

ASX Release

Anatara's gut-targeted dietary supplement completes preclinical testing, demonstrating it can treat inflammatory gastrointestinal disease and may promote mucosal healing

Highlights

- Successful completion of the preclinical program has provided strong scientific proof that the GaRP dietary supplement has the potential to be game changing
- When compared to a placebo control, GaRP reduced the combined disease characteristics of colon inflammation and disrupted bowel habits by 2.5-fold ($p=0.012$)
- Promoted mucosal healing by increasing mucin genes by a factor of 5 to 7-fold (MUC2 and MUC6, $p<0.001$)

BRISBANE & MELBOURNE, 14th October 2019: Anatara Lifesciences Ltd (ASX:ANR) is pleased to report statistically significant efficacy data from its *in vivo* mouse studies and further positive *in vitro* proof of concept data for its **Gastrointestinal ReProgramming (GaRP)** product. GaRP is a proprietary dietary supplement designed to restore and maintain a healthy human gut and microbiome.

Anatara's lead human health product, GaRP, is being developed to specifically target two human gastrointestinal (GI) disorders, Inflammatory Bowel Disease (IBD), including ulcerative colitis and Crohn's disease, and Irritable Bowel Syndrome (IBS). IBS is the most common GI condition affecting approximately 11% of the global population¹, while IBD affects an estimated five million people globally².

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. As many patients perceive the risk-benefit of CAMs to be favourable, patients are willing to spend significant amounts of money on these therapies. In 2018, expenditure on gastrointestinal supplements and over-the-counter (OTC) digestive remedies in the US alone was US\$8 billion^{5,6}.

The current treatment approach with IBD is to suppress the inflammation with the goal of inducing and maintaining remission, while in the case of IBS, gastroenterologists primarily treat the symptoms of abdominal pain, bloating and alternating constipation and diarrhoea. These therapeutic approaches have high treatment failure rates. Consequently, there is a significant unmet medical need for products that can i) re-establish the homeostasis of the microbiome, ii) treat the inflammation and iii) repair the mucosal damage, which will in turn have the downstream effect of reducing disease-associated diarrhoea.

During preclinical development of the GaRP dietary supplement, the proprietary formulation has provided strong scientific evidence that it can combat the three underlying causes of chronic bowel conditions. In summary, GaRP:

- **Addressed the dysbiosis of the microbiome** by inhibiting the attachment and invasion of pro-inflammatory bacteria (obtained from IBD and IBS patients) into healthy gut cells by >95% (p=0.002).
- **Reduced gut inflammation** by 85% by significantly reducing the production of pro-inflammatory proteins, p<0.001). Daily treatment with GaRP demonstrated a therapeutic benefit by significantly reducing the key disease indicators of colitis in mice. When compared to a placebo control, GaRP reduced the combined disease characteristics of colon inflammation and disrupted bowel habits by 2.5-fold (p=0.012).
- **Promoted mucosal healing** by increasing mucin genes by a factor of 5 to 7-fold (MUC2 and MUC6, p<0.001). These genes have been shown to be significantly reduced in both IBD and IBS patients. Through increasing the genes, it is expected that the proteins which produce gut protecting and healing mucins will also increase, which in turn may promote mucosal healing.

Anatara anticipates initiation of human clinical study activities in late 2019, with a view to partnering in the second half of calendar 2020.

Anatara's CEO, Mr Steven Lydeamore said, "The successful completion of the preclinical program has provided strong scientific proof that the GaRP dietary supplement has the potential to be game changing. Our proprietary over-the-counter product has demonstrated that it not only has the potential to manage the symptoms of IBD and IBS patients, but may also reduce the underlying causes of these chronic bowel conditions. This is a major milestone for Anatara's GaRP development program bringing us closer to partnering."

For more information please contact:

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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 FONA International, 2018 Category Insight Report: *Follow Your Gut* - A Global Look at Digestive Health Products.

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.