Neurotech

20 January 2021

Q&A with NTI Company Chairman, Brian Leedman

Neurotech International Limited (ASX: NTI) ("Neurotech" or "the Company") is pleased to provide the following update in the form of a Q&A with the Company's Chairman, Brian Leedman.

The below Q&A provides a detailed overview of the Company's cannabis strains, development strategy and some of the key near-term objectives expected to be delivered.

1. What is the background to the unique strains of cannabis that NTI has the rights to?

The DOLCE/ NTI cannabis strains were sourced from China over 20 years ago with full documentation and traceability. The strains have been preserved and can be covered under plant breeders' rights. NTI has exclusive access to these strains which have been cultivated, preserved and improved over the years.

2. What is unique about the makeup of the cannabis strains?

Our strains contain less than 0.3% THC (>0.3% is regulated as a restricted drug) which puts us in a unique position in respect to other ASX listed Australian cannabis companies that have to deal with the potential regulatory risks of commercialising a controlled substance.

In addition to having little or no THC in our strains, another key point of differentiation is that our strains also express high concentrations of unique cannabinoids including CBDA and the rarer, newly discovered varieties: CBDP and CBDB as well as CBG.

Latest international data is now focused on the efficacy of the "rarer" cannabinoids and their efficacy profile that goes beyond CBD alone. These strains contain rare cannabinoids which have powerful effects on inflammatory pathways, supress cytokine activity and work via different pathways to CBD in regulating these complex processes. The fact that we have identified three active pathways which are involved in cell health, cell survival and cell maintenance is unique.

3. NTI is looking to find new treatments for Autism, ADHD and Epilepsy. What trials have been conducted in the past that show CBD may have some impact on these indications?

There have been over 30 international CBD focused trials specifically focusing on the treatment of ADHD, Epilepsy and Autism. To date, the clinical trial data has been inconclusive and irreproducible. There is only one CBD product that has FDA approval to date – for a rare form of epilepsy. Given that the in vitro results to date demonstrate 2 active pathways not seen with CBD alone, the Company is optimistic moving into the initial clinical trials.

https://clinicaltrials.gov/ct2/

U.S. Food & Drug Administration (FDA) **approved** EPIDIOLEX® in 2018 (cannabidiol, **CBD**) oral solution for the treatment of **seizures** associated with two **epilepsy** syndromes - Lennox-Gastaut syndrome and Dravet syndrome - in people two years of age or older.

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4. What is the regulatory route sought by NTI for its products? Does the low level of THC reduce the regulatory risk?

Our upcoming clinical trials will be designed and conducted under the Therapeutic Goods Act Special Access Scheme (SAS). The THC levels (<0.3%) allows our clinicians to focus on the younger paediatric patient population. By eliminating the side effects commonly associated with the presence of THC, we will be able to accelerate the development process in relation to demonstrating efficacy, patient compliance and uptake.

5. What did you find in NTI's in-vitro trials?

Our studies were designed to assess:

a) Neuro-protective – neuro-modulatory activities of the NTI strains versus CBD alone.
b) Anti-inflammatory properties versus CBD alone.
c) iNOS suppression properties versus CBD alone.
d) Safety in relation to cell survival and cell health versus CBD alone.
e) Anti-inflammatory activity versus Aricept (Leading Alzheimer's Disease drug).
f) "Entourage efficacy" versus single isolate.

We were able to achieve positive and significant outcomes with all these main studies. NTI's full spectrum plants exhibit properties that are much more powerful and novel when compared to CBD alone. CBD products are currently market leaders and considered to be the gold standard in the medicinal cannabis field. We have conclusively demonstrated that our strains exhibit powerful anti-inflammatory, neuro-protective and neuro-modulatory properties – full entourage effect, which are much more powerful than CBD alone.

As mentioned earlier, unlike CBD, our strains modulate various pathways which are involved in cell health, cell survival and cell maintenance. These are vital processes which are involved in the development and progression of various neurological diseases (including Autism, ADHD, Multiple Sclerosis, Alzheimer's Disease, etc).

Company announcement: 21st December 2020

6. How do the NTI strains work?

Our neuronal cell studies demonstrate that NTI strains regulate Arginase1 pathway, B-tubulin pathway and iNOS pathway. NTI strains regulate and supress inflammation by acting on Arginase1 protein and therefore regulating the Arginase1 pathway. Results also demonstrate the up-regulating and modulation of the of beta-tubulin protein and related pathways.

NTI strains were able to suppress and modulate the activity of iNOS – which is directly involved in the complex cytokine pathways relating to immunity and natural defence mechanisms.

Company announcement: 30th November 2020

7. Did the trials give any indication for the safety of your strains when taken by patients?

Dosage studies which have been conducted as part of these "efficacy and mode of action" studies

have demonstrated that the neuronal cells tolerated the DOLCE/NTI strains. There were no signs of cell apoptosis or cell toxicity. This gives us confidence that there will be no safety related issues in our clinical trials.

8. Were NTI's strains tested against any other formulations in respect to their anti-inflammatory and neuro modulatory properties?

Yes, we did compare NTI's strains to Aricept. Even though CBD is the gold standard, we wanted to establish an "efficacy" baseline. Aricept was chosen because it is a blockbuster in the category of "neuro-regulation". Aricept increases the communication between neuronal cells and provides "relief" and protection against dementia. With annual sales of over US$1 billion, it is the leading therapy in the early treatment of AD.

Our studies showed NTI's strains to be 30% more potent than Aricept and 80% more potent than CBD alone – these results were statistically significant.

Aricept https://www.webmd.com/drugs/2/drug-14335/aricept-oral/details

Study results:
Assessment of primary outcomes: Mitochondrial respiration (MTT reduction)

Aricept Alone:
MTT output: 132, 126, 143, 128, 119
Mean +/- SEM: 129.6 +/- 3.53
Statistically significant at $p<0.05$

NTI Strains:
MTT output: 186, 163, 174, 191
Mean +/- SEM: 178.6 +/- 4.35
Statistically significant at $p<0.05$

CBD alone:
MTT output: 87, 65, 132, 112, 105
Mean +/- SEM: 100.2 +/- 10.1
Statistically significant at $p<0.5$

9. Why do you think NTI's strains were so much more effective than CBD?

Our strains contain the rare – newly discovered cannabinoids, CBDP and CBDB, which work synergistically via full plant "entourage effect" and have multi-pathway regulating capabilities going beyond CBD alone.

The **entourage effect*** refers to the cannabinoids in the full plant to interact with each other synergistically to modulate activity and overall effects of the plant. There is growing evidence to suggest that the entourage effect is much more powerful than single isolate or extract and that synergy matters.

The term "entourage effect" was first coined in 1998 by Dr. Ben-Shabat in his paper, **An Entourage Effect: Inactive Endogenous Fatty Acid Glycerol Esters Enhance 2-Arachidonoyl-Glycerol Cannabinoid Activity.** The concept has most notably been explained and expanded upon by Dr. Ethan Russo in his 2011 peer-reviewed article entitled, Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects.

10. Where to next for NTI?

The next logical step is to assess these strains in a human clinical setting. We have developed a program that will enable us to conduct an open-label human clinical trial under the SAS scheme to

allow us to assess our strains in a paediatric population. Our target indication profile is Autism with Epilepsy. The study will be designed and assessed in accordance with OECD and TGO-93 guidelines. These programs will be conducted under the guidance of A/Prof Michael Fahey – Head of Paediatric Neurology, Monash Children's Hospital.

A/Prof Fahey and his team are world experts in the clinical development and translation of medicinal cannabis.

11. When will the trial start?

First dosage is expected to be late 1st quarter CY2021.

12. What will you be hoping to find?

The study is designed to assess safety/tolerability as well as efficacy (measured by reduction in daily seizures, increase in focus and attention span, increase in school attendance and various other approved phycological tools).

Further details will be released when the trial program is finalised.

13. What will successful results in this clinical trial mean to NTI?

It will be a ground-breaking, first in class "full plant" application for indications that have limited medical treatment options. Providing paediatric patients with life changing options, to improve quality of life. In the event this study is successful, we intend to expand our studies to treat adult neurological disorders.

Authority

This release has been authorised by the Board of Directors.

Further Information

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About Neurotech

Neurotech International Limited is a medicinal cannabis company conducting clinical studies to assess the neuroprotective, anti-inflammatory and neuro-modulatory activities of our proprietary DOLCE/NTI cannabis strains which include CBDA, CBDP and CBDB. The licensed strains contain < 0.3% THC potentially providing a clearer pathway to regulatory approval than all other cannabis companies that contain far higher THC levels. Neurotech is also commercialising Mente, the world's first home therapy clinically proven to increase engagement and improve relaxation in autistic children with elevated Delta band brain activity. For more information about Neurotech and Mente Autism, please visit:

http://www.neurotechinternational.com