ASX Release

# Anatara Gastrointestinal ReProgramming (GARP) dietary supplement – summary of preclinical studies

**Highlights**

- Successful preclinical program has provided strong scientific proof that Anatara's GaRP dietary supplement may be the breakthrough product so desperately needed by patients suffering chronic bowel conditions
- GaRP has been shown to:
  - Address the dysbiosis of the microbiome
  - Reduce gut inflammation
  - Promote mucosal healing,
- GaRP has the potential to provide:
  - An adjuvant effect in reducing inflammation with the co-administration of disease-modifying medications
  - Dose reduction of disease-modifying medications known to have devastating side-effects
- GaRP does not affect the uptake or potential activity of probiotics

BRISBANE & MELBOURNE, 22nd January 2020: Anatara Lifesciences Ltd (ASX:ANR) is pleased to provide a summary of the preclinical studies conducted to date for its Gastrointestinal ReProgramming (GaRP) dietary supplement as it targets commencement of a human clinical trial in 2Q 2020.

The Company remains highly encouraged by the successful *in vitro* and *in vivo* preclinical data reported for its GaRP dietary supplement to date, providing the Company with every confidence going into a human clinical study this year. Anatara believes its GaRP dietary supplement may be the breakthrough product so desperately needed by patients suffering chronic bowel conditions, such as irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).

During the 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 ($p=0.012$).

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- **Promoted mucosal healing** by increasing mucin genes by a factor of 5 to7-fold (MUC 2 and MUC6, $p<0.001$). These genes have been shown to be significantly reduced in both IBD and IBS. 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's GaRP dietary supplement has the potential to be used in a wide range of chronic gastrointestinal (GI) indications. As such, it was important that the Anatara team establish that the product would not interfere with the effectiveness of commonly used prescription medications indicated for GI disorders, as well as other commonly used complementary and alternative medicines, such as probiotics.

Anatara's preclinical data, as announced on 19th December 2019, suggests the co-administration of GaRP with a commonly used disease-modifying medication (these medications are the backbone of current IBD treatment regimens) demonstrated a significant increase in the reduction in inflammation.

GaRP administered in combination with 5-ASA, dexamethasone or prednisolone demonstrated increased the inhibition of IL-8 release from Caco-2 cells. All points reached statistical significance ($p<0.05$, students t-test).

This is an exciting observation of an adjuvant effect and suggests the potential to significantly reduce the dose of relevant prescription medications. If this clinically-relevant finding translates into humans, patients will have the advantage of being able to reduce their dose of disease-modifying medications which are renowned for their devastating side-effects, such as sepsis. These findings are currently being confirmed in animal models of IBD.

Anatara also demonstrated that pre-treatment of probiotics with GaRP did not affect the efficacy of the probiotics. Pre-treatment of probiotics with GaRP, in all cases, did not significantly affect the attachment of the probiotics to the polarised Caco-2 enterocytes. In addition, the co-incubation of the probiotics with GaRP did not affect the efficacy of the probiotics, as determined by transepithelial electrical resistance (TEER) of polarised, inflamed Caco-2 cultures. These studies used *in vitro* gut models which are standard in the industry.

**Anatara's Gastrointestinal ReProgramming (GaRP) dietary supplement**

Anatara's GaRP dietary supplement 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[1] 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 IBS[3] and IBD[4] patients trying complementary and alternative medicines (CAMS) in the hope of effectively managing their chronic bowel condition. As many patients and healthcare providers believe the risk benefit of CAMs to be favourable, patients are willing to invest in their health, with this market segment being significant. 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.

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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.