ASX Release



Anatara market update

MELBOURNE, 7th April 2021: Anatara Lifesciences Ltd ("Anatara" or "the Company"; ASX:ANR) provides an update on development and commercialisation activities for human health and animal health projects.

Anatara is pleased that activities for the March quarter progressed favourably and near to anticipated timelines. There appears to be a wider appreciation of Anatara's human health initiatives with a focus on using the restoration and/or maintenance of gastrointestinal tract harmony to improve overall wellbeing and with a market differentiating focus on *evidence based* complementary medicine.

Anatara has ethics approval to commence the human clinical trial in irritable bowel syndrome (IBS) with Anatara's Gastrointestinal ReProgramming (GaRP) complementary medicine. Due to a scheduling delay in manufacturing placebo for this trial as a result of reduced shifts under covid restrictions, the Company now anticipates commencing recruitment for the trial in May. This randomised, double-blind, placebo-controlled trial will be conducted in two stages as a virtual trial, with minimal on-site visits and participants completing most assessments online. Up to 6 sites will be used and approximately 200 participants enrolled. All six sites have been initiated with two sites in Victoria, two sites in Queensland, one site in New South Wales and one site in Western Australia.

Anatara has also applied for ethics approval to commence a human clinical trial in depression, anxiety and stress with "3FDC" (3FDC refers to 3 specific components in GaRP specifically formulated for release in the colon). The Company looks forward to providing more detail once the approval process is complete and anticipates commencing recruitment for this trial in mid-2021.

The Company remains encouraged by the progress in animal health areas, particularly targeting the need for feed products for growth enhancement without antibiotics or zinc oxide¹.

The BONIFF-SMEC piglet challenge study for enterotoxigenic *Escheria Coli* is anticipated to commence this month with completion in late May/early June 2021.BONIFF-SMEC is Anatara's formulated feed additive in Ridley Corporation's semi-moist extruded creep feed for piglets. The study is being conducted at Murdoch University,WA.

Pleasingly, as announced on the 1st Feb.2021 the University of New England's Poultry Hub Australia successfully completed the ANR-pf poultry challenge study for subclinical and necrotic enteritis. The commercial significance is being evaluated by animal feed companies and poultry producers.

 $^{^{1}\ \}text{Farmers Weekly, 24 September 2020: https://www.fwi.co.uk/livestock/pigs/survey-highlights-pig-health-worry-ahead-of-zinc-oxide-bankly and the state of the state of$



As a general business update, Anatara followed the successful capital raise and SPP with a buyback of over 211,000 shares from unmarketable parcels . The Company has a strong balance sheet with funding well beyond the trial timeframes and is actively reassessing as a priority both in house and external resources and capabilities to assist with investor relations during the exciting phase anticipated with the various trials, as outlined.

More on Anatara's Gastrointestinal ReProgramming (GaRP) complementary medicine

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 population¹ while IBD affects an estimated five million people globally.²

Current pharmaceutical treatments have high failure rates and severe side-effects, leading to over 50% of IBS³ and IBD⁴ 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. ^{5,6}



¹ Clinical Gastroenterology and Hepatology 2012: 10, 712-721.

² Crohn's and Colitis Australia.

³ Grundmann O & Yoon S (2014) World J. Gastroenterol 20 (2). p.346.

⁴ Lovell R & Ford A (2012) Clin. Gastroenterol. Hepatol. 10. p.712

⁵ Mintel's 2018 Digestive Health U.S., July 2019.

 $^{^{6}}$ 2018 category insight Report: follow your gut-a global look at Digestive Health Products.

More on Anatara's 3FDC dietary supplement

Restoration of a healthy microbiome is increasingly considered important for the "gut-brain axis" balance. Anatara's 3FDC components of the GaRP formulation have drawn additional interest particularly as these components are specifically designed for release in the large intestine or colon. The 3FDC component has been selected for use in a trial to explore the effect on mood, anxiety and stress in otherwise healthy individuals.

Mood/relaxing supplements estimated spend grew to 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 pharma<u>linea</u>: https://pharmalinea.com/wp-content/uploads/2020/01/Stress-supplements-opportunity-news.pdf

 $^{^2\,\}text{National Center for Complementary and Integrative Health:}\,\underline{\text{https://www.nccih.nih.gov/health}}$

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

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

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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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