ASX announcement & media release

Medlab receives positive NRGBiotic™ Phase IIa Depression trial independent preliminary results.

- showed a significant reduction in depression scores from baseline
- showed significant improvement in quality of life from baseline
- safe and tolerable, with NO reported adverse effects

Medlab Clinical (ASX: MDC), a company with a portfolio of novel pharmaceutical candidates enhanced by its patented delivery platform and used for the treatment of chronic pain and disease, has received a positive preliminary analysis of a Phase IIa clinical trial to support the expanded use of Medlab's probiotic NRGBiotic™ in relation to helping treat major depression.

Medlab's Director of Medical Research, Prof Luis Vitetta, said: "The preliminary analysis on the group of patients who were administered NRGBiotic™ in combination with the patient's prescribed anti-depressant medication, showed a significant reduction in depression scores from baseline to eight weeks – a statistically significant, preliminary result.

" The other standout points were the confirmed safety and tolerability factors for the NRGBiotic™ administered cohort that presented with no adverse effects from the probiotic formulation.

"The preliminary analysis shows a very nice, significant and encouraging trend for reducing the level of depression among the test patients; however, further analyses are required to complete. Unfortunately, the process has been interrupted by COVID-19 restrictions."

The Trial

Listed on ANZCTR: http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=372580&isReview=true
HREC Approval: 2017000186

The blinded, placebo-controlled trial was completed at the end of March 2020, with 120 out of 150 patients treated. The independent pathology covering multiple timepoints across 120 patients was carried out by the Queensland University of Technology, and in part by the QIMR Berghofer Medical Research Institute with significant delays due to COVID-19 restrictions.

Positive preliminary results

The Depression Study investigated NRGBiotic™ as an adjunct to commonly prescribed anti-depressant medications (SSRI or SNRI) for patients diagnosed with major depression.

Globally, more than 264 million people of all ages suffer from depression, is a leading cause of disability worldwide and is a major contributor to the overall global burden of disease (https://www.who.int/news-room/fact-sheets/detail/depression).

NRGBiotic™ is a multi-patented probiotic that is currently available in Australian pharmacies.

Preliminary analysis of the Depression Study primary outcome with NRGBiotic™ shows that in the group of patients administered the test formulation, the participants had:

- Significant reduction in depression scores from Baseline mean = 30.09 (severe range) to Week 8 mean = 15.93 (mild range) [$F(1, 55) = 72.26$ $p<0.001$].
- Significant improvement in quality of life from baseline mean = 61.54 to Week 8 mean = 56.59. $F(1,55)=8.01$ $p=.006$
- Significant improvement in psychosocial functioning baseline mean = 91.92 to Week 8 mean = 70.95. $F(1,55) = 55.34$ $p<.001$

The CEO of Medlab Clinical, Dr Sean Hall, said: "The completion of the NRGBiotic™ Depression Study during the COVID-19 pandemic was worthy of note, and we look forward to receiving the full analysis of the trial.

"The encouraging preliminary results of the Depression Study affirm our belief that NRGBiotic™, used as an adjunct, can be of great help to people who suffer from depression and whose current medication regime may not be producing a desired outcome. Depression is a global epidemic, affecting just over five per cent of the world's population. Health authorities expect this to rise, and medication strategies as they stand now may only work on two-thirds of the patient group.

"NRGBiotic™ is a very unique formulation based on years of hard work, I look forward to the ongoing development of this program, and the real-world opportunities NRGBiotic™ offers."

Investigating gut bacteria

The Depression Study showed that the administration of the probiotic combination NRGBiotic™ that contained the probiotic species *Lactobacillus acidophilus, Bifidobacterium bifidum* and *Streptococcus thermophilus* with Orotic Acid achieved a safety and tolerability as secondary outcomes in clinical trial participants.

The administration of the probiotic combination showed a significant (p=0.046 ANOVA) faecal abundance increase in the concentration of *Bifidobacterium bifidum* from baseline to eight weeks. There was also a significant increase in abundance (p=0.034 ANOVA) in the immune regulating/enhancing intestinal bacterial Genus Bifidobacteria in the treatment group, a genus reported to be significantly associated with anti-inflammatory / pro-inflammatory regulating properties in the intestines.

Finally, the gut microbiome of patients diagnosed with major depression correlated a decreased abundance in the gut bacterial Phyla Firmicutes and Proteobacteria, confirming results from previous studies. Furthermore, there was observed a strong positive association of depression severity with increased abundance from the bacterial Genus Paraprevotella.

ENDS

Authorisation & Additional information

About Medlab – www.medlab.co
Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and other global territories. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, NanoCelle™ is being applied to its medicines, nutritional products and off-patent pharmaceuticals like statins, Medlab has a growing patent portfolio.

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