ASX Release

Anatara Lifesciences clinical trials update

- **Recruitment to commence Monday, 21 February 2022 at CSIRO Adelaide for trial of 3FDC in adults with moderate anxiety, stress or depression**
- **Adelaide CSIRO site commences recruiting for GaRP in IBS-D**
- **Melbourne site anticipated to commence recruiting for GaRP in IBS-D in May 2022**

MELBOURNE, 17 February 2022: Anatara Lifesciences (ASX: ANR), a developer of evidence-based solutions for gastrointestinal diseases, provides an update on progress of clinical trials in psychological functioning and irritable bowel syndrome, diarrhoea subtype (IBS-D).

Commenting on progress with human clinical studies, CEO Steve Lydeamore said, "3FDC in adult participants with moderate anxiety, stress or depression are to be evaluated for safety and efficacy in a trial conducted by CSIRO, Australia's national science agency, at their Nutrition and Health Research Clinic in Adelaide. Investigational product has been delivered to the site. Following successful completion of the site initiation visit, recruitment will commence on Monday, 21 February 2022. The final study report is anticipated in late 2022.

"This CSIRO site has also been initiated for the GaRP trial in IBS-D and recruitment has commenced. The interim report is anticipated in August 2022 and the final report in January 2023.

"We continue to take actions to bring these reporting dates forward.

Evrima commenced digital marketing of the IBS-D trial, launching a new recruitment website: https://trials.evrima.com.au/irritable-bowel-syndrome-ibs-medical-study-registration.

"We are in late stage negotiations to add an additional site for the IBS-D trial in Melbourne. Recruitment is anticipated to commence in May 2022 after receiving ethics approval.

"With the high prevalence of digestive disorders, including irritable bowel syndrome (IBS), and the burgeoning interest in the "gut-brain" axis globally, there are significant market opportunities in addressing these issues while improving individuals' quality of life. Each of these trial milestones is anticipated to be impactful in commercialising Anatara's evidence-based solutions."

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Psychological functioning Trial

Anatara's 3FDC is several of the components of the GaRP (Gastrointestinal reprogramming) complementary medicine. The 3FDC components are coated for targeted release predominately beyond the small intestine to allow delivery and influence in the large intestine. The 3FDC components are anticipated to have direct and indirect effects including assisting the homeostasis of a healthy microbiome. The delivery of these components and the microbiome influences are considered important for gut-brain axis balance, hence the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

This randomised, double-blinded, placebo-controlled study into the effects of 3FDC in adults with moderate anxiety, stress or depression will be conducted at CSIRO's Nutrition and Health Research Clinic in Adelaide. Approximately 100 participants will be randomised in a 1:1 manner for treatment with 3FDC or a placebo, dosed twice a day for 6 weeks.

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."

Anatara's 3FDC components have been selected to explore their effect on mood, anxiety and stress in otherwise healthy individuals as the delivery of these components to the large intestine is considered likely to have beneficial effects on the gut-brain axis including positively influencing the homeostasis of the microbiome . Mood/relaxing supplements were 1,3 billion EUR in 2019 (Euromonitor's Health and Nutrition Survey Jan & Feb 2020).[1] 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.[2] 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).[3] 24% of U.S. adults with a mental illness report an unmet need for treatment.[4] 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.[5]

[1] pharmalinea: https://pharmalinea.com/wp-content/uploads/2020/01/Stress-supplements-opportunity-news.pdf

[2] National Center for Complementary and Integrative Health: https://www.nccih.nih.gov/health

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

[4] Mental Health America: https://www.mhanational.org/issues/state-mental-health-america

[5] Mental Health America: https://www.mhanational.org/sites/default/files/MHA_CAM.pdf

About GaRP

This GaRP trial in IBS-D consists of two stages (Stage 1, Stage 2), with an interim analysis between stages. Stage 1 will assess the safety, tolerability and efficacy of two different strengths of GaRP against placebo in a 1:1:1 randomisation protocol. Following interim analysis, one dose will be selected, and the remaining participants recruited in a 1:1 randomisation protocol. Of the 200 planned participants, at least 90 will enrol in stage 1, and 110 participants will enrol in stage 2. For each participant in each stage, the study will last for 12 weeks; including 8 weeks of treatment, preceded by a 2-week screening/baseline period and followed by a 2-week washout period. Measurements will include a number of surveys including the IBS specific surveys: IBS-SSS (severity scoring system), IBS QoL (quality of life) and IBS-AR (adequate relief) and Bristol Stool Form Scale.

CEO Steve Lydeamore commented, "There is a major unmet need and significant market opportunity for an evidence-based complementary medicine for IBS. Anatara's GaRP has demonstrated that it has the potential to manage the devastating symptoms experienced by IBS and IBD patients, by addressing processes that contribute to the pathophysiology of these chronic bowel conditions."

Anatara's GaRP complementary medicine is being developed to specifically target two human gastrointestinal disorders, irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD). IBS is the most common GI condition affecting approximately 11% of the global population[6] while IBD affects an estimated five million people globally.[7]

Current pharmaceutical treatments have high failure rates and severe side-effects, leading to over 50% of IBS[8] and IBD[9] patients trying complementary and alternative medicines (CAMS) in the hope of effectively managing their chronic bowel condition. This is a very significant market segment and while these products may have limited efficacy data by usual evidence based standards, many patients and healthcare providers believe the risk benefit of CAMs to be favourable enough for use . In 2018, expenditure on gastrointestinal supplements and OTC digestive remedies in the US alone was US$8 billion.[10,11]

[6] Clinical Gastroenterology and Hepatology 2012: 10, 712-721.
[7] Crohn's and Colitis Australia.
[8] Grundmann O & Yoon S (2014) World J. Gastroenterol 20 (2). p.346.
[9] Lovell R & Ford A (2012) Clin. Gastroenterol. Hepatol. 10. p.712
[10] Mintel's 2018 Digestive Health U.S., July 2019.
[11] 2018 category insight Report: follow your gut-a global look at Digestive Health Products.

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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 human and animal 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.