



Improving Lives



Investor Presentation:

Autism Phase II/III Clinical Trial Results

Rett Syndrome Phase I/II Clinical Trial Top-Line Results

Capital Raise

Dr Tom Duthy
Executive Director

17 April 2024

Disclaimer



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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.”¹



Autism Spectrum Disorder (ASD)

PREVALENCE OF ASD
~1 in 44 children
in the US¹



- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years⁵

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\$2.0bn²



2 Approved Drugs
(* limited use)
Risperidone,
Aripiprazole

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

No FDA-approved drugs for the core symptoms of ASD (i.e. social communication, social interaction, restricted behaviours)
SIGNIFICANT UNMET MEDICAL NEED



Clinical Trial

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

Initial Phase I/II data positive at 4 weeks, 20 weeks and 52 weeks...safety past 90 weeks



ASD and the NDIS



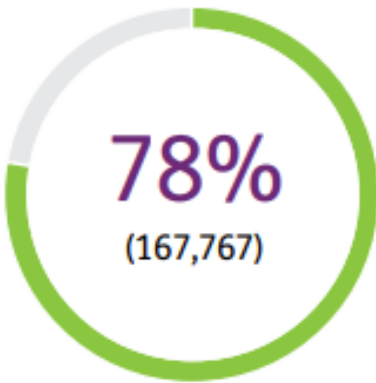
The National Disability Insurance Scheme (NDIS) provides assistance to people with a disability, as well as their families and carers



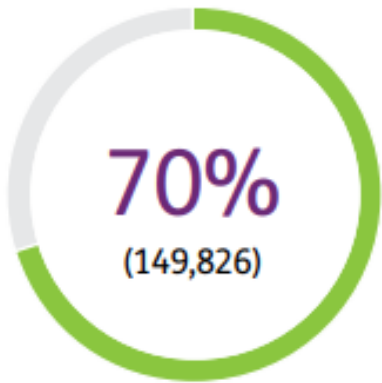
There is a strong market need for an effective therapeutic intervention such as NTI164 to improve ASD symptoms & reduce healthcare costs

\$35.5 Billion

Cost of NDIS in 2022, to increase to \$52 billion by 2026, \$100 billion by 2033¹

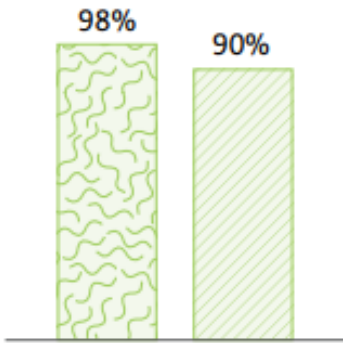


of participants with autism **are aged 18 years and under**, with **112,565 (52%) participants aged 7 to 14 years.**

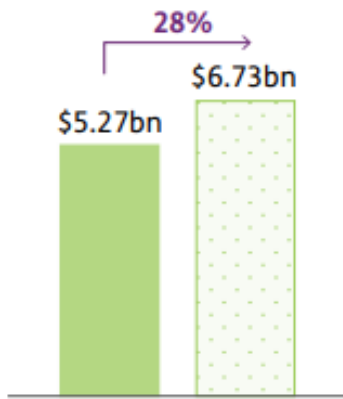


of participants with autism **are male.**

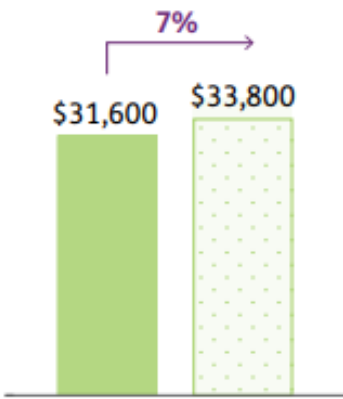
In the year ending 30 June 2023:



98% of access decisions for applicants with autism **aged 18 years and under** resulted in the applicant joining the Scheme, **compared to 90% for those aged over 18 years.**



\$6.73 billion of paid supports were provided to participants with autism, compared to **\$5.27bn** in the previous year, an increase of **28%.**



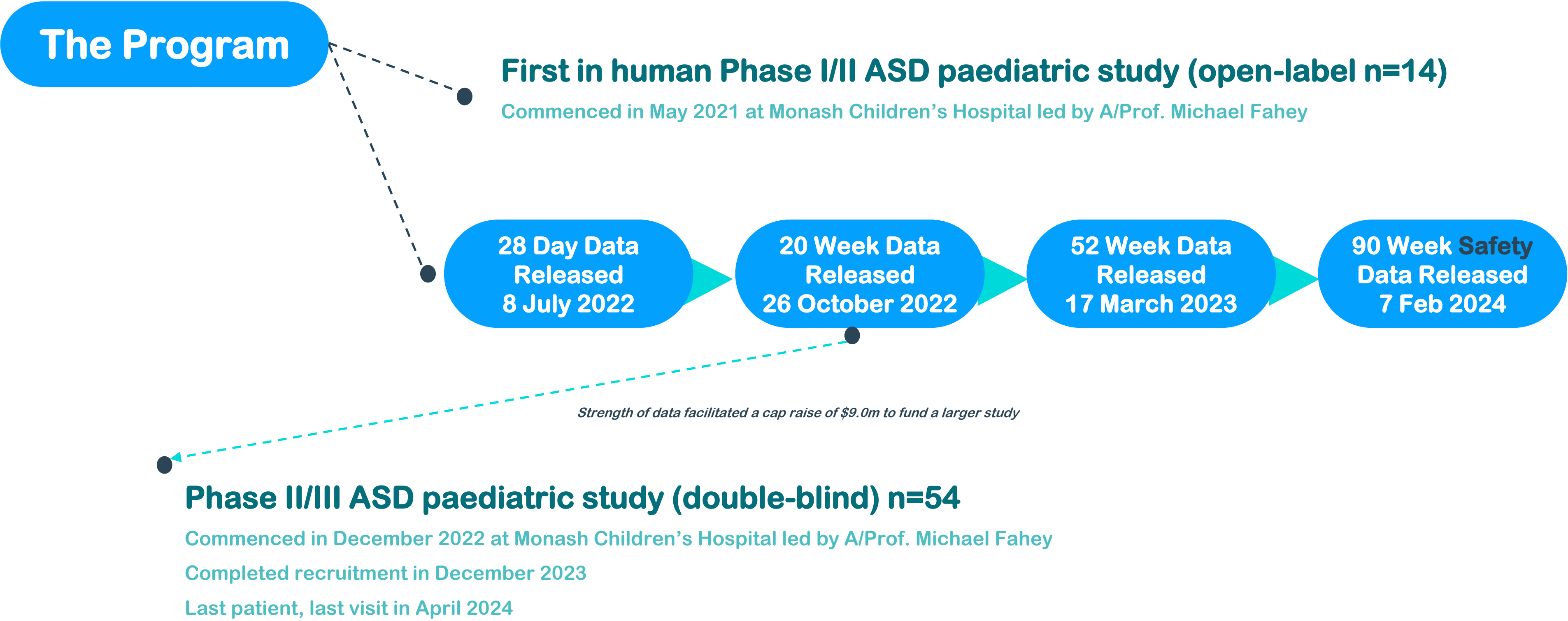
\$33,800 was the average payment for a participant with autism, an increase of **7%** compared to the previous year.

The majority of participants with autism are aged **7 to 14 years (52%)** and **15 to 18 years (16%)**

230,119 as at 31 December 2023

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>
Source: NDIS data 30 June 2023

NTI164 ASD Program Highlights



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



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



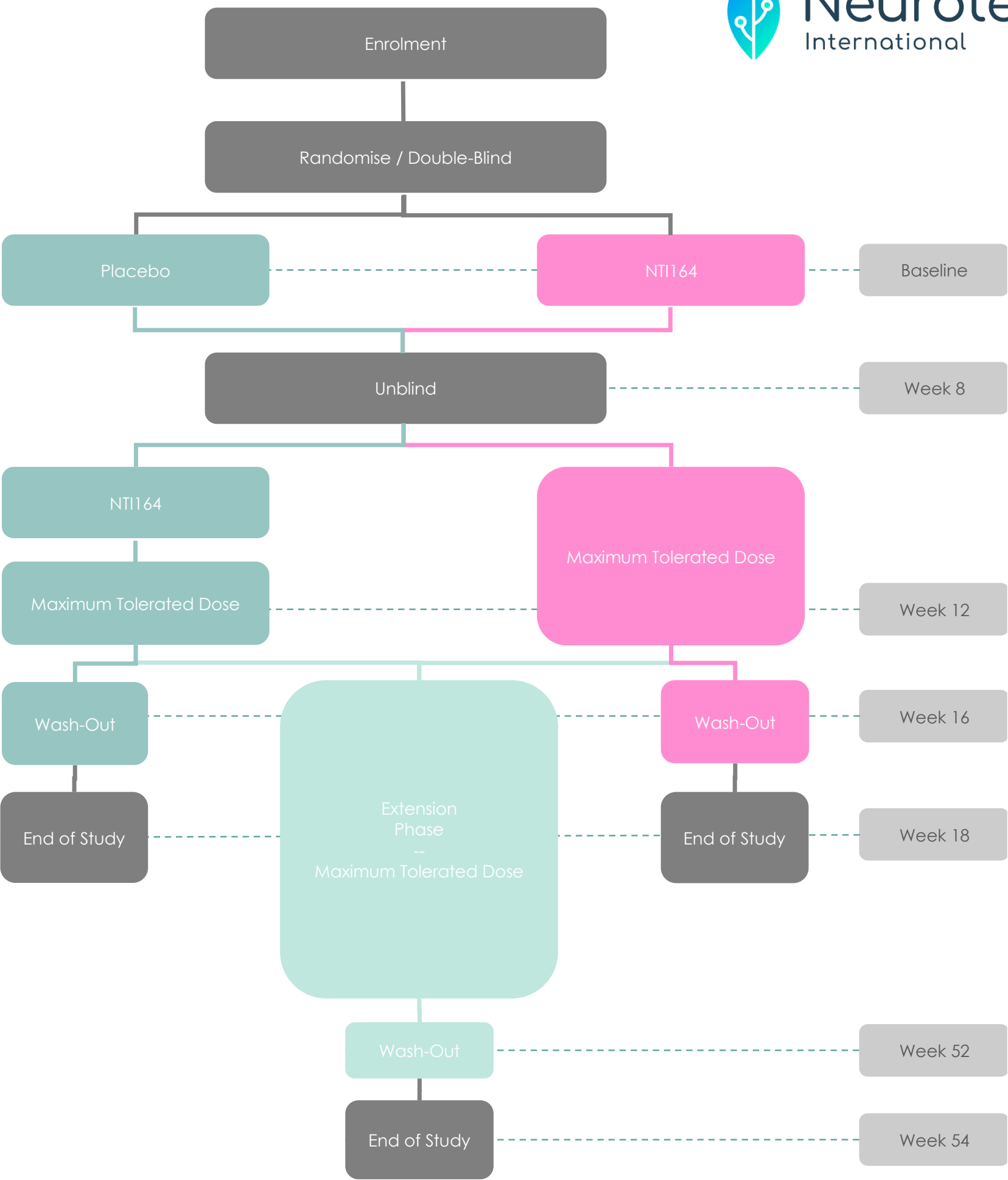
Entourage Effect



Neuroprotective



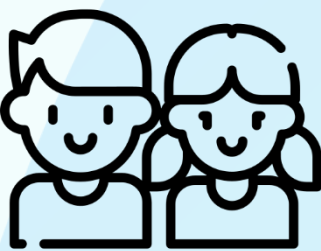
Anti- Neuroinflammatory



1. DAYBUE is a trademark of Acadia Pharmaceuticals Inc
2. Pending data

Baseline Patient Characteristics

Characteristic		Number (%) / Mean		
		NTI164 (n=26)	Placebo (n=28)	P Value
Age		12.4 years	12.0 years	0.442
Sex	Male	14 (54%)	15 (54%)	0.982
	Female	12 (46%)	13 (46%)	
CGI-S ¹	Overall Score	5.54 (100%)	5.21 (100%)	0.106
	Mild Pts	1 (4%)	1 (4%)	N/A
	Moderate Pts	2 (8%)	9 (32%)	N/A
	Marked Pts	11 (42%)	5 (18%)	N/A
	Severe Pts	12 (46%)	13 (46%)	N/A



A total of 54 patients
evaluable for Primary
Endpoint

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 clinician’s impression of severity of illness on a 7-point scale ranging from 1 = not at all to 7 = among the most extremely ill. N/A – not available

Summary of Efficacy Measures

Primary Endpoint

CGI-S



Significant treatment effect -1.65 (95% CI; -2.3, -1.0) versus placebo at 8 weeks ($p<0.001$)

Key Secondary Endpoints

Vineland-3™



Significant treatment effect 3.23 (95% CI; 0.44, 6.0) versus placebo at 8 weeks ($p=0.024$)

CGI-I



Significant treatment effect -1.42 (95% CI; -2.0, -0.82) versus placebo at 8 weeks ($p<0.001$)

SRS



Significant treatment effect -3.064 (95% CI; -5.781, -0.348) versus placebo at 8 weeks ($p=0.028$)

Expert Interpretation of Results



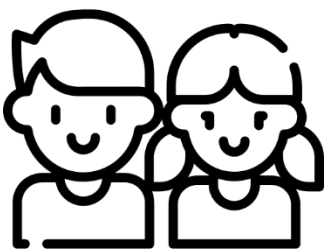
Professor Michael Fahey – Lead Investigator

“The analysis so far of the trial, which compared NTI164 to placebo over 8 weeks of daily treatment, have demonstrated statistically significant and clinically meaningful improvements in the severity of illness and adaptive behaviours such as communication and socialisation without any significant side effects. Currently, there are no FDA or TGA-approved treatments that show clinically significant improvements in one or more of autism's three core symptom domains: communication, impaired social interaction, and restricted behaviours. Therefore, the NTIASD2 clinical trial data look promising, given the substantial unmet market need for safe and effective therapies for autism, like NTI164.”

8 Week Safety Data

NTI164 Exhibits Excellent Safety Over 8 Weeks

A total of 54 patients
evaluable at 8 weeks



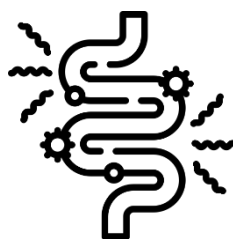
No serious adverse events (SAEs) recorded for NTI164 & placebo, across entire period (8 weeks)

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)

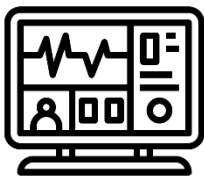


Diarrhoea

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



**Kidney/Liver
Function**



Vital Signs



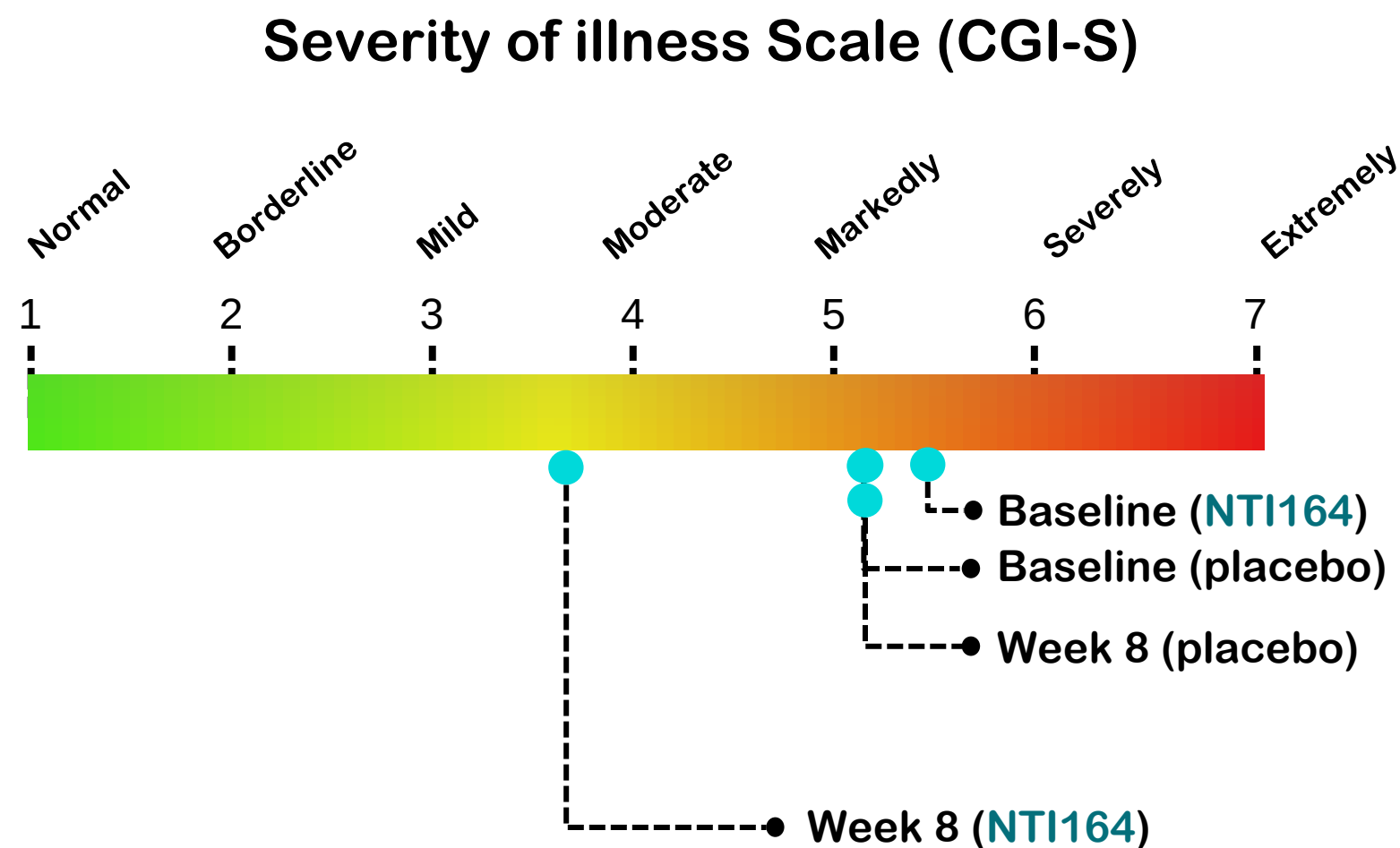
Blood Chemistry



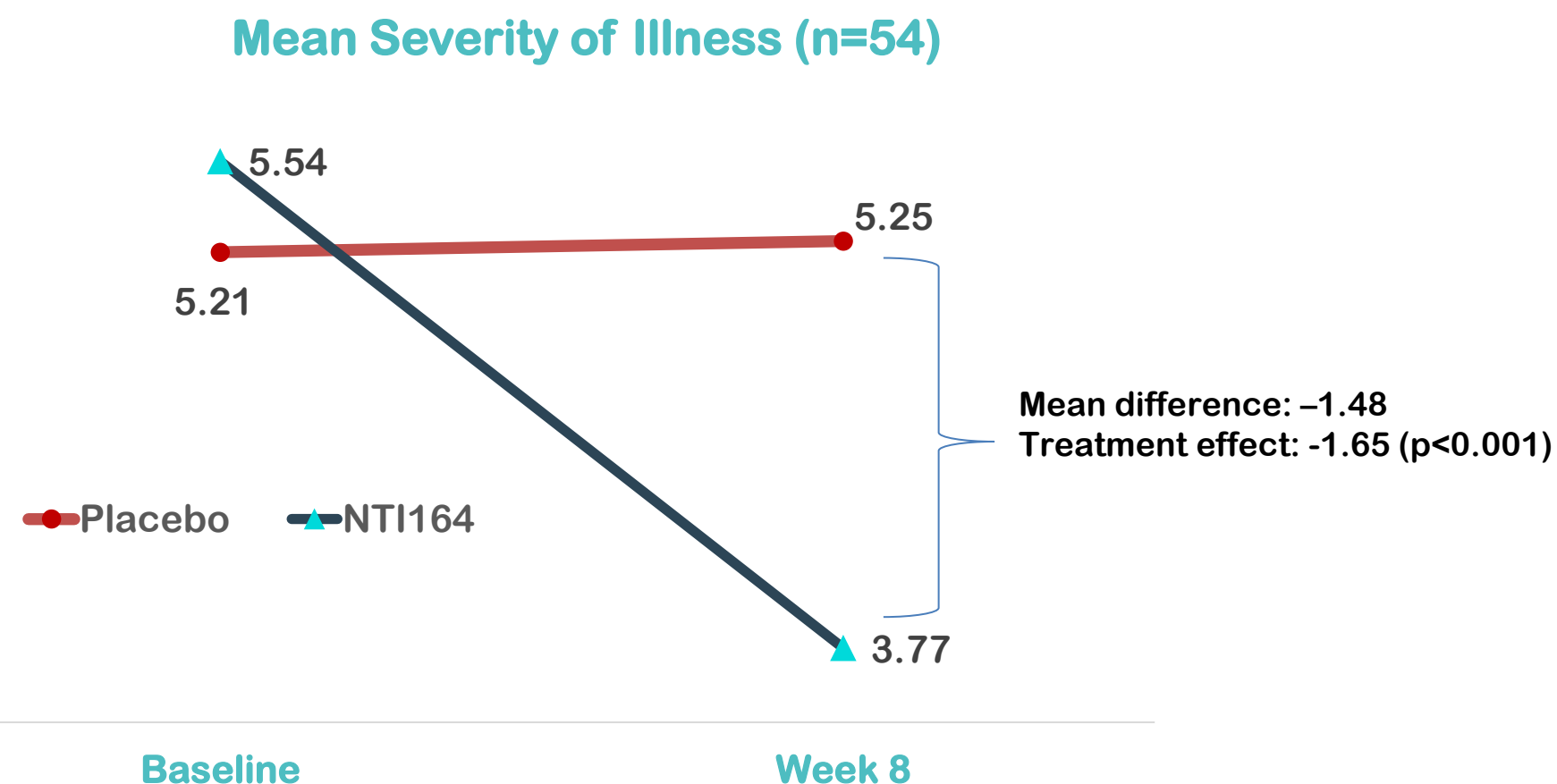
Normal

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 weeks¹ ($p < 0.001$)



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

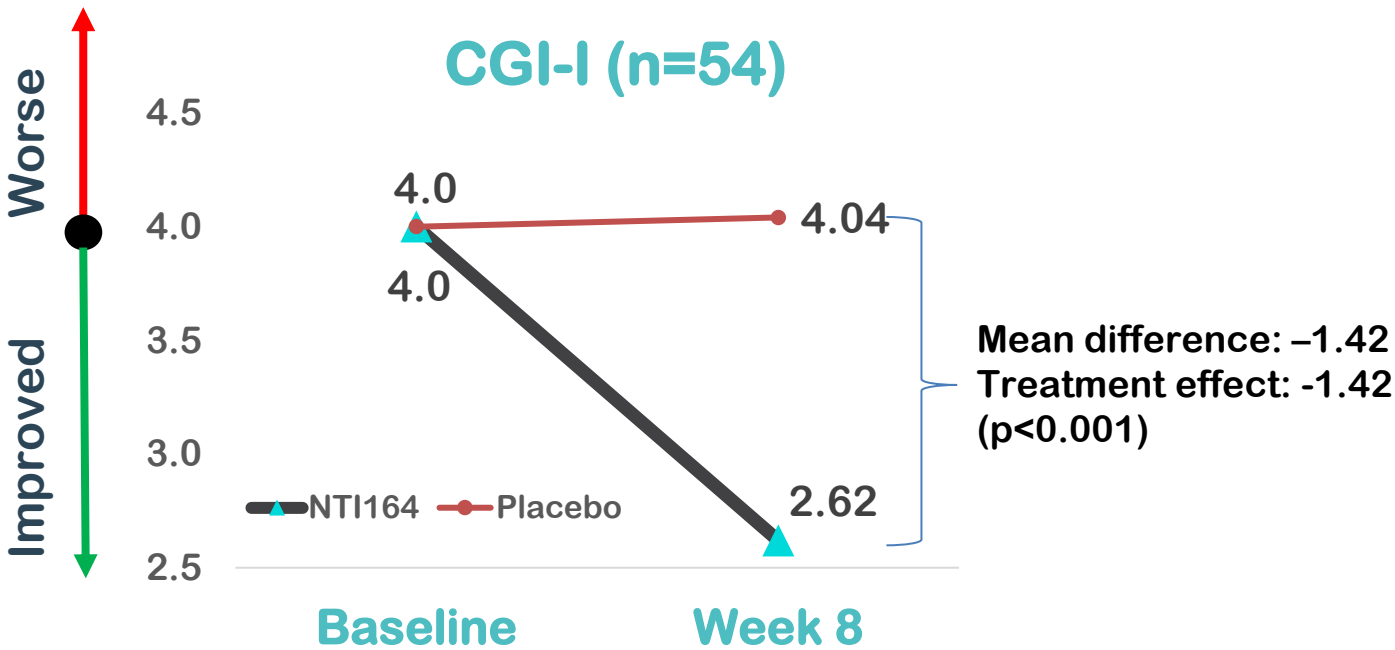
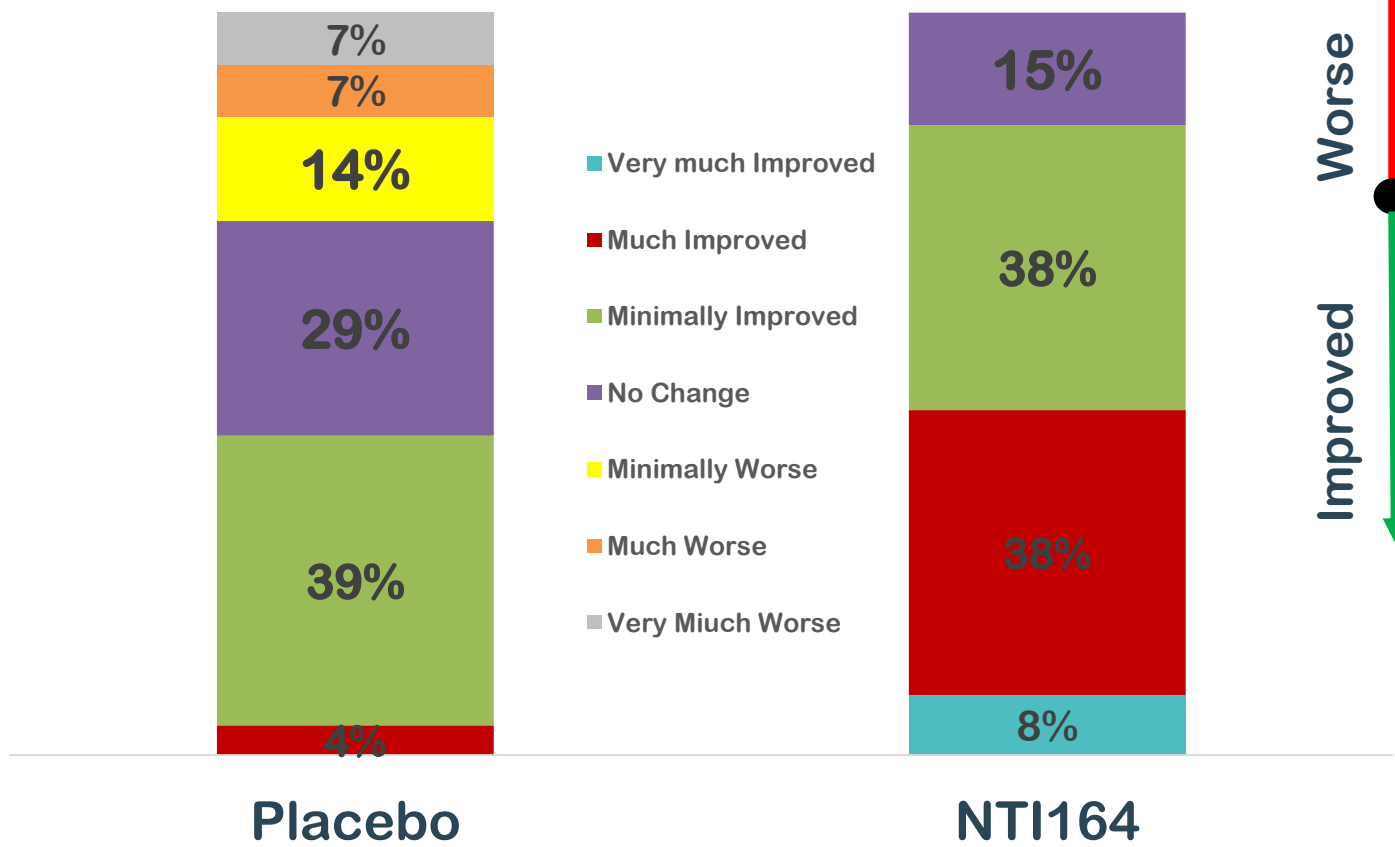
Secondary Endpoint: CGI-I



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%)	-	-	-

Week 8 CGI-I



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

CGI-I at 8 weeks (p<0.001)

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™-3¹

Standardised measure of adaptive behaviour

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

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



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

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

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



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 months¹
- (n=38): -0.7 from baseline at 48 weeks²

- -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 baseline³
 - 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 communication⁴



- 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 0.62¹
- Weight gain²
- Increase in appetite, sedation³

- 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

Secondary Endpoint: SRS

SRS™-2¹

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



Clinical Interpretation

- Clinically meaningful and statistically significant treatment effect at 8 weeks
- Reinforces positive impacts of NTI164 on an important core symptom of ASD - social behaviours, including communication

SRS-2 Domain (8 week measure)	Treatment Effect	P-value
Total Score	-3.064	0.028

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

Conclusions

Met Primary Endpoint

Met All Secondary Endpoints¹

NTI164 has demonstrated a statistically significant and clinically meaningful improvement in ASD across multiple measures of assessments relating to severity of illness, drug-related improvement, adaptive behaviours and socialisation

NTI164 Very Safe

No serious adverse events. Small number of adverse events, relating to nausea/vomiting (formulation-related) and no diarrhoea observed in NTI164 arm. None of these adverse events were serious and were not considered to significantly interfere with the patient's functioning and none of the adverse events required any additional medications (i.e. anti-nausea, anti-diarrhoea).

Huge Unmet Need

No FDA, TGA or EMA-approved drugs for the core symptoms of ASD (i.e. social communication, social interaction, restricted behaviours)

Rett Syndrome Phase I/II Trial

“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



About Rett Syndrome



About

- Rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome: **impaired brain development and function**
- Currently there is no cure for people with Rett syndrome and classified as a “rare/orphan disease” (by definition, less than 200,000 affected individuals in the US) by the Office of Rare Diseases of the National Institutes of Health

Neuroinflammation

- Numerous scientific reports support neuroinflammatory effects in Rett Syndrome
- NTI164 shown to exhibit anti-neuroinflammation and neuroprotective effects *in vitro*

MeCP2 deficiency exacerbates the neuroinflammatory setting and autoreactive response during an autoimmune challenge

M. I. Zalosnik^{1,2}, M. C. Fabio³, M. L. Bertoldi^{1,2}, C. N. Castañares³ & A. L. Degano^{1,2,3}

Chapter 14

Microglia Involvement in Rett Syndrome

Noël C. Derecki, James C. Cronk, Jonathan Kipnis

First Ever Approval

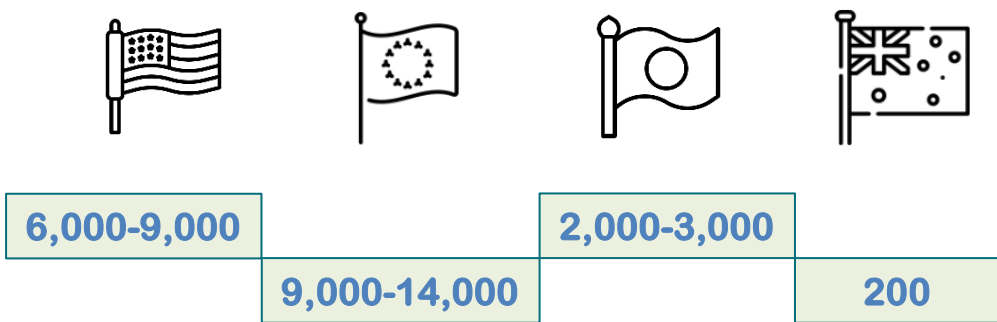


- Neuren Pharmaceuticals (ASX:NEU) / Acadia Pharmaceuticals (NASDAQ:ACAD): FDA Approval **10 March 2023**
- Sets benchmark for FDA accepted clinical endpoints, safety and tolerance

Rett Syndrome Market Dynamics



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



- 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



- 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)

Safety Data of Interest

Safety Over 12 Weeks: Key Focal Points



Weight Loss



**12% pts with
>7% weight loss**

No significant weight change noted for Neurotech ASD & PANDAS/PANS Phase I/II trials

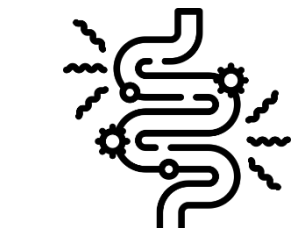


Nausea/Vomiting



29% pts

5% of pts for ASD (20 weeks) and 13% of pts for PANDAS/PANS (12 weeks) for NTI164
8% NTI164 v 11% placebo in Phase II/III ASD

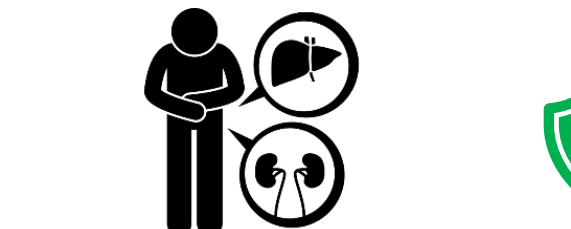


Diarrhoea

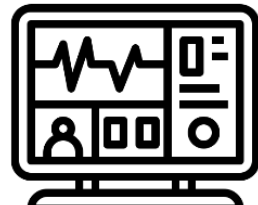


82% pts

0% reported in Neurotech ASD Phase I/II and Phase II/III (placebo 8%) and PANDAS/ PANS trials



Kidney/Liver Function



Vital Signs

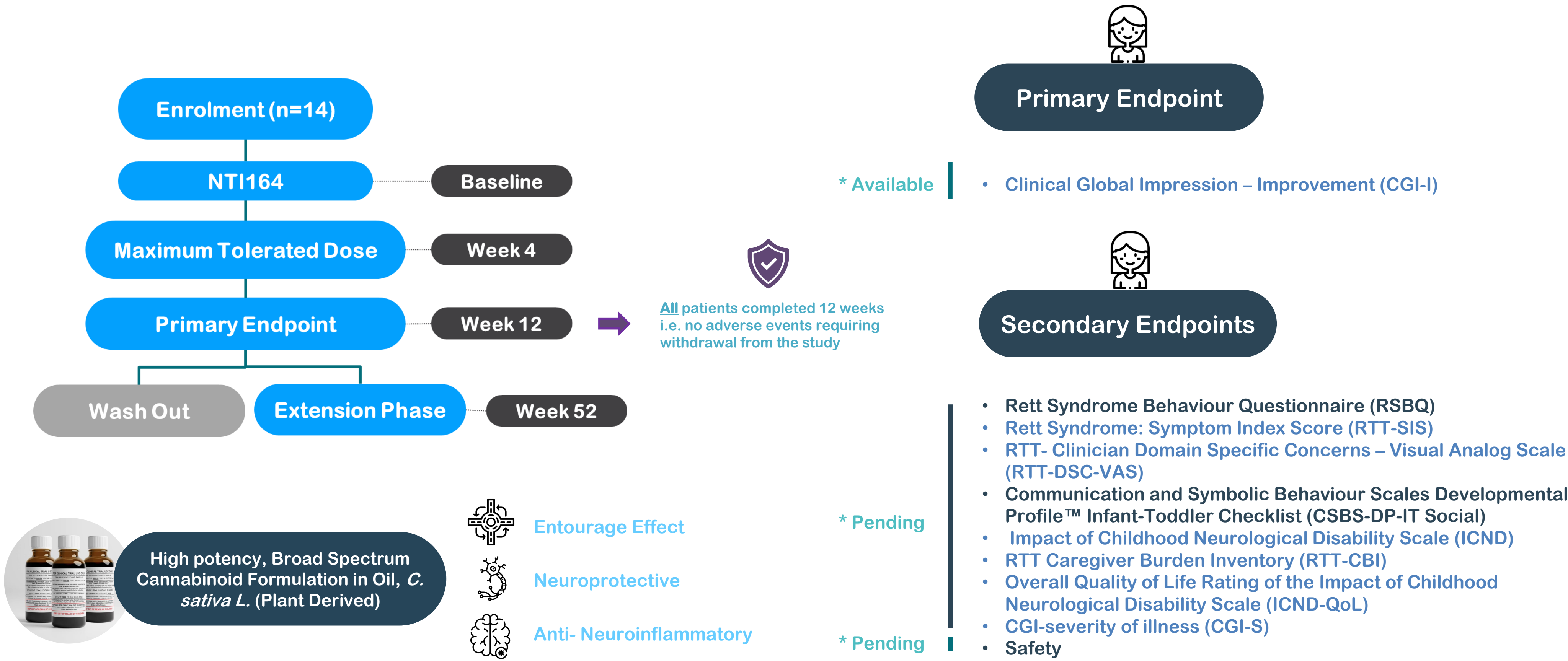


Blood Chemistry



All normal across Neurotech's previous ASD (90 weeks+) and PANDAS/PANS (24 weeks) Studies

Rett Syndrome Trial Design (NTIRTT1)



* No participants received DAYBUE™ (trofinetide)¹

1. DAYBUE is a trademark of Acadia Pharmaceuticals Inc & is not approved in Australia

Top-Line Clinical Results

A total of 14 patients evaluable at 12 weeks



CGI-I Primary Endpoint Significantly Improved

CGI-I versus baseline mean difference of -0.3 (95% CI -0.015, -0.56; $p = 0.04$)

Data compares favourably to DAYBUE™ (trofinetide) Phase 3 data v placebo (mean difference -0.3, $p=0.003$)¹

[DAYBUE CGI-I reported – 61% of patients “Unchanged”, 25% of patients “Minimally Improved”, 13% of patients “Much Improved”]

Data analysis and interpretation remains ongoing for further primary endpoint analysis, reporting of secondary endpoints (inc. RSBQ) and safety/tolerability

Neurotech on-track to report further clinical trial data in the next 2-4 weeks

1. Neul, J.L. et al. Trofinetide for the treatment of Rett syndrome: a randomized phase 3 study. Nat Med 29, 1468–1475 (2023).

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-Improvement (CGI-I) is a 7-point scale that requires the clinician to assess how much the patient's illness has improved or worsened relative to a baseline state at the beginning of the intervention (1 – “Very Much Improved” 2 - “Much Improved” 3 - “Minimally Improved” 4 - “No Change” 5 - “Minimally Worse” 6 - “Much Worse” 7 - “Very Much Worse”).

Capital Raise



Pro-Forma Capital Structure

PRO-FORMA CAPITAL STRUCTURE - \$10 Million Placement	
Current Shares on Issue	917.4M
New Shares	100.0M
Pro-Forma Shares on Issue	1017.4M
Pro-Forma Cash ¹	\$15.5M
Pro-Forma Enterprise Value (undiluted) ²	\$86.2M

1. Cash at 31 December 2023 - \$4.5 million, Option exercises - \$1.5m; Placement of \$10.0m minimum, transaction costs of \$(0.5m)

2. Placement price shares on issue post placement less pro-forma net cash position post placement (no debt)

Event	Date
Settlement of Placement Shares & Unlisted Options	23 April 2024
Allotment of Placement Shares on ASX & Commencement of Trading	24 April 2024
Allotment of Unlisted Options	24 April 2024

* Timetable is indicative and subject to change

Use of Funds

EVENT	ALLOCATION OF FUNDS (PLACEMENT)
Further human clinical trials NTI164 (Rett, PANS, Other)	\$5.5M
Regulatory Development	\$0.5M
IND Enabling Toxicology	\$2.4M
Manufacturing / Production Expansion	\$1.0M
Offer Costs / Other	\$0.6M
TOTAL	\$10.0M

* In addition, the Company is entitled to 43.5% to 48.5% of eligible R&D expenditure returned in cash through the Australian government R&D Tax Incentive

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 – TGA¹ 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 Europe – Rett Syndrome
- Orphan Drug Designation Europe – PANDAS/PANS
- Orphan Drug Designation USA – Rett Syndrome
- Orphan Drug Designation USA – PANDAS/PANS
- Commence Phase I/II Cerebral Palsy Clinical Trial
- FDA IND / EMA² toxicology
- Presentation of Phase I/II Rett Syndrome data at international Rett meeting

ENDS



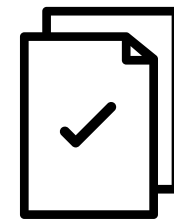
Neurotech: Strategies, Pipeline, Milestones, Outlook



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



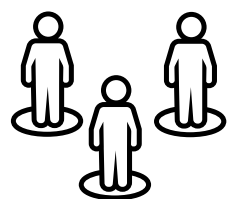
NTI164 exclusive worldwide licence for neurological disorders



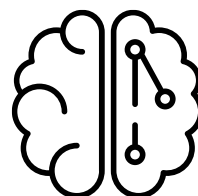
Patents Pending – Use, Composition



Novel oral biopharmaceutical cannabinoid platform (NTI164)



Focus on Paediatric Patients

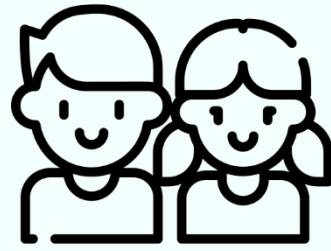


Multiple Phase I/II and Phase II/III Clinical Trials

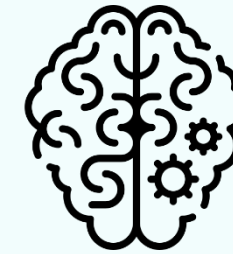


Supportive Efficacy & Safety Data in Children

Neurotech Four Core Strategies



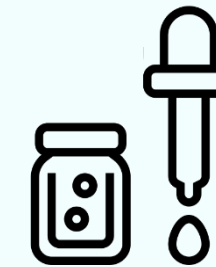
Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

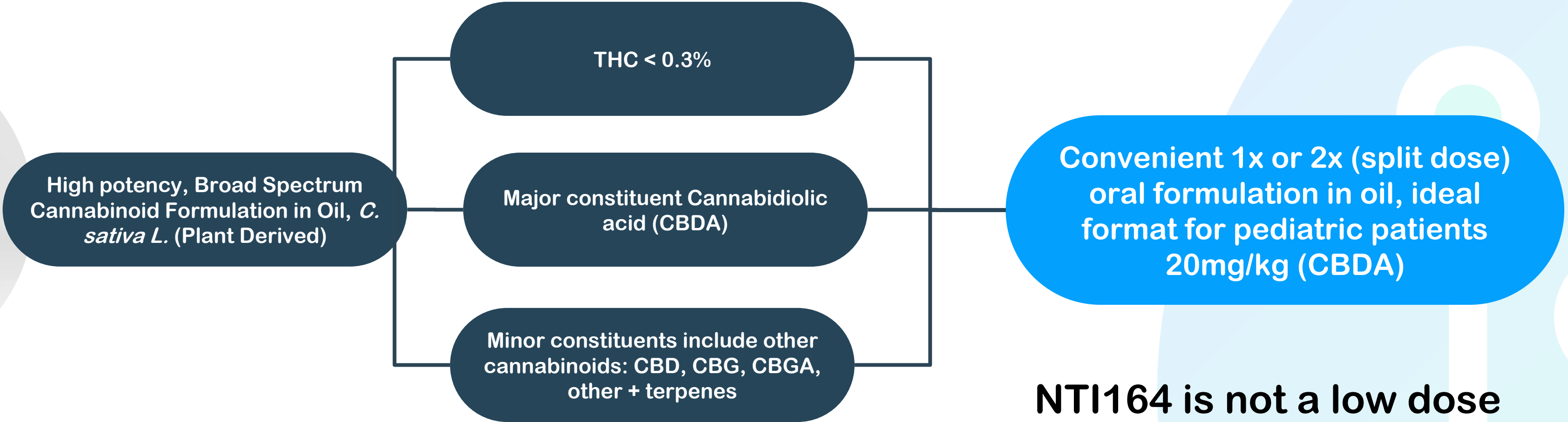


Focus on Partnering with Key Opinion Leaders / Clinicians

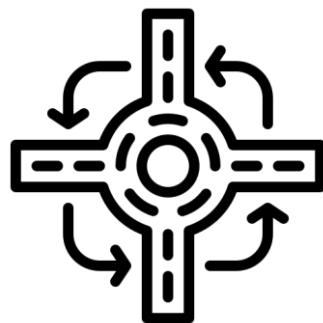


Focus On Drug Product Development

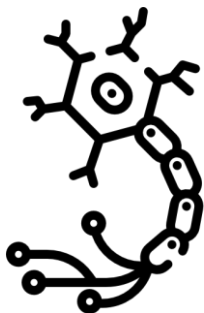
Therapeutic Agent: NTI164



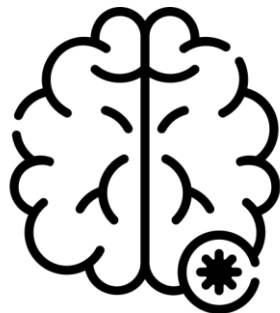
NTI164 is not a low dose CBD oil to be sold over-the-counter



Entourage Effect



Neuroprotective



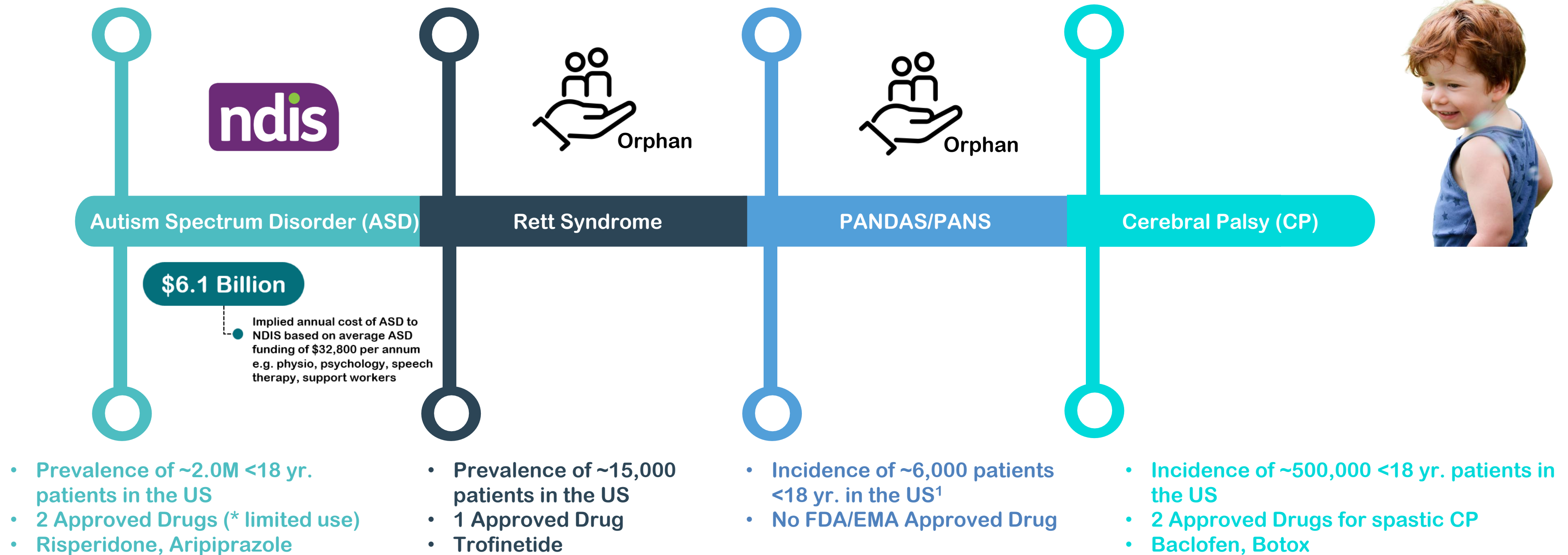
Anti- Neuroinflammatory

Our Target Markets

Lack of effective therapies, significant unmet medical need

Annual Drug Therapy Market opportunity

US\$2 billion* US\$2 billion US\$1.4 billion¹ US\$4.3 billion





Neurotech

International

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

www.neurotechinternational.com

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