

## Anatara Receives Ethics Approval to Start Psychological Functioning Trial in Adults

### Highlights:

- Study will evaluate safety and efficacy of 3FDC in adult participants with moderate anxiety, stress or depression
- Study design is a Randomised, Double-Blinded and Placebo-Controlled trial to address future evidence-based claims
- Study will be conducted by CSIRO, Australia's national science agency at their Nutrition and Health Research Clinic in Adelaide.

MELBOURNE, 20 April 2021: Anatara Lifesciences (ASX: ANR) is pleased to advise that it has received Human Research Ethics Committee (HREC) approval to undertake a clinical trial on the effects of 3FDC dietary supplementation on psychological functioning in an adult population.

3FDC is one of the components of Anatara's GaRP (Gastrointestinal reprogramming) dietary supplement. GaRP is a combination of two different minitablets, which is under investigation in another study focused on diarrhoea predominant Irritable bowel syndrome (IBS-D), announced on February 5<sup>th</sup>, 2021. The different minitablets in the formulation target different parts of the gastrointestinal tract. 3FDC is targeted to release at the junction between the small and large intestine (ileocecal junction) and exert its effects on the microbiome in the large intestine. Since restoration of a healthy microbiome is considered important for gut-brain axis balance, the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

Anatara in collaboration with the CSIRO have now received ethics approval to conduct a study into the effects of 3FDC in adults with moderate anxiety, stress or depression. This randomised, double-blinded, placebo-controlled study will be conducted at CSIRO's Nutrition and Health Research Clinic in Adelaide. Approximately 100 participants will be randomised in a 1:1 manner to treatment with 3FDC or placebo which is dosed twice a day for 6 weeks. Participants will be assessed at the start and end of the study period 'in-clinic' and will complete a series of questionnaires on a customised smartphone app over the duration of the study. In the event of tightening COVID-19 restrictions impacting 'in-clinic' visits, the study will transition to a virtual study with telehealth consultations. Such a transition is not anticipated to impact the primary outcome.

The primary outcome is a clinically significant reduction in Hospital Anxiety and Depression Scale (HADS) scores. The study is powered at ~95% to detect a clinically relevant reduction of  $\geq 1.5$  points in HADS scores from baseline to end of treatment (6 weeks) with significance set at 5%<sup>1</sup>. Secondary outcomes include mood and wellbeing questionnaires, gut symptom ratings and blood plasma markers.

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<sup>1</sup>  $\alpha = 0.05$ ;  $\beta = 0.95$ ;  $f = 0.15$



Having now achieved Human Research Ethics Committee approval to conduct the study, The CSIRO team will develop the work guidelines and initiate recruitment with the aim of dosing the first participants in Q3, 2021. Recruitment is anticipated to take 6 months after which data analysis will be undertaken prior to final reporting.

CEO Steve Lydeamore commented, “There is a major unmet need and significant market opportunity for an evidence-based complementary medicine for stress, anxiety and depression. According to *Beyond Blue* a quarter of Australians will experience an anxiety condition in their lifetime. I am excited that Anatara’s 3FDC dietary supplement may be of benefit to some of the many who experience these conditions. It is gratifying that Anatara’s focus on gut health and integrity has allowed us to capitalise on our research in IBS with the potential to address other microbiome centric conditions. The current study has the potential, not only to help those suffering mood disorders, but to significantly add to our understanding of GaRP in non-IBS participants. ”

**For more information please contact:**

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**About Anatara Lifesciences Ltd**

Anatara Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based products for gastrointestinal health where there is significant unmet need. Anatara is a life sciences company with expertise in developing products for animal and human health. Anatara is focused on building a pipeline of human gastrointestinal health products. Underlying this product development program is our commitment to delivering real outcomes for patients and strong value for our shareholders.

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## Anatara's 3FDC dietary supplement

Since restoration of a healthy microbiome is considered important for gut-brain axis balance, Anatara's 3FDC components have been selected to explore their effect on mood, anxiety and stress in otherwise healthy individuals.

Mood/relaxing supplements were 1,3 billion EUR in 2019 (Euromonitor's Health and Nutrition Survey Jan & Feb 2020).<sup>1</sup> About 19 percent of U.S. adults have an anxiety disorder in any given year, and an estimated 31 percent have an anxiety disorder at some time in their lives, and depression is a medical condition that affects about 1 in 10 U.S. adults.<sup>2</sup> An estimated 38.2% of the population of the EU member states (approximately 165 million people; 2010) met the criteria for a psychiatric disorder, while fewer than one-third received treatment for it (Wittchen et al., 2011).<sup>3</sup> 24% of U.S. adults with a mental illness report an unmet need for treatment.<sup>4</sup> 40% or more of Americans treat themselves with CAM without professional supervision, often without disclosing it to their psychiatrist or primary care provider. People considering using CAM treatments need to make an informed decision, just as they would with any synthetic medication or other treatment, weighing the evidence about effectiveness, drug interactions, side effects, and less dangerous options, to come up with a risk/benefit assessment.<sup>5</sup>

<sup>1</sup> pharmlinea: <https://pharmlinea.com/wp-content/uploads/2020/01/Stress-supplements-opportunity-news.pdf>

<sup>2</sup> National Center for Complementary and Integrative Health: <https://www.nccih.nih.gov/health>

<sup>3</sup> Wemrell M et. al (2020) Issues in Mental Health Nursing, Volume 41: <https://doi.org/10.1080/01612840.2020.1744203>

<sup>4</sup> Mental Health America: <https://www.mhanational.org/issues/state-mental-health-america>

<sup>5</sup> Mental Health America: [https://www.mhanational.org/sites/default/files/MHA\\_CAM.pdf](https://www.mhanational.org/sites/default/files/MHA_CAM.pdf)

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