vineland-3	0.002	0.0001
Daily living skills	Vineland-3	0.019	0.005
Socialisation	Vineland-3	0.014	0.118
Social responsive scale – Total	SRS-2	0.012	0.049
Social awareness	SRS-2	0.596	0.421
Social cognition	SRS-2	0.028	0.105
Social communication	SRS-2	0.019	0.216
Social motivation	SRS-2	0.118	0.005
Restricted interest and repetitive behaviour	SRS-2	0.009	0.109
Social communication and interaction	SRS-2	0.029	0.081
Anxiety scale for children - Child's total	ASC-ASD-C	0.025	NM
Performance anxiety	ASC-ASD-C	0.364	NM
Anxious arousal	ASC-ASD-C	0.12	NM
Separation anxiety	ASC-ASD-C	0.025	NM
Uncertainty	ASC-ASD-C	0.033	NM
Anxiety scale for children - Parent's total	ASC-ASD-P	0.034	NM
Performance anxiety	ASC-ASD-P	0.07	NM
Anxious arousal	ASC-ASD-P	0.333	NM
Separation anxiety	ASC-ASD-P	0.025	NM
Uncertainty	ASC-ASD-P	0.066	NM
Sleep disturbances scale for children - Total	SDSC	0.016	NM
Disorders of initiating and maintaining sleep	SDSC	0.01	NM
Sleep breathing disorders	SDSC	0.047	NM
Sleep-wake transition disorders	SDSC	0.094	NM
Anxiety, depression and mood scale – Total	ADAMS	0.001	NM

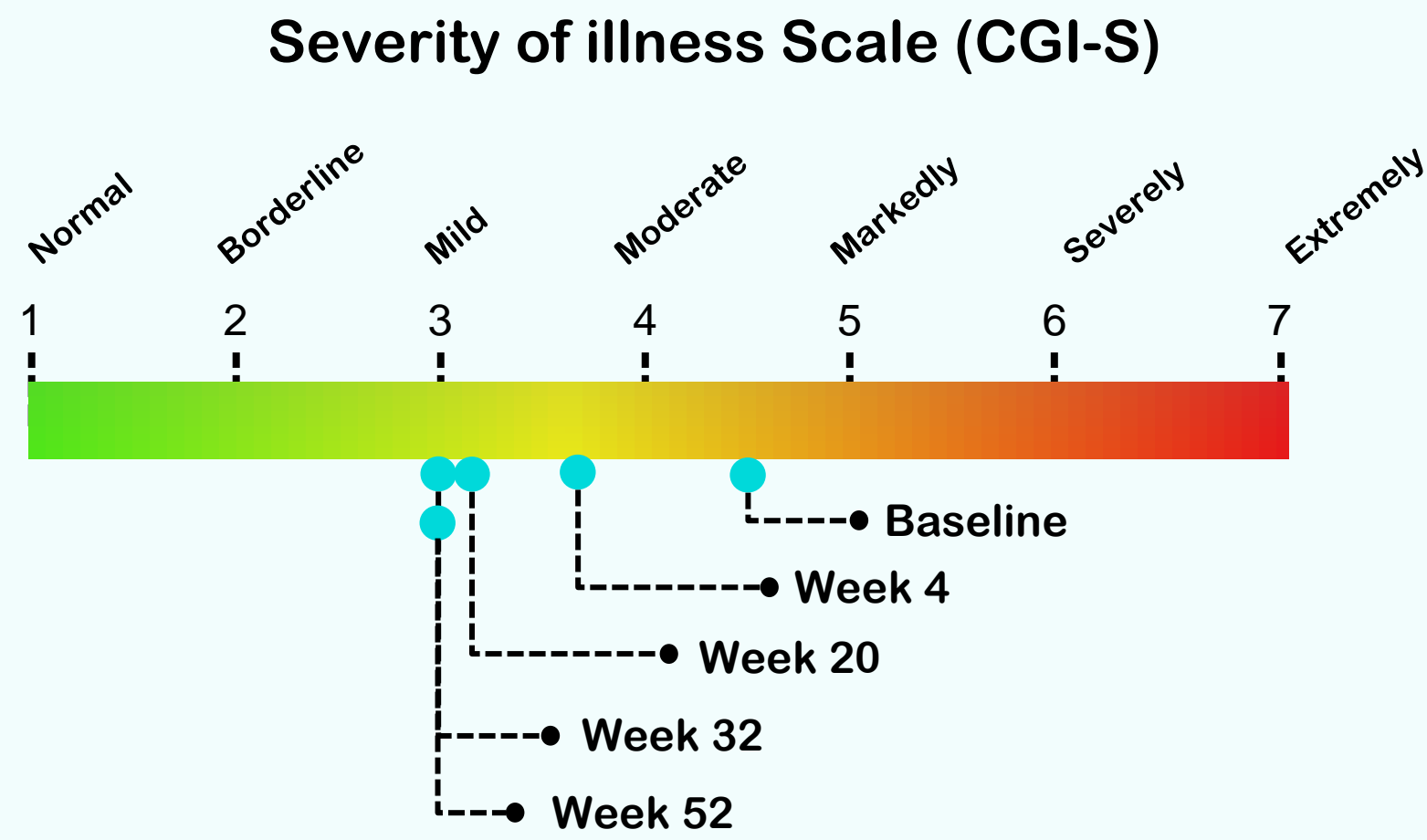
\* t-test cannot be performed due to different measurement scale used at baseline; NM – not measured



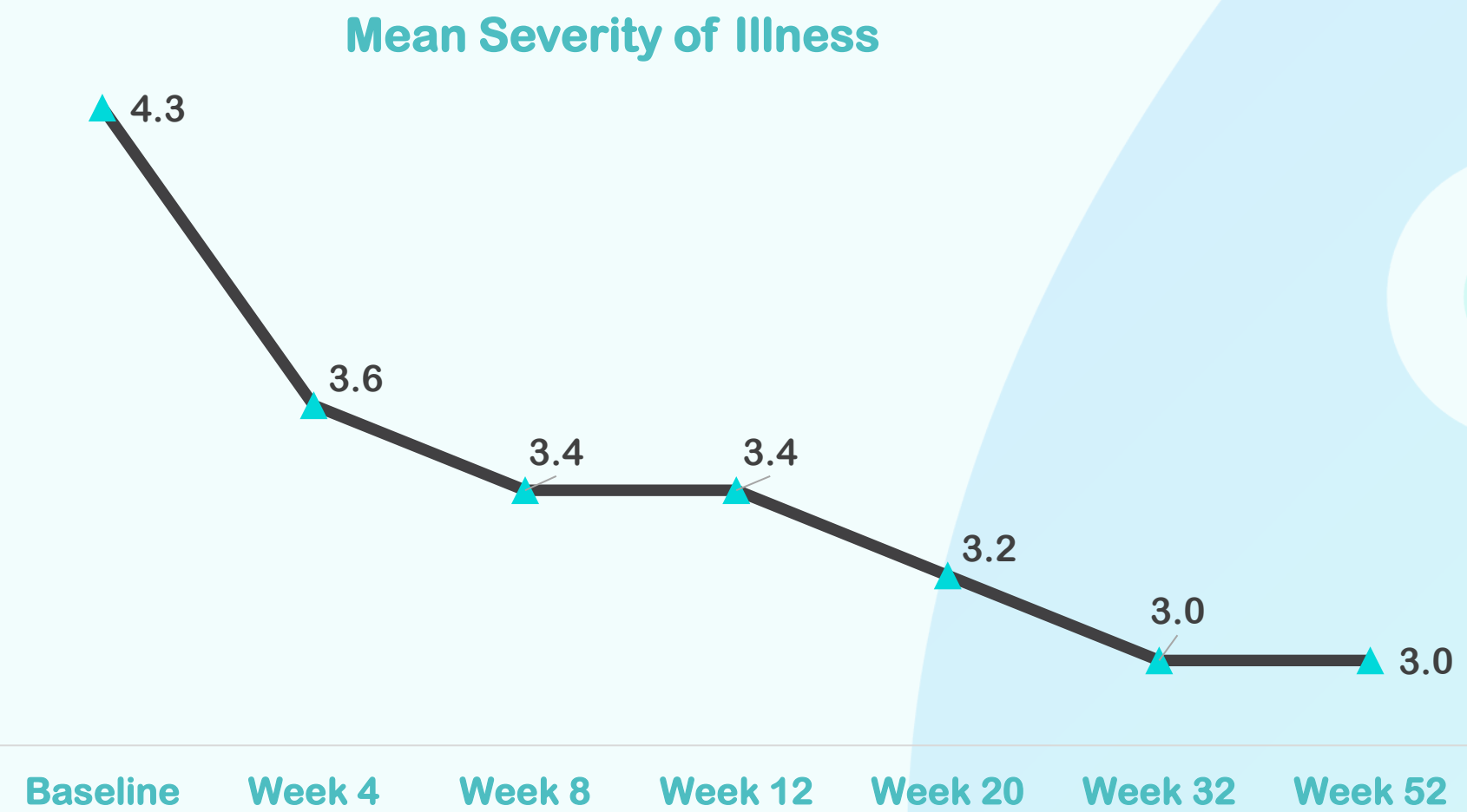
## Clinical Interpretation

- Statistical significance (p<0.05):
  - Study was **never** statistically powered for any efficacy measures (safety was primary endpoint)
- Highly significant results for the most clinically important measures:
  - Severity of illness
  - Adaptive behaviour
  - Social responsiveness
- Consistent improvements across multiple standard clinical measures at 52 weeks versus baseline do not support a placebo effect

# NTI164 ASD Phase I/II – Efficacy (52 Week Data)



**CGI-Severity of illness<sup>1</sup> (p = 0.03)**



## Clinical Interpretation

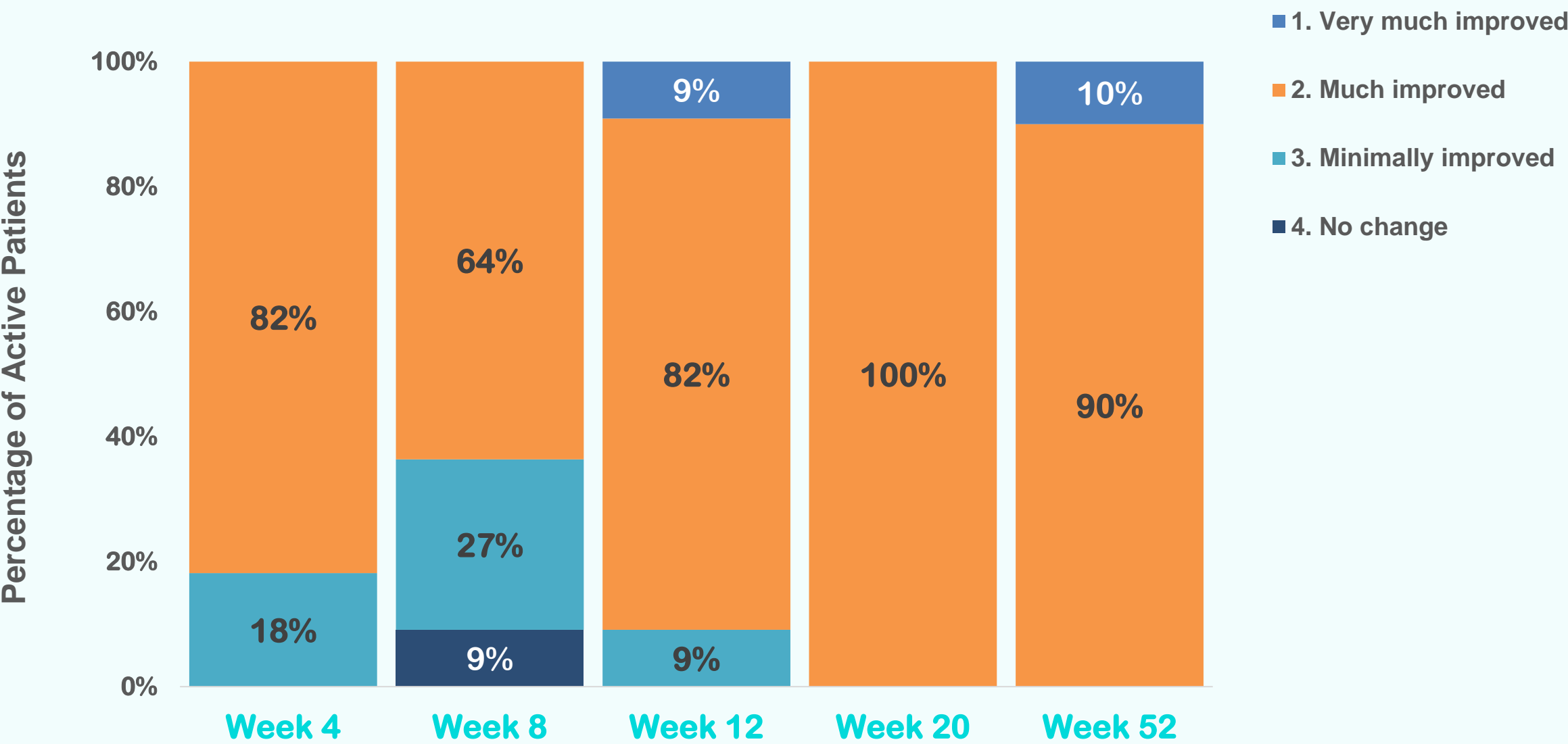
- NTI164 treatment is associated with a significant reduction in disease severity (1.3 scale change, 30% improvement)
- ~40% of subjects markedly or severely ill at baseline – 0% from week 4 onwards


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. Baseline and 28 day data as previously reported has been normalised to exclude those two patients who did not complete 20 weeks of daily NTI164 treatment and one patient at 52 weeks. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.



# NTI164 ASD Phase I/II – Efficacy (52 week Data)


## CGI-Global improvement <sup>1</sup>





### Clinical Interpretation

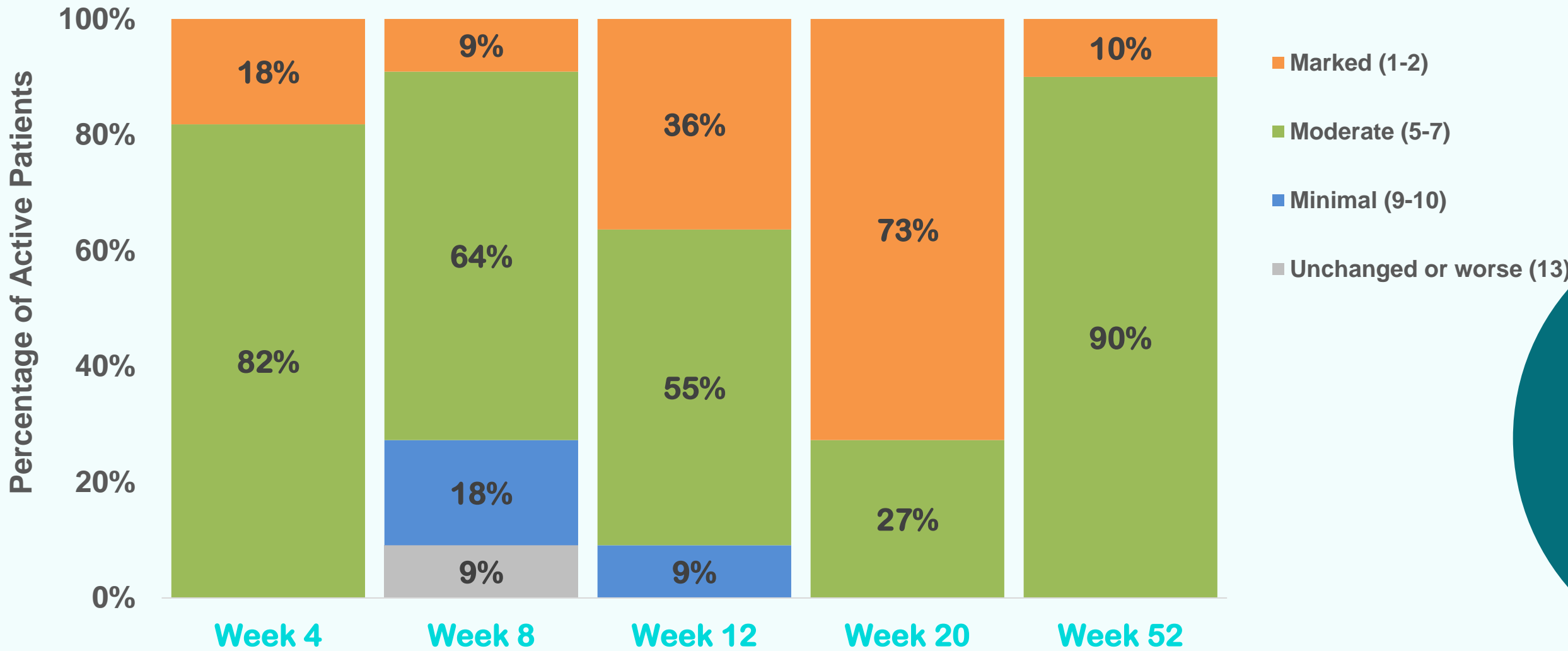
- 100% of active patients showed improvement after 20 weeks of daily treatment with NTI164
- After 52 weeks of daily treatment with NTI164, 90% of active patients (n=10) had a global improvement of Much improved and 10% (n=1) had a score of Very much improved.



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. Baseline and 28 day data as previously reported has been normalised to exclude those patients who did not complete 20-52 weeks of daily NTI164 treatment. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.

# NTI164 ASD Phase I/II – Efficacy (52 week Data)

## CGI-Therapeutic Effect<sup>1</sup>



## Clinical Interpretation

- After 52 weeks of daily NTI164 treatment, 10% of active patients demonstrated the highest possible efficacy index of 1: *Marked therapeutic effect – Vast improvement. Complete or nearly complete remission of all symptoms.* 90% of patients had an efficacy index of either 5 or 6: *Moderate therapeutic effect – Decided improvement. Partial remission of symptoms.*

**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.

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. Baseline and 28 day data as previously reported has been normalised to exclude those patients who did not complete 20-54 weeks of daily NTI164 treatment. The CGI is a 3-item observer-rated scale that measures illness severity, global improvement and therapeutic effect.



# NTI164 ASD Phase I/II – Efficacy (52 week Data)

## Vineland™-3<sup>1</sup>

Standardised measure of adaptive behaviour (3 month+ measure)

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

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

Vineland-3 Domain	P-value (Paired T-Test) 20 weeks	P-value (Paired T-Test) 52 weeks
Adaptive behaviour composite	0.0005	0.0278
Communication	0.002	0.0001
Daily living skills	0.019	0.0050
Socialisation	0.014	0.118



## Clinical Interpretation

- Adaptive behaviour improvement is a treatment goal in ASD
- Highly significant improvements in composite outcome AND individual domains of communication, daily living at 20 weeks continued through to 52 week endpoint

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.

# NTI164 ASD Phase I/II – Efficacy (20 week Data)

## SRS™-2<sup>1</sup>

*Children with autism spectrum disorder have difficulty with social interaction behaviours, including establishing and maintaining relationships, reciprocating social interaction, and communicating with others. SRS-2 is a validated measurement tool of assessing these factors*

SRS-2 Domain	P-value (Paired T-Test) 20 weeks	P-value (Paired T-Test) 52 weeks
Total	0.012	0.049
Social awareness	0.596	0.421
Social cognition	0.028	0.105
Social communication	0.019	0.216
Social motivation	0.118	0.005
Restricted interest and repetitive behaviour	0.009	0.109
Social communication and interaction	0.029	0.081



### Clinical Interpretation

- At 20 weeks of daily treatment with NTI164, the study achieved strong overall statistical significance for social responsiveness (p=0.012). This positive change remained statistically significant at 52 weeks (p=0.049)
- NTI164 targets social skills: beneficial for social functioning and social anxiety symptoms

1. Social Responsiveness Scale (SRS™-2) is internationally recognised as a leading instrument (65 items) for identifying the presence and severity of social impairment within the Autism spectrum and differentiates it from that which occurs in other disorders. The SRS-2 total score is the most reliable measure for social deficits related to ASD. SRS-2 is distinct from other measures in that it provides a continuous measure of social ability (from impaired to above average) instead of a categorical yes/no identification of ASD impairments. High scores are associated with more severe social impairments. SRS-2 is a valid and reliable quantitative measure of core ASD symptoms related to social impairment



# NTI164 ASD Phase I/II – Conclusions

- Continued excellent durability of results at 52 weeks, with clinical benefits showing a significant improvement across a large number of clinically validated assessments versus baseline (Day 0)
- Any significant change over time for measures of CGI-S, Vineland™-3 and SRS™-2 are considered clinically meaningful: NTI164 showed sig. improvement for all measures at 52 weeks v baseline
- NTI164 is a patient ‘enabling’ drug with non-drug behavioural therapies, by improving daily living and allowing children to integrate into society via significant improvements in socialisation & anxiety versus ‘restrictive’ prescription of Risperidone (prevention of aggression, irritability)

## Professor Michael Fahey – Lead Investigator

*“We continue to see benefits in these ASD patients through daily oral treatment with NTI164 over 52 weeks. Our standardised ASD scales relating to global improvement, severity of illness, socialisation and adaptive behaviour, continued to show a clinically meaningful and statistically significant difference from baseline measures with no serious adverse events recorded and clean pathology results. Importantly, there was no evidence that prolonged use of NTI164 in these patients can lead to any form of therapeutic tolerance as measured by a slow reversion of symptoms through extended use. This is particularly pleasing and highlights chronic administration of NTI164 is required to achieve significant improvements in clinical outcome measures. We certainly look forward to the next phase of this exciting development opportunity in ASD.”*

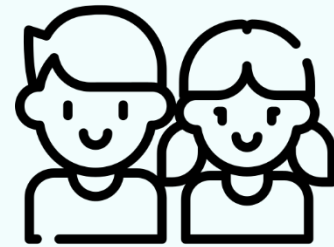


# Neurotech: Strategies, Pipeline, Milestones, Outlook

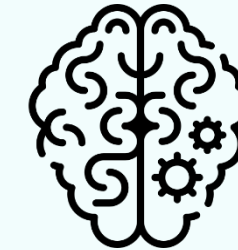




# Neurotech Four Core Strategies



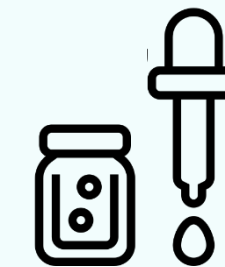
**Focus on Paediatric  
Patients**



**Focus On Rare  
Neurological Disorders  
with Neuroinflammation**



**Focus on Partnering with  
Key Opinion Leaders /  
Clinicians**



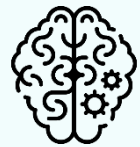
**Focus On Drug Product  
Development**

# Strategic Focus Offers Significant Value Upside



## Focus on Paediatric Patients

- Often overlooked by big pharma
- Can be unencumbered drug therapy markets (no standard of care, no approved treatments)
- Lack of clinical trials that may compete for patients
- Ability to leverage significant regulatory levers at FDA & EMA: orphan designation, breakthrough status, fast-track, priority review



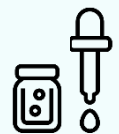
## Focus On Rare Neurological Disorders with Neuroinflammation

- Literature well-established for cannabinoids / extracts on inflammatory processes
- NTI164 shown strong pre-clinical effects on inflammation, neuro-protection, neuro-modulation and neuro-regulation
- NTI164 shown efficacy in serious neuroinflammatory developmental disorder: Autism Spectrum Disorder
- Often chronic disorders requiring continued therapeutic intervention (higher lifetime patient value)



## Focus on Partnering with Key Opinion Leaders / Clinicians

- Paediatric Neurology focus with supportive Human Research Ethics Committees (HRECs)
- Availability of patients / caregivers for clinical trials
- Decades of experience in paediatric clinical trials – sound trial design frameworks and outcomes
- Paediatric neurological disorders tend to have strong clinical networks / advocacy groups



## Focus on Drug Product Development

- Regulated Drug Product via FDA, TGA, EMA (barrier to entry)
- Manufacture under Good Manufacturing Practice (GMP) & robust CMC (Chemistry, Manufacture, Controls)(barrier to entry)
- Premium Drug Pricing
- Reimbursement for “on-label” prescribing



# Clinical Focus



ASD

PANDAS/PANS

Cerebral Palsy

Neurological &  
Neuroinflammation

Lack of effective treatments

Paediatric Onset

Rare / Orphan

## Strong Scientific Rationale for NTI164

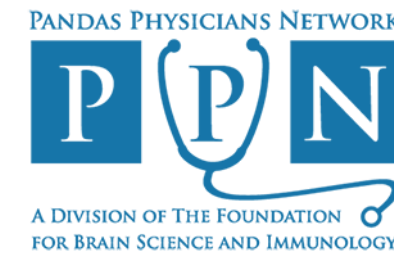
- Anti-inflammatory effects + safety
- Clinician support
- High Patient/Caregiver interest





# About PANDAS / PANS

## About



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

## No Treatments

No FDA or EMA approved treatments: Intravenous immunoglobulin (IVIG) off-label: not proven, v. high cost

## Rare, Neuroinflammation

Considered a rare paediatric orphan disorder, with strong neuroinflammatory effects – ideally suited for NTI164 clinical trial

2015 | 2017 | 2022

Release of PANDAS/PANS Diagnostic Criteria (2015) and Treatment Guidelines (2017) and the World Health Organisation recognition within the International Classification of Diseases (ICD-11) for the first time (2022)



Source: PACE Foundation



# About Cerebral Palsy



*Interventions ideally seek to: improve gross motor function, to increase participation at a social role level, to improve comfort, to improve the ease of care by others or to improve the overall quality of life of the individual*

## About

- Most common motor disability in childhood, abnormal brain development or damage to the developing brain
- Stratified by: Spastic CP (80% of cases), Dyskinetic CP (6% of cases), Ataxic CP (6% of cases) and Mixed CP (balance of cases)

## Lacking Treatments

- Primary treatment options for CP are medication, therapy, and surgery. The goal of CP treatment is to manage symptoms – specifically, spasticity and/or dystonia
  - Botulinum A : no improvement in motor function(s)
  - Baclofen – unwanted side-effects, weak evidence for quality of life benefits

## Neuroinflammation

- Available evidence supports the pathogenic role of inflammation and its ongoing role as a comorbidity of CP – Advantages for NTI164

## Significant Market

- 500,000 children under age of 18 currently have Cerebral Palsy (USA)<sup>1</sup>
- 8,000-10,000 babies born each year with CP
- US\$4.3 billion treatment market (mostly spastic CP) by 2030<sup>2</sup>

# Clinical Pipeline – 2023

## Pre-Clinical

**NTI164**  
Combination Therapies  
Prednisone, Diclofenac, Other

**Other Licensed  
Strains**

## Phase I/II

**NTI164**  
Cerebral Palsy

**NTI164**  
PANDAS / PANS

**NTI164**  
ASD  
(52 week open label extension)

**NTI164**  
[Undisclosed]  
(Expected 1H CY23)

## Phase II/III

**NTI164**  
ASD

### Pipeline (2020/1)

**NTI164**  
Combination Therapies  
Prednisone, Diclofenac, Other

**NTI164**  
Neuronal Cell Assays

**Other Licensed  
Strains**



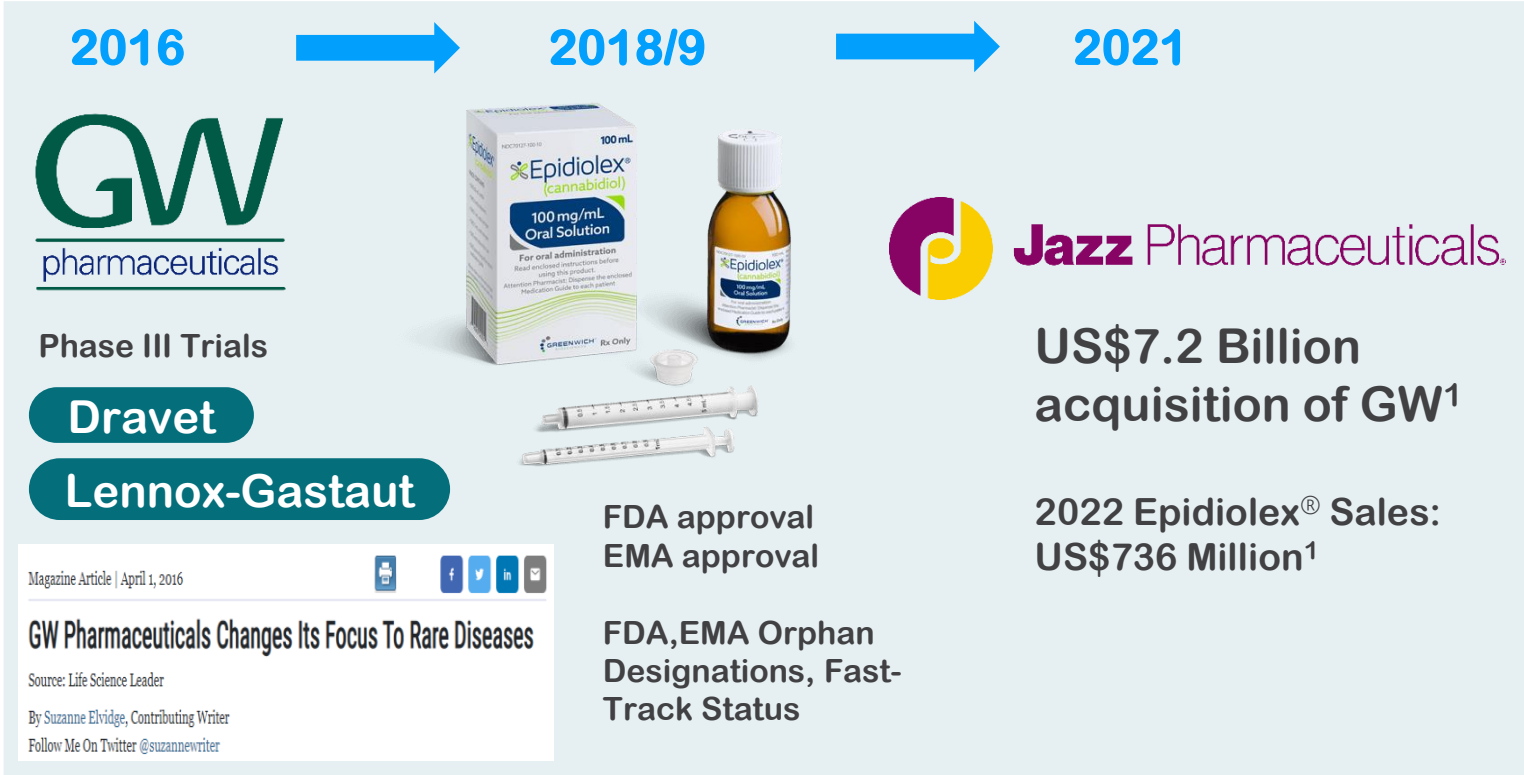
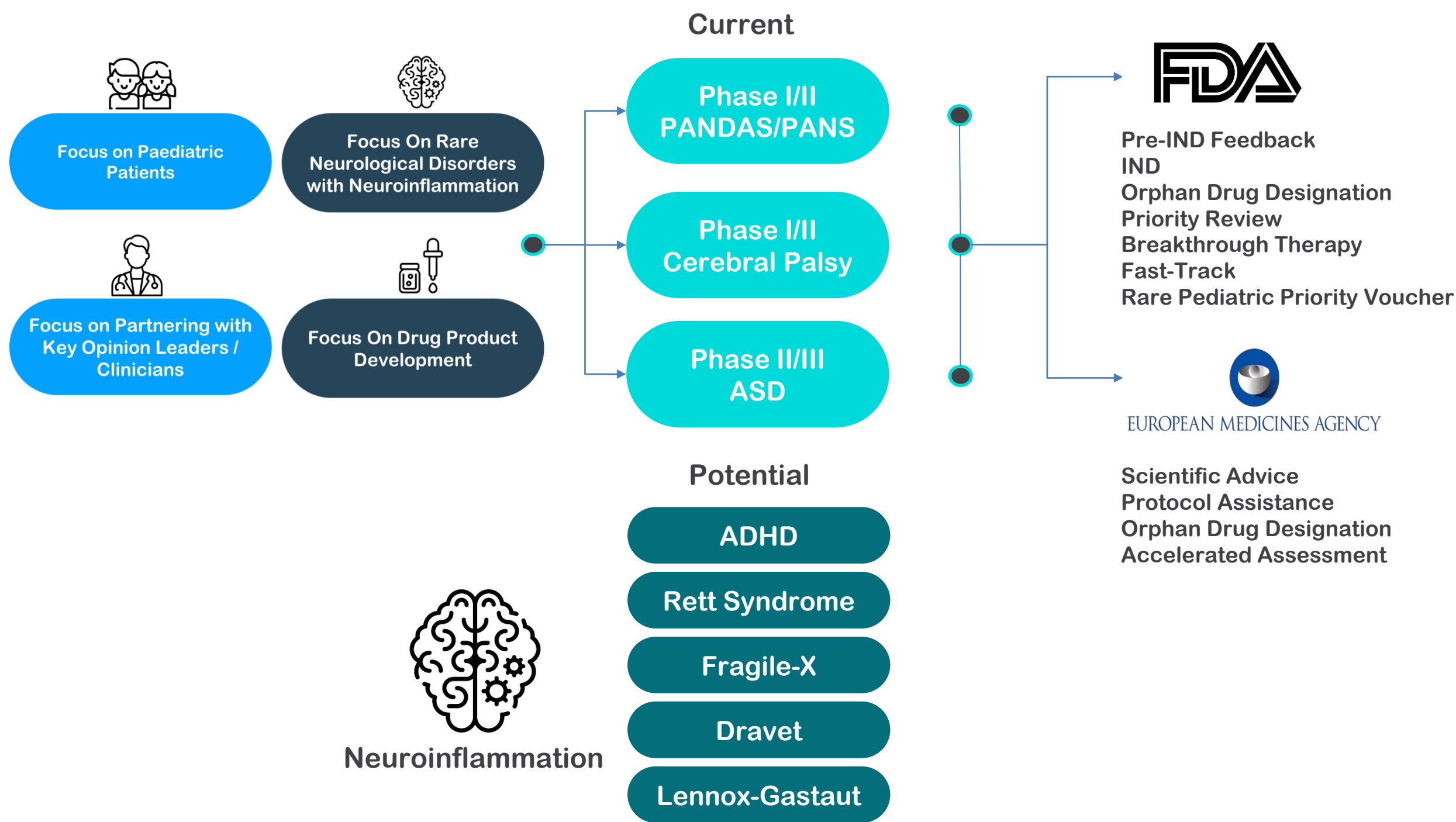
# Summary of Strategy

## Group Strategy

## Implementation to Development

## Potential Regulatory Levers

## Commercialisation Examples\*



**2016** → **2018/9** → **2021**

**GW pharmaceuticals**

Phase III Trials

- Dravet
- Lennox-Gastaut

Magazine Article | April 1, 2016

GW Pharmaceuticals Changes Its Focus To Rare Diseases

Source: Life Science Leader

By Suzanne Elvridge, Contributing Writer

Follow Me On Twitter @suzannewriter

**Epidiolex<sup>®</sup> (cannabidiol)**

100 mg/mL Oral Solution

For oral administration. Read associated information before using this product. See associated information for important information about this product. See associated information for important information about this product.

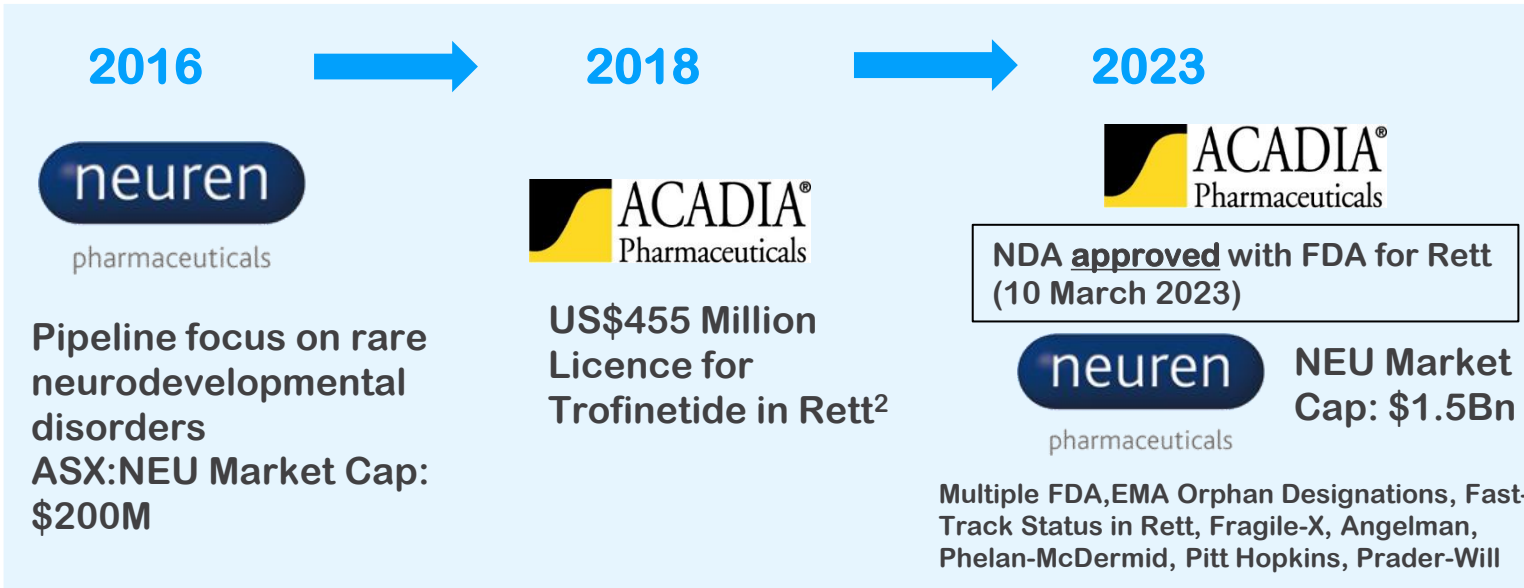
**FDA approval**  
**EMA approval**

**Jazz Pharmaceuticals**

**US\$7.2 Billion acquisition of GW<sup>1</sup>**

**2022 Epidiolex<sup>®</sup> Sales: US\$736 Million<sup>1</sup>**

**FDA,EMA Orphan Designations, Fast-Track Status**



**2016** → **2018** → **2023**

**neuren pharmaceuticals**

Pipeline focus on rare neurodevelopmental disorders

ASX:NEU Market Cap: \$200M

**ACADIA<sup>®</sup> Pharmaceuticals**

US\$455 Million Licence for Trofinetide in Rett<sup>2</sup>

**ACADIA<sup>®</sup> Pharmaceuticals**

**NDA approved with FDA for Rett (10 March 2023)**

**neuren pharmaceuticals**

**NEU Market Cap: \$1.5Bn**

Multiple FDA,EMA Orphan Designations, Fast-Track Status in Rett, Fragile-X, Angelman, Phelan-McDermid, Pitt Hopkins, Prader-Will

1. Jazz Pharmaceuticals 2. Neuren Pharmaceuticals

\* For illustrative purposes only highlighting transactions in the rare paediatric neurological disorder field

# Key 12 Month Milestones – NTI164

## 1H CY2023



- HREC/TGA Extension of ASD Phase I/II Clinical Trial – 6 months



- Final results of ASD Phase I/II Clinical Trial (52 weeks)



- Commence Patient Recruitment PANDAS/PANS Phase I/II Clinical Trial



- FDA Pre-IND Meeting
- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment PANDAS/ PANS Phase I/II Clinical Trial
- Additional paediatric neurological disorder Phase I/II Clinical Trial launch

## 2H CY2023

- Results of PANDAS/PANS Phase I/II Clinical Trial
- Commencement of Patient Recruitment Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment ASD Phase II/III Clinical Trial
- US FDA IND submission
- Completion of recruitment new neurological disorder Phase I/II Clinical Trial



- Focus on rare paediatric neurological disorders
- Long term safety and efficacy of NTI164 now established in a predominant paediatric neurological disorder with strong neuroinflammatory effects (ASD)
- Accelerated clinical development via rapid & cost-effective proof of concept Phase I/II clinical trials in Australia for new paediatric neurological disorders (PANDAS/PANS, CP & 1 Other Undisclosed disorder pending)
- Strong clinician engagement
- Access to numerous regulatory levers from the FDA and EMA
- Funding provides sufficient runway to complete all current clinical trials and pathway with the US FDA – significant valuation upside if met





# Neurotech

International

## Contact Details

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

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