ASX Announcement

17 March 2023

Significant Clinical Improvement at 52 Weeks for Paediatric Autism Patients Treated with NTI164

Highlights:

- **Strong safety and efficacy effects of daily oral treatment with NTI164 maintained at 52 weeks in the treatment of children with Autism Spectrum Disorder (ASD)**
- **Continued excellent durability of results, with clinical benefits showing a significant improvement across a large number of clinically validated assessments versus baseline (Day 0) and additional improvement from 20 week analysis reported in October 2022**
- **After 52 weeks of treatment, gold-standard ASD measures versus baseline for clinical improvement; severity of illness (p=0.032), social responsiveness (p=0.049) and adaptive behaviour (p=0.028) were highly significant and clinically meaningful**
- **Significant, positive effects on severity of illness, with children re-classified from moderately ill (CGI-S: 4.3) at baseline to baseline of borderline/mildly ill (CGI-S: 3.0) at 52 weeks, representing a 30% improvement (p=0.03)**
- **No serious adverse events recorded and no changes to blood analysis or liver function tests over the full 52 week period**
- **Data to inform Investigational New Drug (IND) enabling clinical trials in the US, following pre-IND meeting held on 15 March 2023 with the US Food and Drug Administration (FDA)**

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company"), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, today announces the final clinical results from eleven (11) paediatric Autism Spectrum Disorder (ASD) patients, following daily treatment of NTI164 over a 52 week period. The trial was originally designed as a 28 day study but extended to 52 weeks, and more recently for an additional six months, where Neurotech will collect additional safety data (per ASX announcement dated 14 February 2023). No further clinical efficacy investigations or analyses are planned.

Professor Michael Fahey, Head of the Paediatric Neurology Unit at Monash Medical Centre, Director of Neurogenetics and Chief Investigator of the NTI164 Trial commented *"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 all 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."*

Dr Thomas Duthy, Executive Director of Neurotech said *"This final 52 week data set confirms the durability of the excellent clinical benefits we have seen in these paediatric ASD patients, with no significant safety concerns noted. The improvement we have observed in these patients has been impressive and confirms our earlier findings that NTI164 significantly improves the severity of their illness alongside continued improvements in their socialisation and adaptive behaviour. We remain confident our current Phase II/III trial will confirm these important findings in a larger patient population in a randomised,*

double-blind manner. Recruitment in this trial to date has been solid. We thank the families, the team of staff and clinicians at Monash Children's Hospital for their ongoing commitment to this important clinical trial and their interest to continue treatment for an additional six months as recently approved by the Monash Human Research Ethics Committee."

Clinical Results

Efficacy

Eleven (n=11) paediatric patients remained on daily treatment of NTI164 for the full duration of the 52 week period and were therefore evaluable for the analysis. Their data at this time point (52 weeks) was compared to these same patients' data at baseline, 28 days and 20 weeks. The three patients who discontinued treatment were censored (excluded) from the analysis undertaken (not related to drug effects of NTI164) at 20 weeks onwards.

At 52 weeks of treatment (n=11), the mean severity of illness rating of the CGI-S was 3.0, representing an improvement of 30% from baseline (CGI-S: 4.3). The mean difference between 52 weeks of treatment and baseline was -1.1, 95% Confidence Interval (CI) = -2.08, -0.12, p value=0.032 (28 days: -0.714, 95% CI = -1.332, -0.097, p=0.027; 20 weeks: -1.1, 95% CI = -1.772, -0.3948, p=0.005).

The results continue to demonstrate that of the ~40% of subjects markedly or severely ill at baseline – 0% of patients from week 4 onwards were classified as markedly to severely ill. In addition, these results show a significant improvement in average severity of illness scores over time.

At 52 weeks, the patients' adaptive behaviour as measured by the Vineland™-3 adaptive behaviour scores, was significantly improved overall (mean difference of 6.4; 95% CI = 0.94, 11.81, p value=0.028), and individual domains of communication (mean difference of 6.25; 95% CI = 4.26, 8.24, p value=0.0001), daily living skills (mean difference of 8.5; 95% CI = 3.50, 13.50, p value=0.005), and socialisation (mean difference of 6.5; 95% CI = -2.13, 15.13 p value=0.1181). Adaptive behaviour is an important factor in predicting long-term outcomes for people with ASD and improving this behaviour is a goal of any treatment intervention in ASD. One patient achieved scores within the normative mean range across all measures at 52 weeks.

The Social Responsive Scale, 2nd Edition (SRS-2) is an internationally recognised tool used to identify social impairment associated with ASD and quantifies its severity using a Total score plus six sub-scales (Social Awareness, Social Cognition, Social Communication, Social Motivation, Restricted Interest and Repetitive Behaviour and Social Communication and Interaction). The mean total T-score for the 11 patients after 52 weeks of daily NTI164 treatment was 73.8 which is a significant improvement from baseline where it was 78.7 (mean difference of -4.1, 95% CI = -8.17, -0.033, p value=0.049).

Safety

Across the 20-52 weeks of the trial a total of 6 adverse events were recorded. None of these adverse events were serious and were not considered to significantly interfere with the patient's functioning.

Conclusions

NTI164 has shown to be safe and well tolerated up to doses of 20/mg/kg/day. NTI164 has shown statistically significant efficacy in improving the symptoms associated with ASD after 52 weeks of daily therapy. The side effects reported were not serious or severe and did not significantly interfere with patients' functioning. No clinically significant abnormal laboratory values were reported.

The durability of the clinical efficacy and safety observed at 20 weeks continued through to 52 weeks of treatment, with further improvements noted in gold standard ASD measures, and no additional safety

concerns noted. The Company will continue to collect important safety information on patients who have elected to continue to receive daily treatment with NTI164 for an additional six months.

Appendix 1 *provides further information on the 52 week safety and efficacy results.*
Appendix 2 *provides the important background information on the trial.*

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 is currently conducting a world-first clinical trial to assess the potential application of NTI164 for the treatment of Autism Spectrum Disorder (ASD). Results of the Phase I/II clinical trial indicated that 93% of participants had notable improvements relating to the severity of illness with no serious side effects. The next step will be initiation of a Phase II/III clinical trial to further assess the long-term safety and efficacy of NTI164, with the potential to lead to drug registration. Neurotech is also commercialising Mente, the world's first home therapy that is clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity.

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

About NTI164

NTI164 is a proprietary drug formulation derived from a unique cannabis strain with low THC (M<0.3%) and a novel combination of cannabinoids including CBDA, CBC, CBDP, CBDB and CBN. NTI164 has been exclusively licenced for neurological applications globally. Pre-clinical studies have demonstrated a potent anti-proliferative, anti-oxidative, anti-inflammatory and neuro-protective effects in human neuronal and microglial cells. NTI164 is being developed as a therapeutic drug product for a range of neurological disorders in children where neuroinflammation is involved.

About the Phase I/II ASD Clinical Trial

The clinical trial was a Phase I/II Open-Label Study to Evaluate the Safety and Efficacy of Orally Administered Full-Spectrum Medicinal Cannabis Plant Extract 0.08% THC (NTI164) in Children with Autism Spectrum Disorder (ASD).

For more information on the trial, please visit www.clinicaltrials.gov Identifier **NCT05516407** or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: **ACTRN12621000760875**.

Appendix 1 – 52 Week Results

Summary of Efficacy Measures

Sub-Domain	Scale	Paired T-Test	Paired T-Test
		20 weeks	52 weeks
Severity of illness	**CGI-S**	**0.005**	**0.032**
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 *T*-score	**SRS-2**	**0.012**	**0.049**
Social awareness – *T*-score	SRS-2	0.596	0.421
Social cognition – *T*-score	SRS-2	0.028	0.105
Social communication – *T*-score	SRS-2	0.019	0.216
Social motivation – *T*-score	SRS-2	0.118	0.005
Restricted interest and repetitive behaviour – *T*-score	SRS-2	0.009	0.109
Social communication and interaction – *T*-score	SRS-2	0.029	0.081
Anxiety, depression and mood scale - Total	**ADAMS**	**0.001**	**NM**
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	0.120	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	0.070	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	0.010	NM
Sleep breathing disorders	SDSC	0.047	NM
Sleep-wake transition disorders	SDSC	0.094	NM

** Statistical analysis versus baseline; NM – not measured*

Clinical Global Impression (CGI)

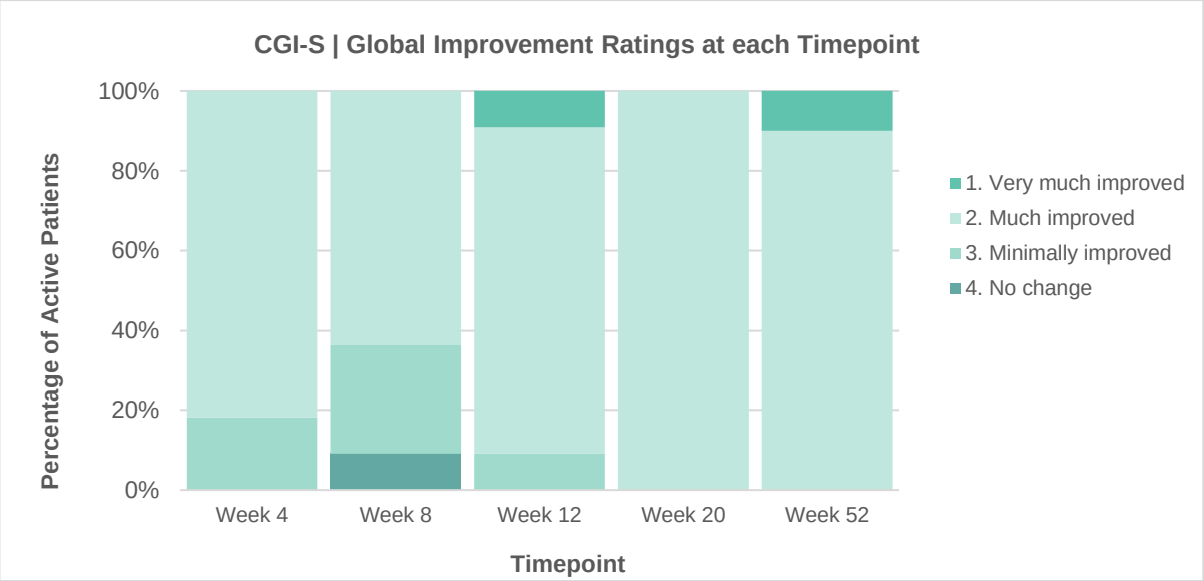
The CGI-S 3-item clinician-rated scale was used to analyse the therapeutic effects of NTI164 and its changes to severity of illness.

- **Global Improvement**: rates the total improvement whether or not, in the clinician's judgement, is due entirely to drug treatment.
- **Severity of Illness:** a comparison of baseline and post-baseline (28 days, up to 20 weeks)
- **Efficacy Index (Therapeutic Effect):** rated based on drug effect only. This is a calculated score based on the degrees of therapeutic effect and side effects.

Global Improvement

Of the 11 assessable patients at 52 weeks of daily treatment with NTI164, 100% of active patients showed improvement. 90% of these patients had a global improvement of 'Much improved', relative to baseline, with 10% scoring 'Very much improved'.

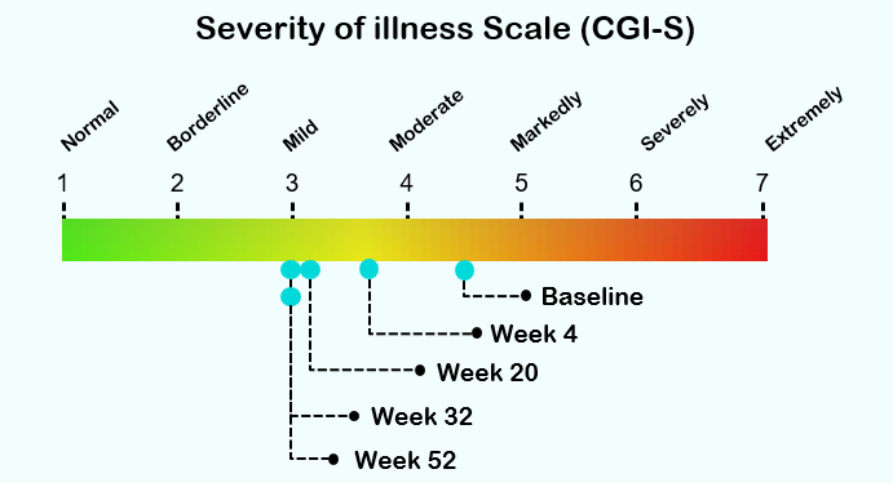
At 20 weeks of treatment, 100% of the 11 patients showed improvement. 75% of these patients had a global improvement of 'Much improved' and 25% had a global improvement of 'Minimally improved', at 20 weeks relative to baseline.

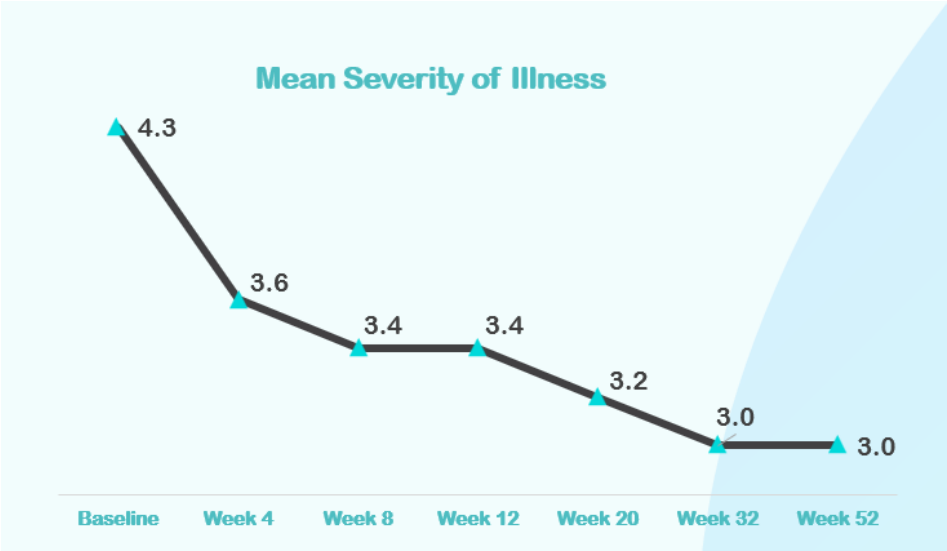


Severity of Illness

At 52 weeks of treatment (n=11), the mean severity of illness rating of the CGI-S was 3.0, representing an improvement of 30.2% from baseline (CGI-S: 4.3). The mean difference between 52 weeks of treatment and baseline was -1.1, 95% Confidence Interval (CI) = -2.08, -0.12, p value=0.032 (28 days: -0.714, 95% CI = -1.332, -0.097, p=0.027; 20 weeks: -1.1, 95% CI = -1.772, -0.3948, p=0.005).

The results for severity of illness at 52 weeks versus all other timelines, including baseline for the 11 patients assessed is shown below:



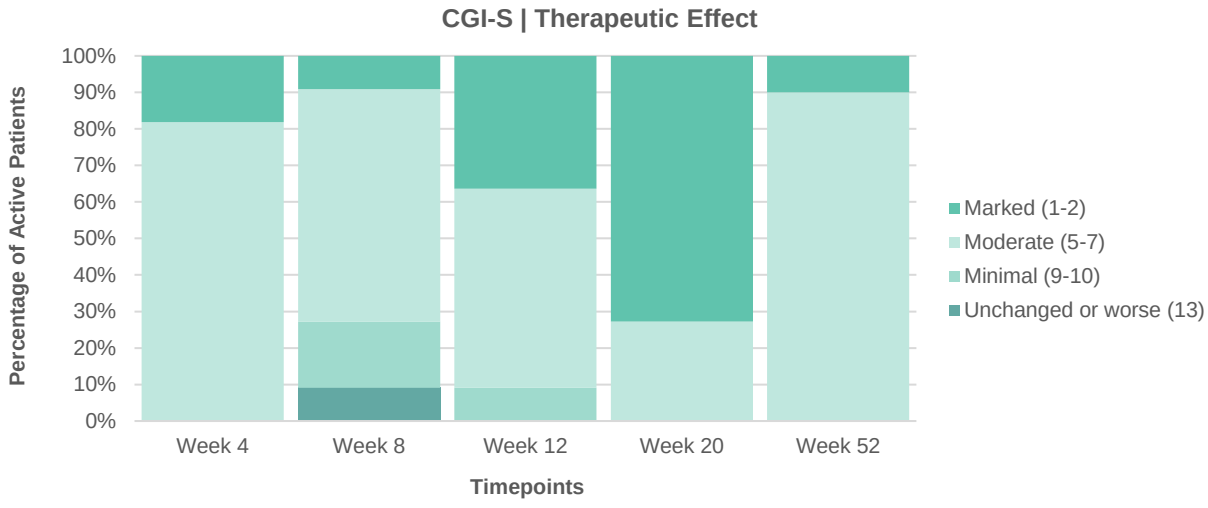


The results demonstrate that of the ~40% of subjects markedly or severely ill at baseline – 0% of patients from week 4 onwards were classified as markedly to severely ill. In addition, these results show a significant improvement in average severity of illness scores over time.

Therapeutic Effect

After 52 weeks of daily treatment with NTI164, relative to baseline, of the 11 patients evaluable, 10% of patients demonstrated the highest and second highest possible efficacy index scores of 1 and 2: Marked therapeutic effect – Vast improvement.

Moderate therapeutic effect with partial remission of symptoms was seen in 90% of patients at 52 weeks.



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.

Adaptive Behaviour – Vineland™-3

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.

Vineland™-3 measures are typically assessed every 3 months. Vineland™-3 is a norm-based instrument, where adaptive function is compared to others of the same age (the normative mean of 100 and the normative standard deviation is 15).

The tabulated results for 52 weeks versus 20 weeks and baseline is shown below:

Vineland-3 Scale ***n=11***	**Mean Standard Score**			**Highest Score Achieved**			**Max. decrease Week 52**	**Max. increase Week 52**	**Mean Diff. Week 52**
	Base	**Week 20**	**Week 52**	**Base**	**Week 20**	**Week 52**			
Adaptive Behaviour Composite	66.9	71.1	73.3	82	91	102	0	+20	**+6.4**
Communication	69.6	74.0	75.9	88	100	96	0	+10	**+6.3**
Daily Living Skills	63.5	68.4	72.0	86	85	101	0	+16	**+8.5**
Socialisation	68.0	73.8	74.5	81	95	109	-5	+28	**+6.5**

The results showed a statistically significant change in the adaptive behaviour composite endpoint at 52 weeks versus baseline (mean difference of 6.38, 95% confidence interval = 0.94, 11.81, p value = 0.028), and individual domains of communication (mean difference of 6.25; 95% CI = 4.26, 8.24, p value= 0.0001), daily living skills (mean difference of 8.5; 95% CI = 3.50, 13.50, p value= 0.005), and socialisation (mean difference of 6.5; 95% CI = -2.13, 15.13, p value= 0.118).

As previously reported, at 20 weeks versus baseline the adaptive behaviour composite endpoint was also significant (mean difference of 3.8; 95% CI = 2.06, 5.61, p value= 0.0005), and individual domains of communication (mean difference of 3.9; 95% CI = 1.76, 6.08, p value= 0.002), daily living skills (mean difference of 4.7; 95% CI = 0.93, 8.40, p value= 0.019), and socialisation (mean difference of 4.6; 95% CI = 1.12, 8.05, p value= 0.014).

Social Responsive Scale, 2nd Edition (SRS-2)

The SRS-2 is an internationally recognised tool used to identify social impairment associated with autism spectrum disorders (ASDs) and quantifies its severity using a Total score plus six sub-scales (Social Awareness, Social Cognition, Social Communication, Social Motivation, Restricted Interest and Repetitive Behaviour and Social Communication and Interaction). Total *T*-score's that range 76 or higher are classified as the *severe range* and indicate deficiencies in reciprocal social behaviour that are clinically significant and lead to severe interference with everyday social interactions.

The mean of the total *T*-score for the 11 patients after daily NTI164 treatment was 73.8 which is a significant improvement from baseline where it was 78.7 (mean difference of –4.1, 95% CI = -8.17, -0.03, p value=0.049).

The tabulated results for 52 weeks versus 20 weeks and baseline for the eleven patients assessed, is shown below:

	Mean			Min Score			Max Score			Max decrease in total score		Max increase in total score		Mean Difference	
SRS-2	**Base**	**W 20**	**W 52**	**Base**	**W 20**	**W 52**	**Base**	**W 20**	**W 52**	**W 20**	**W 52**	**W 20**	**W 52**	**W 20**	**W 52**
Total *T*-Score	78.7	74.8	73.8	55	51	51	89	88	88	-13	-12	3	7	**-4.4**	**-4.1**
Social Awareness	66.7	66.2	67.2	51	51	48	87	87	78	-12	-12	16	13	**-0.6**	**+2.5**
Social Cognition	75.4	72.6	71.3	50	46	46	92	94	91	-10	-13	6	6	**-3.0**	**-3.2**
Social Communication	75.8	72.8	73.4	59	53	51	85	83	91	-8	-9	4	7	**-3.7**	**-2.4**
Social Motivation	75.4	73.3	68.7	52	51	46	89	87	83	-16	-16	5	3	**-2.5**	**-5.8**
Restricted Interest and Repetitive Behaviour	80.3	72.5	72.6	52	52	55	100	94	91	-28	-26	7	15	**-8.1**	**-6.7**
Social Communication and Interaction	77.1	74.5	73.3	56	51	48	85	87	86	-8	-8	2	5	**-3.0**	**-3.0**

Safety Measures

At 20-52 weeks a total of 6 adverse events were reported by four participants. None of these adverse events were serious and were not considered to significantly interfere with the patient's functioning.

This compared to the 20 weeks (representing the 11 assessable patients), a total of 39 adverse events were reported by 10 participants. 31% of these reports were digestive related (n=12) i.e., stomach pain, diarrhoea, vomiting. Stomach pain was the most reported adverse events and accounted for 13% of reports (n=5). No serious adverse events were reported.

APPENDIX 2 - Study Details

The full study details described below represent the original trial design to assess the safety and efficacy of NTI164 after 28 days of daily treatment, as reported to ASX on 8 July 2022. For more information on the trial, please visit www.clinicaltrials.gov Identifier NCT05516407 or the Australian New Zealand Clinical Trials Registry (ANZCTR) under Registration Number: ACTRN12621000760875P.

Neurotech was subsequently granted HREC approval to continue dosing patients for a further 54 weeks due to the positive therapeutic effects of NTI164 combined with feedback from parents and clinicians at 28 days. In February 2023, Neurotech received HREC approval to extend patient treatment for an additional 6 months. Neurotech continues to collect data on safety and some efficacy measures in patients who continue to receive daily treatments of NTI164 beyond 52 weeks. The Company today has announced the results of continued treatment with NTI164 at 52 weeks.

This study was conducted in accordance with this protocol, ICH GCP guidelines, federal and local governing regulatory requirements and laws and in accordance with HREC guidelines.

Title: Phase I/II Open – Label Study to Evaluate the Safety and Efficacy of Orally Administered Full-Spectrum Medicinal Cannabis Plant Extract (0.08% THC) – NTI164 in Children with Autism Spectrum Disorder

Site: Monash Children's Hospital Clayton, Melbourne Victoria

Study Population: Aged between 8 to 17 years old population that have a medical diagnosis of Level 2 or 3 Autism Spectrum Disorder (ASD) as confirmed by the Autism Diagnostic Observational Schedule (ADOS-2) criteria.

Subject inclusion criteria:

- Participant is aged 8 years to 17 years (inclusive)
- Participant is at a healthy weight at the discretion of the Principal Investigator.
- Parents or caregivers can give informed consent for participation in the trial with assent from individuals with autism.
- Participants can comply with trial requirements.
- According to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria the participant has a diagnosis of Level 2 or 3 Autism Spectrum Disorder (ASD) confirmed by Autism Diagnostic Observational Schedule (ADOS-2) criteria
- All treatments including medications and therapies for ASD related symptoms must have been stable for 4 weeks before enrolment and for the duration of the trial wherever possible.
- Participants must be able to swallow liquid.
- Consent giver must be able to understand the requirements of the study.

Subject exclusion criteria:

- Current diagnosis of bipolar disorder, psychosis, schizophrenia, schizoaffective disorder, or active major depression
- Has a diagnosis other than ASD that dominates the clinical presentation (e.g., Attention Deficit Hyperactivity Disorder [ADHD])
- Has a degenerative condition
- Changes in anticonvulsive therapy within the last 12 weeks
- Taking omeprazole, lansoprazole, tolbutamide, warfarin, sirolimus, everolimus, temsirolimus, tacrolimus, clobazam, repaglinide, pioglitazone, rosiglitazone, montelukast, bupropion, or efavirenz

- Currently using or has used recreational or medicinal cannabis, cannabinoid-based medications (including Sativex., or Epidiolex.) within the 12 weeks prior to screening and is unwilling to abstain for the duration of the trial
- Participant has any known or suspected hypersensitivity to cannabinoids or any of the excipients
- Participant has moderately impaired hepatic function hepatic function at screening, defined as serum alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 2 × upper limit of normal (ULN) or total bilirubin (TBL) > 2 × ULN. This criterion can only be confirmed once the laboratory results are available; participants enrolled into the trial who are later found to meet this criterion must be screen-failed
- Participant is male and fertile (i.e., after puberty unless permanently sterile by bilateral orchidectomy) unless willing to ensure that they use male contraception (condom) or remain sexually abstinent during the trial and for 12 weeks thereafter.
- Participant is female and with childbearing potential (i.e., following menarche and until becoming postmenopausal for ≥ 12 consecutive months unless permanently sterile by hysterectomy, bilateral salpingectomy, or bilateral oophorectomy) unless willing to ensure that they use a highly effective method of birth control (e.g., hormonal contraception, intrauterine device/hormone-releasing system, bilateral tubal occlusion, vasectomized partner, sexual abstinence) during the trial and for 12 weeks thereafter.
- Female participant who is pregnant (positive pregnancy test), lactating or planning pregnancy during the course of the trial or within 12 weeks thereafter.
- Participant had brain surgery or traumatic brain injury within 1 year of screening.
- Participant has any other significant disease or disorder which, in the opinion of the investigator, may either put the participant, other participants, or site staff at risk because of participation in the trial, may influence the result of the trial, or may affect the participant's ability to take part in the trial.
- Any abnormalities identified following a physical examination of the participant that, in the opinion of the investigator, would jeopardize the safety of the participant if they took part in the trial
- Any history of suicidal behaviour (lifelong) or any suicidal ideation of type 4 or 5 on the Columbia-Suicide Severity Rating Scale (C-SSRS) in the last 4 weeks or at screening or randomization
- Participant has donated blood during the past 12 weeks and is unwilling to abstain
- from donation of blood during the trial.
- Participant has any known or suspected history of alcohol or substance abuse or positive drugs of abuse test at screening (not justified by a known concurrent medication).
- Participant has previously been enrolled into this trial.
- Participant has plans to travel outside their country of residence during the trial, unless the participant has confirmation that the product is permitted in the destination country/state.

Safety Evaluation:

Full blood examination, liver function test, renal function test, vital signs & adverse events.

Assessments of efficacy:

Efficacy will be monitored and measured through parent/carer and physician questionnaires
The secondary outcomes measures listed below will be used to assess potential improvements of:

- Irritability
- Hyperactivity
- Mood
- Self-stimulation
- Sleep disorders
- Seizures
- Behavioural Crises
- Social Interaction

- Communication

Secondary Endpoints

1. Social Responsiveness Scale, 2nd Edition (SRS-2)

School-Age Form Five domains are assessed including: Social Awareness, Social Cognition, Social Communication, Social Motivation, and Restricted Interests and Repetitive Behaviour. Items are scored on a 4-point scale (ranging from 1=not true to 4=almost always true).

2. Anxiety, Depression and Mood Scale (ADAMS)

28 symptom items that resolve into five subscales labelled: Manic/Hyperactive Behaviour, Depressed Mood, Social Avoidance, General Anxiety, and Compulsive Behaviour. Items are rated on 4-point scale ranging from 0=not a problem to 3=severe problem.

3. Sleep Disturbance Scale for Children (SDSC)

Six subscales including Disorders of Initiating and Maintaining Sleep, Sleep Breathing Disorders, Disorders of Arousal, Sleep Wake Transition Disorders, Disorders of Excessive Somnolence, and Sleep Hyperhydrosis. Items are rated on 5-point scale where 1=never and 5=always (daily). Subscale scores sum to equal a total score

4. Clinical Global Impression-Severity (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.

5. Autism Family Experience Questionnaire (AFEQ)

Parent/Caregiver form used to measure impact of autism interventions on family experience and quality of life. Items are rated on a 5-point scale where 1=always and 5=never.

6. Anxiety Scale for Children - Autism Spectrum Disorder - Parent Versions (ASCASD-P)

Parent/Caregiver form developed to detect symptoms of anxiety in youth with ASD. Composed of four subscales (Performance Anxiety, Uncertainty, Anxious Arousal, and Separation Anxiety), items are rated on a 4-point scale (0=never and 3=always). Subscales sum to equal a total score.

7. Anxiety Scale for Children - Autism Spectrum Disorder (ASC-ASD-C)

Child Versions Child form developed to detect symptoms of anxiety in youth with ASD. Composed of four subscales (Performance Anxiety, Uncertainty, Anxious Arousal, and Separation Anxiety), items are rated on a 4-point scale (0=never and 3=always). Subscales sum to equal a total score.

8. The Child Behaviour Checklist for Ages 6–18 (CBCL)

A parent/carer measure to assess patterns of behaviour. The measure is a Likert scale rated over 3 or 4 points.

9. Caregiver Global Impression of Change in Attention (CGI-CA)

Reflects clinician's impression of change in attention on a 7-point scale ranging from 1=not at all to 7=very severe problem. Provided as Baseline and Post- Baseline questionnaires.

10. Caregiver Global Impression of Change (CGI-C)

Target Behaviour Reflects clinician's impression of change of behaviour on a 7-point scale ranging from 1=not at all to 7=very severe problem. Provided as Baseline and Post-Baseline questionnaires.

11. Clinical Global Impression Scale -Improvement (CGI-I)

This is a 7-point scale measuring symptom change from baseline. Provided as baseline and post-baseline Caregiver and Clinician questionnaires, ranging from 1. Very much improved to 7. Very much worse

12. Vineland Adaptive Behaviour Scales, Third Edition (Vineland-3)

Parent/Caregiver Form. Used to measure adaptive functioning across three core domains (Communication, Daily Living Skills, and Socialization), and two optional domains (Motor Skills and Maladaptive Behaviour); items are rated on a 3-point scale (0=never; 1=sometimes; 2=usually or often). The core domains sum to a total Adaptive Behaviour Composite.