

Anatara Lifesciences progressing towards first human clinical studies

Key highlights

- **Anatara anticipates launching Gastrointestinal Re-Programming (GaRP) trial recruitment website within the next two weeks**
- **Anatara anticipates commencing subject screening for enrolment in targeted delivery formulation (3FDC) Clinical Trial, assessing Psychological Functioning, in August**
- **Active program in place to progress commercialisation over the coming 6 to 12 months, including pursuing a potential partnership agreement**

MELBOURNE, 31 May 2021: Anatara Lifesciences (ASX: ANR), a developer of *evidence based* solutions for gastrointestinal diseases in humans and animals is pleased to provide this update on clinical trial activities.

Commenting on progress made towards the human clinical studies, CEO Steve Lydeamore said, “We are pleased to report on the progress made towards two separate human trials for our Gastrointestinal complementary medicines GaRP and 3FDC. Having recently completed the necessary pre-clinical safety and efficacy testing required to commence human trials and gained ethics approval, we are excited to be imminently commencing recruitment activities.

“We have completed the design of our trial recruitment website for the GaRP trial ahead of enrolments. We have also made progress towards our Psychological Functioning clinical trial with 3FDC, where the CSIRO team will develop work guidelines prior to initiating recruitment, which we anticipate occurring from August 2021.”

Irritable Bowel Syndrome (IBS) Trial Recruitment website to launch in June

Anatara has strong pre-clinical data to support GaRP use in IBS, the most commonly diagnosed gastrointestinal condition and a significant cost burden on health care. In February, Anatara announced that it had received Human Research Ethics Committee approval to undertake a clinical trial of GaRP for participants with irritable bowel syndrome – diarrhoea subtype (IBS-D), having completed the required pre-clinical safety and efficacy testing.

The Company now anticipates launching the trial recruitment website and screening of subjects for enrolment in the trial within the next two weeks. Recruitment for phase one of this trial is anticipated to be completed in December 2021 following which a futility analysis will be undertaken to determine which dose of GaRP will progress in phase two of this trial.

Psychological Functioning Trial recruitment to commence in August

In April, Anataara advised that it had received Human Research Ethics Committee approval to undertake a clinical trial on the effects of 3FDC dietary supplementation on psychological functioning in an adult population, in collaboration with CSIRO.

3FDC is one of the components of Anataara's GaRP dietary supplement that exerts its effects due to absorption characteristics and influence on the microbiome in the large intestine. The gut-brain axis balance is considered important for depression, anxiety and stress symptoms in otherwise healthy individuals. The components of 3FDC and the delivery coating target the complex physiology of these considerations by ensuring the components are able to influence the important and relevant section of the GIT (gastrointestinal tract or 'gut').

The CSIRO team will develop the work guidelines and initiate recruitment with the aim of dosing the first participants in the third quarter of calendar year 2021. Anataara anticipates commencing screening of subjects in August 2021.

"More than ever, the world is looking for safe and effective solutions to gut health. The progress that Anataara has achieved in developing *evidence based* solutions for GIT is very encouraging. The human trials are the key next step to moving closer to commercialisation, and entering the US\$8+ billion gastrointestinal supplements and over-the-counter digestive remedies market¹."

"We have a very active program in place over the coming 6 to 12 months to progress the commercialisation of our health products, including pursuing a potential partnership agreement. We remain very encouraged about Anataara's future prospects", added Mr Lydeamore.

For more information please contact:

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About Anataara Lifesciences Ltd

Anataara Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based products for gastrointestinal health where there is significant unmet need. Anataara is a life sciences company with expertise in developing products for human and animal health. Anataara 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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¹ Mintel's 2018 Digestive Health U.S. – July, 16; Nutrition Business Journal (NBJ)

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