Neurotech to Present at Spark Plus Healthcare Conference in Singapore

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces an upcoming presentation by Dr Thomas Duthy, Executive Director at the Spark Plus Healthcare Day in Singapore.

For those investors based in Singapore who wish to attend this in-person event can register at: https://www.eventbrite.sg/e/singapore-healthcare-day-tickets-827942356877?aff=oddtdtcreator

A copy of the presentation is attached.

Authority
This announcement has been authorised for release by the Board of Neurotech International Limited.

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About Neurotech

Neurotech International Limited (ASX:NTI) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. Neurotech has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days, 20 weeks and 52 weeks of treatment with NTI164. The Company has commenced a Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD, a Phase I/II trial in Rett Syndrome and completed a Phase I/II trial in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS. In addition, Neurotech has received human ethics committee clearance for a Phase I/II clinical trial in spastic cerebral palsy.

For more information about Neurotech please visit http://www.neurotechinternational.com.

Improving Lives

Neurotech International

Spark Plus Healthcare Day - Singapore

Dr Tom Duthy
Executive Director

14 March 2024

Disclaimer

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

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- 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

Corporate / Capital Summary

$0.10
Share price
(as at 7 Mar 2024)

$89.2M
Market capitalisation

$4.5M
Cash as 31 Dec ‘23

~1,900
No. of shareholders

892.4M
Share on issue

135M^
NTIOA (13.5c, 65M) + Other Options

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

53%
Top 20 Holders

^Options are comprised at various strike prices between $0.06 to $0.16 as at 19 February 2024

Neurotech Four Core Strategies

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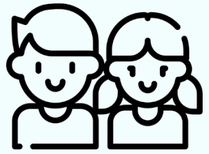
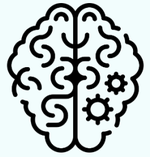
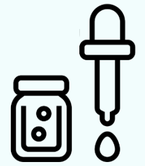


Focus on Paediatric Patients



Focus On Rare Neurological Disorders with Neuroinflammation

Focus on Partnering with Key Opinion Leaders / Clinicians



Focus On Drug Product Development

Strategic Focus Offers Significant Value Upside

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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 disorders: Autism Spectrum Disorder (ASD), PANDAS/PANS
- 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

Summary of Strategy

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Group Strategy

- Focus on Paediatric Patients
- Focus On Rare Neurological Disorders with Neuroinflammation
- Focus on Partnering with Key Opinion Leaders / Clinicians
- Focus On Drug Product Development

Implementation to Development

Current

- Phase I/II PANDAS/PANS
- Phase I/II Cerebral Palsy
- Phase II/III ASD
- Phase I/II Rett Syndrome

Potential

- Fragile-X
- ADHD
- Dravet
- Lennox-Gastaut

Neuroinflammation

Potential Regulatory Levers

FDA

Pre-IND Feedback
IND
Orphan Drug Designation
Priority Review
Breakthrough Therapy
Fast-Track
Rare Pediatric Priority Voucher

EUROPEAN MEDICINES AGENCY

Scientific Advice
Protocol Assistance
Orphan Drug Designation
Accelerated Assessment

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 Elvidge, Contributing Writer
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FDA approval
EMA approval

FDA,EMA Orphan Designations, Fast-Track Status

Jazz Pharmaceuticals

2021: US$7.2 Billion acquisition of GW[1]

2022 Epidiolex® Sales: US$736 Million[1]

On track for US$1 billion in 2024

2016 → 2018 → 2023

neuren pharmaceuticals

Pipeline focus on rare neurodevelopmental disorders
ASX:NEU Market Cap: $200M

ACADIA Pharmaceuticals

US$455M Licence for Trofinetide in Rett[2]

ACADIA Pharmaceuticals

FDA Approval for Rett
ROW licence for US$527M[2]

neuren pharmaceuticals

NEU Market Cap: ~$3Bn

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

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

Developing NTI164 as a Therapeutic Agent

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- **NTI164 to be registered as a prescription-only medicine**
- **Neurotech investment into clinical trials to show safety and benefit**
- **Regulatory approval(s) will allow Neurotech to make a medical claim**
- **Significantly higher pricing and reimbursement + regulatory levers = strong competitive position**

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Clinical Focus

Neurotech International

ASD

PANDAS/PANS

Cerebral Palsy

Rett Syndrome

Strong Scientific Rationale for NTI164

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

Neurological & Neuroinflammation | Lack of effective treatments | Rare / Orphan | Paediatric Onset

Clinical Pipeline – 2024

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Pre-Clinical

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

Other Licensed Strains

Phase I/II

NTI164
Cerebral Palsy

NTI164
PANDAS / PANS[1]

NTI164
ASD
(90 week+ open label extension)

NTI164
Rett Syndrome

Phase II/III

NTI164
ASD

Pipeline (2020/1)

NTI164
Combination Therapies
Prednisone, Diclofenac, Other

NTI164
Neuronal Cell Assays

Other Licensed Strains

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

Autism Spectrum Disorder (ASD)

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Market

PREVALENCE OF ASD

~1 in 44 children in the US[1]

- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years[5]

Current Treatment

TREATMENT MARKET SIZE

US$2.0bn[2]

2 Approved Drugs (* limited use)
Risperidone,
Aripiprazole

Clinical Trial

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

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

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

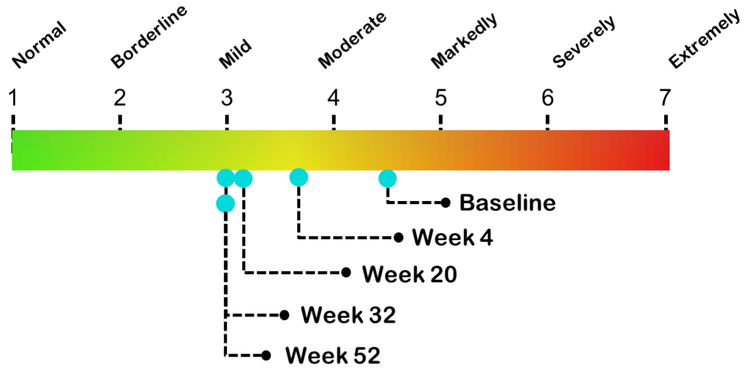
Initial Phase I/II data positive at 4 weeks, 20 weeks and 52 weeks…safety past 90 weeks

1. www.cdc.gov/ncbddd/autism/addm.html
2. https://www.fortunebusinessinsights.com/industry-reports/autism-spectrum-disorder-therapeutics-market-101207-CAGR-of-7-4.html

Autism Spectrum Disorder (ASD)

- Phase I/II Clinical Trial reported data out to 52 weeks of treatment

Severity of illness Scale (CGI-S)



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

- 34% of the 550,000 NDIS participants have ASD, 40% ≤ 14 years old (860,000 by 2030)

Federal government set to cut NDIS funding for autism

21 hours ago · sky news .COM.AU

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

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

- Prevalence of ASD in Australia est. 1 in 50
- 40-fold increase in 20 years[5]

- World first trial of broad-spectrum cannabinoid therapy
- 11 children continue treatment under Extension HREC > 90 weeks
- NTI164 is a patient ‘enabling’ drug with non-drug behavioural therapies
- Chronic administration required to maintain effects
- No serious adverse events over 52 weeks of daily oral treatment (now 90 weeks as at Feb ‘24)
- About to complete larger Phase II/III trial

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.

Data Comparison & Context - Risperidone

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	RISPERIDONE	NTI164 Phase I/II (n=11)
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

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)

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)
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

"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

PANDAS/PANS

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

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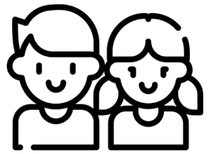
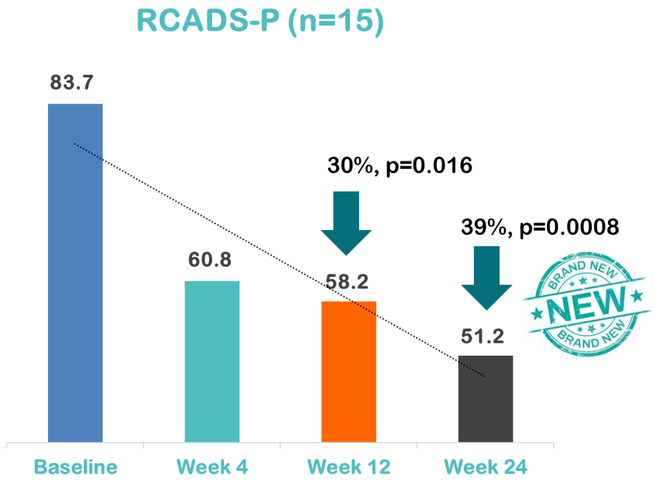


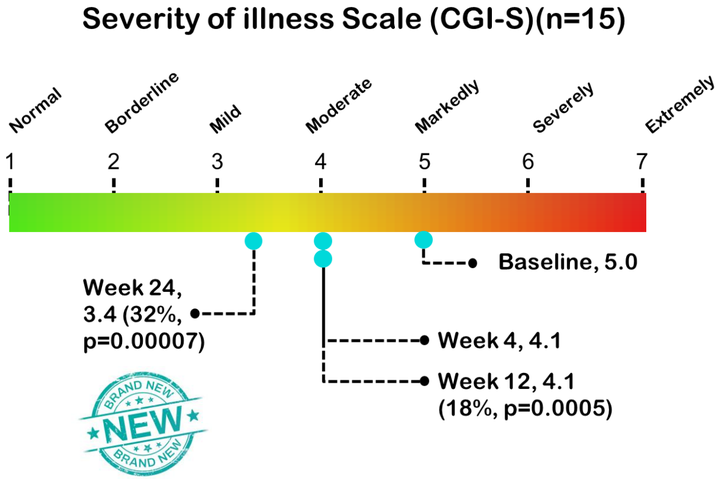
Phase I/II reported: 15 patients with moderate-severe PANDAS/PANS recruited,12-week data (Oct 23), 24-week data (Feb 24)

Significant Improvement in anxiety / depression



RCADS-P[1]

Significant Improvement in Disease Severity



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.

Rett Syndrome Market Dynamics

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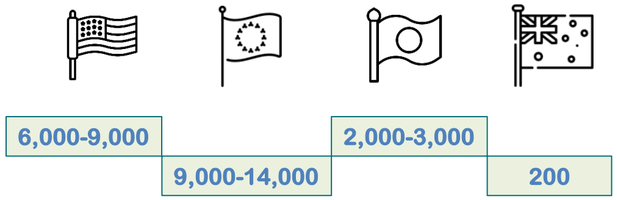
Significant Market



- 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

Improvement was seen by doctors in nearly 4 out of 10 patients (38%) taking DAYBUE at 12 weeks, compared with less than 2 out of 10 (15%) of those taking the placebo.

	1 Very much improved	2 Much improved	3 Minimally improved	4 No change	5 Minimally worse	6 Much worse	7 Very much worse
DAYBUE	0%	13%	24.7%	61%	1.3%	0%	0%
Placebo	0%	4.7%	10.5%	81.4%	3.5%	0%	0%

Individual results may vary.

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)

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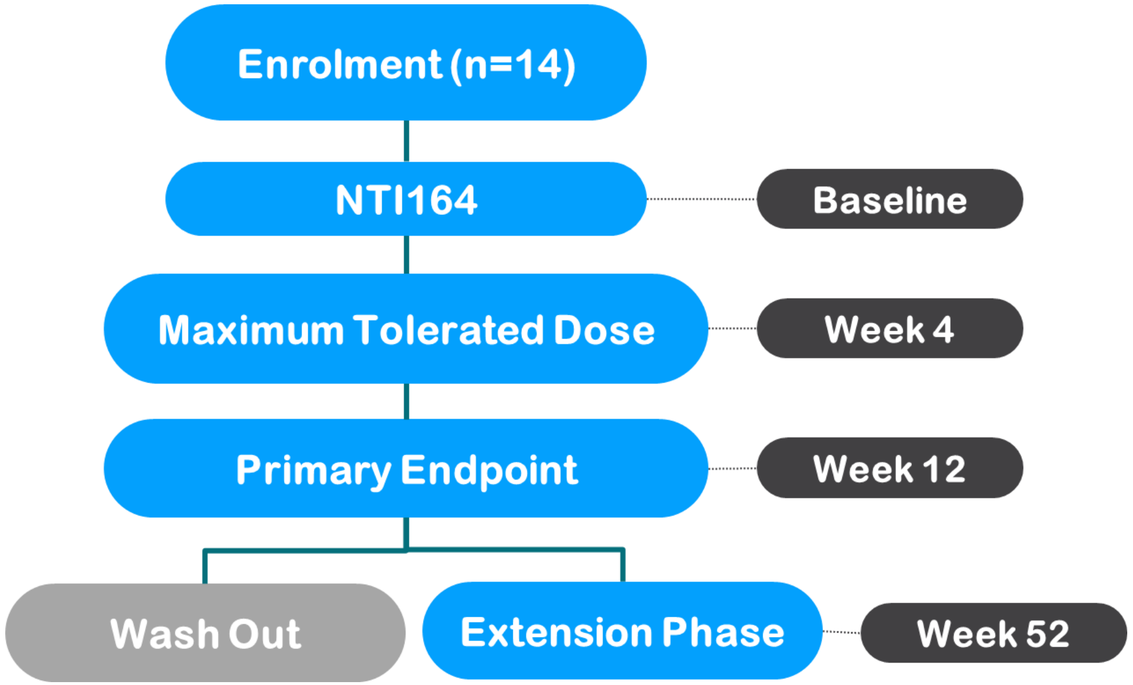


High potency, Broad Spectrum Cannabinoid Formulation in Oil, *C. sativa L.* (Plant Derived)

- Entourage Effect
- Neuroprotective
- Anti- Neuroinflammatory

Primary Endpoint

- Clinical Global Impression – Improvement (CGI-I)

Secondary Endpoints

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

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

1. DAYBUE is a trademark of Acadia Pharmaceuticals Inc

Safety Data of Interest

Safety Over 12 Weeks: Key Focal Points

Weight Loss

Daybue™ (trofinetide)

12% pts with >7% weight loss

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

Nausea/Vomiting

Daybue™ (trofinetide)

29% pts

5% of pts for ASD (20 weeks) and 13% of pts for PANDAS/PANS (12 weeks) for NTI164

Diarrhoea

Daybue™ (trofinetide)

82% pts

0% reported in Neurotech ASD 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

1. DAYBUE data sourced from Acadia Pharmaceuticals Inc

Cerebral Palsy

Neurotech International

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

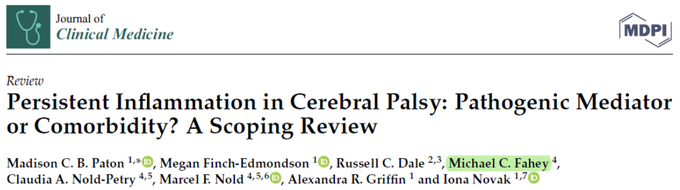
- Primary treatment options for cerebral palsy are medication, therapy, and surgery. The goal of cerebral palsy treatment is to manage symptoms – specifically, spasticity and/or dystonia
  - Botulinum A : no improvement in motor function(s)
  - Baclofen – unwanted side-effects, weak evidence for quality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

Neuroinflammation

- Available evidence supports the pathogenic role of inflammation and its ongoing role as a comorbidity of CP – Advantages for NTI164 – HREC received Jan ’24: 14 pts at Monash for 12 weeks on NTI164

Significant Market

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


Journal of *Clinical Medicine* MDPI

Review

Persistent Inflammation in Cerebral Palsy: Pathogenic Mediator or Comorbidity? A Scoping Review

Madison C. B. Paton [1,*], Megan Finch-Edmondson [1], Russell C. Dale [2,3], Michael C. Fahey [4], Claudia A. Nold-Petry [4,5], Marcel F. Nold [4,5,6], Alexandra R. Griffin [1] and Iona Novak [1,7]

1. www.cerebralpalsy.org
2. https://www.emergenresearch.com/industry-report/cerebral-palsy-treatment-market

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
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

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

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/)

Key Milestones – NTI164

1H CY2023

- Final results of ASD Phase I/II Clinical Trial (52 weeks)
- Commencement of Patient Recruitment PANDAS/PANS Phase I/II Clinical Trial
- HREC/TGA Extension of ASD Phase I/II Clinical Trial – 6 months
- FDA Pre-IND Meeting
- Launch Rett Syndrome Clinical Trial Initiative
- HREC/TGA Approval Rett Syndrome Phase I/II Clinical Trial *
- Completion of Patient Recruitment PANDAS/ PANS Phase I/II Clinical Trial

2H CY2023

- Commence Phase I/II Clinical Trial in Rett Syndrome
- Results of PANDAS/PANS Phase I/II Clinical Trial
- Completion of patient recruitment of Rett Syndrome Phase I/II Clinical Trial
- Completion of Patient recruitment ASD Phase II/III Clinical Trial (Q4)

Q1 CY2024

- HREC/TGA Approval Cerebral Palsy Phase I/II Clinical Trial
- Publication(s) of ASD Phase I/II data
- Results of Rett Syndrome Phase I/II Clinical Trial (to early Q2)
- Results of ASD Phase II/III Clinical Trial (to early Q2)

* 10 July 2023

Outlook

- Focus on rare paediatric neurological disorders
- Accelerated clinical development via rapid & cost-effective proof of concept Phase I/II clinical trials in Australia for new paediatric neurological disorders (PANDAS/PANS, Rett and CP)
- Two further clinical trial read-outs in Q1 CY2024 (to early Q2 for ASD)
- Access to numerous regulatory levers from the FDA and EMA – initial focus on Orphan Drug Designations for PANDAS/PANS and Rett Syndrome in Europe and the US
- Planned meetings with TGA and FDA to refine regulatory process in 2024
- Fully funded to complete all current clinical trials

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

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