Q&A With Company CEO, Dr Alex Andrews

Can you remind readers what is unique about the makeup of the NTI cannabis strains and why it is very different to CBD and THC?

NTI164 is a proprietary full spectrum medicinal cannabis strain (patent pending) with multiple biopharmaceutical applications.

NTI164 has a novel composition, comprising of high CBDA and assortment of other minor cannabinoids – some of which were discovered as recently as 2019/20[1]. Latest international and national data demonstrates that 'minor' cannabinoids including CBDA, CBDP, CBDB, CBN and CBG work together to create an "entourage effect" that is more potent than CBD isolate alone[2].

These cannabinoids have powerful effects on inflammatory pathways, suppress 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.

In addition to having high concentrations of these unique cannabinoids, NTI164 also has a key point of differentiation in that our strain contain less than 0.3% THC (>0.3% is regulated as a restricted drug) - which puts us in a unique position in respect to potential regulatory pathways.

References:

1. A phytocannabinoid isolated from *Cannabis sativa*L. with an *in vivo* cannabimimetic activity higher than Δ^9-tetrahydrocannabinol: Δ^9-Tetrahydrocannabiphorol. Citti, C., et al 2019. www.nature.com/articles/s41598-019-56785-1
2. Cannabis constituents interact at the drug efflux pump BCRP to markedly increase plasma cannabidiolic acid concentrations. Anderson, L. et al., 2021. www.nature.com/articles/s41598-021-94212-6

Prior to NTI's Phase I/II trials in ASD, what did you find in NTI's preclinical studies which has led to the success of the current trial program?

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 in 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, significantly superior to CBD alone.

As mentioned earlier, unlike CBD, our strains support 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 Spectrum Disorder (ASD), Cerebral Palsy, Attention Deficit Hyperactivity Disorder (ADHD), Multiple Sclerosis, Alzheimer's Disease). Company ASX announcement: 21st December 2020

Is the company happy with the current results that have been released in respect of the ASD paediatric trial being conducted at Monash Children's Hospital in Melbourne?

Yes, the Company is extremely pleased. The study was designed primarily to assess safety and tolerability. The fact that we're seeing positive behavioural indicators so early in our clinical program is very encouraging and gives us the confidence to move forward with our phase II/III program without delay.

Briefly outline for stakeholders the importance of safety and tolerability as well as efficacy?
NTI164 is a naturally derived full spectrum cannabis strain, however, it has never been assessed for safety in humans. There were no material adverse events reported with the patients (who were aged between 8 and 17) - giving NTI further safety and tolerability data that is paramount for all our future studies. Without safety we cannot continue. This study forms the foundation for many other studies in the field of neuroinflammation and allows us to demonstrate therapeutic efficacy in targeted clinical indications.

What is the significance of the existing behavioural improvements following through into forthcoming results?
It's very significant. Not only were we able to identify these positive trends so early in our program, we have also demonstrated that we can design focused and strategic trials with possibly fewer number of subjects moving forward. This will save both time and money – and therefore achieve commercialisation in a shorter time period. We are looking forward to the release of the efficacy results in May / June 2022.

What are the current treatments for childhood ASD and are there any side effects?
The only FDA and TGA approved drug for ASD is Risperidone. The side effects include dizziness, fatigue, nausea and muscle spasms – and therefore is not very well tolerated. ASD is a very prevalent disorder (affecting 1:44 children) with little to no medical treatment options. Therefore, to be able to provide a naturally derived safe and efficacious product will demand market and clinical attention globally. The current ASD global market size is $2.3b[3]. This is expected to grow to $5.5b by 2028. [3]www.coherentmarketinsights.com/market-insight/autism-spectrum-disorder-therapeutics-market-2643

Can you elaborate on the phase II / III trials planned for H2 2022?
We are in discussions with the US FDA and the TGA in relation to protocol design and setup. We will ensure that we capture enough information which will allow for product registration to follow on. We will strategically map this out with our clinical and regulatory advisors. These discussions will add significant commercial value to our partnering discussions.

Given the significance of the results to date, can you describe to stakeholders a potential pathway to drug registration in North America assuming trials continue to be successful?
Our focus will be the US FDA. The roadmap we are currently paving:

1. Pre-IND FDA meeting.
2. FDA signoff on phase II/III trial
3. Completion of successful phase II/III trial
4. New product application process
5. Product registration

We envisage undertaking this work over the next 24 months.

Based on the Company's initial combination therapy announcement in December 2021, can you briefly outline the early stage success with prednisone combination work?
The Company believes that the regulatory pathway for the combination strategy will be under an accelerated process. Simply because the actives that we are currently assessing are not only off patent but have been in use for a very long period of time which positions us favourably with the US FDA and the TGA in Australia. We are in advanced stages of having a Phase II combination trial approved which will springboard a number of combination therapy activities including potential strategic partnerships.

What can we look forward to in terms of company updates over the next few months?
The Company has been making significant progress and will look to update the market on:

1. Efficacy results from the phase I/II trial
2. A strengthening to its patent positions
3. Continuation of its preclinical program
4. An expansion of its clinical indications (i.e. beyond ASD)
5. Design, recruitment and commencement of the phase II/III clinical trial

6. Developments in our drug combination therapies

We currently have multiple significant preclinical programs in place to assess the neuroprotective effects of NTI164 as well as the synergistic effects of NTI164 in combination with various pharmaceutical actives.

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

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About Neurotech

Neurotech International Limited is a medical device and solutions company conducting clinical studies to assess the neuro-protective, anti-inflammatory and neuro-modulatory activities of our proprietary NTI/Dolce cannabis strains. Neurotech has submitted key provisional patents relating to the composition and use of NTI164 for the treatment of a range of neurological disorders including ASD. 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 and Mente Autism please visit http://www.neurotechinternational.com