ASX Release

Anatara Receives Ethics Approval to Start IBS Trial

Highlights:

- Study will evaluate safety and efficacy of GaRP in patients with IBS (irritable bowel syndrome)
- Study design is Randomised, Double-Blinded and Placebo-Controlled to address future evidence-based claims
- Virtual study with ObvioHealth Australia to provide digital clinical trial platform "ClaimIt"
- Supported by leading CROs: GenesisCare Clinical CRO, Microba, Sonic Clinical Trials

MELBOURNE, 8 February 2021: Anatara Lifesciences (ASX: ANR) is pleased to advise that it is has received Human Research Ethics Committee (HREC) approval to undertake a clinical trial of its **Ga**strointestinal **R**e-**P**rogramming complementary medicine (GaRP) in participants with irritable bowel syndrome – diarrhoea subtype (IBS-D).

Ethics approval is confirmation Anatara has completed the necessary pre-clinical safety and efficacy testing of GaRP required to commence human clinical studies. Now that HREC approval of the protocol has been received, we are able to immediately undertake site initiation procedures a prerequisite for patient recruitment which is planned for March 2021.

This randomised, double-blind, placebo-controlled study will be conducted in two stages as a virtual study using ObvioHealth Australia's ClaimIt platform. This involves minimal on-site visits and participants completing most assessments online. Up to 6 sites will be established by Sonic Clinical Trials and approximately 200 participants enrolled. GenesisCare Clinical CRO will provide medical advisory and medical monitoring services whereas Microba will provide microbiome testing using shotgun metagenomic sequencing and proprietary bioinformatics.

The study design 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. Human ethics approval is another milestone for Anatara and clinicians and patients seeking effective remedies to address IBS. Anatara's GaRP has demonstrated that it has the potential to manage the devastating symptoms experienced by IBD and IBS patients, by addressing processes that contribute to the pathophysiology of these chronic bowel conditions."

Anatara Lifesciences Limited
Registered Office
Level 3, 62 Lygon Street, Carlton South, VIC, 3053, Australia
Administration and R&D
343 Royal Parade, Parkville, Melbourne, VIC 3052, Australia
Email info@anatara.com | Website anataralifesciences.com

For more information please contact:

General inquiries	
Steven Lydeamore CEO, Anatara Lifesciences Ltd +61 (0) 438 027 172 slydeamore@anatara.com	Sue MacLeman Chair, Anatara Lifesciences Ltd +61 (0) 437 211 200 smacleman@anatara.com

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.

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 population[2] while IBD affects an estimated five million people globally.[3]

Current pharmaceutical treatments have high failure rates and severe side-effects, leading to over 50% of IBS[4] and IBD[5] 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.[6,7]

[1] Sperber et. al. Gastroenterology 2020; 1–16 .
[2] Clinical Gastroenterology and Hepatology 2012: 10, 712-721.
[3] Crohn's and Colitis Australia.
[4] Grundmann O & Yoon S (2014) World J. Gastroenterol 20 (2). p.346.
[5] Lovell R & Ford A (2012) Clin. Gastroenterol. Hepatol. 10. p.712
[6] Mintel's 2018 Digestive Health U.S., July 2019.
[7] 2018 category insight Report: follow your gut-a global look at Digestive Health Products.