



Anatara Lifesciences Update on GaRP- Irritable Bowel Syndrome trial

Preliminary data readout of Anatara’s GaRP - Irritable Bowel Syndrome (IBS) trial supports continuation.

- **Statistical analysis of the first 31 “Intent-to-Treat” (ITT) participants has encouraged Anatara to progress Stage 1 and consider preparations for Stage 2 of the GaRP-IBS trial.**
- **Following the successful implementation of the revised protocol for the GaRP-IBS trial, recruitment for Stage 1 was finalised in May with expectation of greater than 70 Stage 1 ITT patients by completion.**
- **Interim analysis anticipated late Q3 CY2023.**

ADELAIDE, 6th June 2023: Anatara Lifesciences (ASX:ANR or “the Company”), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to provide an update on the Gastrointestinal ReProgramming (GaRP) trial for IBS (Irritable Bowel Syndrome).

GaRP – Irritable Bowel Syndrome (IBS) - Trial Update

The Company is pleased to advise that, following the statistical analysis of the cohort of the initial 31 ITT participants in the GaRP-IBS trial, the Company is encouraged to proceed with the ongoing trial and planning for Stage 2. The DSMB (Data Safety Monitoring Board) have reviewed the preliminary data and were satisfied the continuation of the current trial protocol was supported, noting the small data set. There were no safety concerns across the participant groups.

Executive Chair of Anatara, Dr. David Brookes commented:” *While the Company emphasises that these are very limited numbers, we take reassurance from this preliminary analysis of the available data in continuing the GaRP-IBS trial. Continuation of the trial following this analysis is a crucial step towards the Company’s goal of establishing a non-prescription, licensed product for the maintenance and restoration of the gastrointestinal tract lining and homeostasis of the microbiome. There is a need for such a product both as an adjunctive mainstream treatment and one that can be readily available for the many sufferers of gut disorders and non-specific symptoms. The next review point is the formal interim analysis on the completion by all participants of Stage 1 and is expected in a few months.*

The trial has been quite disjointed due to the Covid dynamics initially and then the need for changes to the protocol inclusion/exclusion criteria through the appropriate processes. This led to a group of participants with finalised locked data at a time when enrolments and randomisation to product are

still occurring in the trial. It seemed prudent to consider the progress of the study given the protracted recruitment and the availability of data. Following advice from external statisticians and in consultation with the DSMB, a preliminary analysis has been done that will contribute to and be continued with the full interim analysis at the conclusion of Stage 1, at which time Anantara expects statistical detail to be available.

The good safety and tolerance profile was anticipated given the GaRP formula is based on the combination and specialised coating of GRAS (FDA “Generally Recognised as Safe”) ingredients that are not associated with serious side-effects such as toxicity or bleeding mechanisms. “

The trial recruitment momentum slowed after the processing of the previous backlog that occurred during the process of ethic committee reviews of modifications to inclusion/exclusion criteria and subsequent site administrative considerations to these amendments. The decision was made to curtail recruitment in late May 2023 as the forecast rate of further enrolments was too disjointed for the overall trial management. The total of enrolled participants now anticipated to complete Stage 1 is approximately 70.

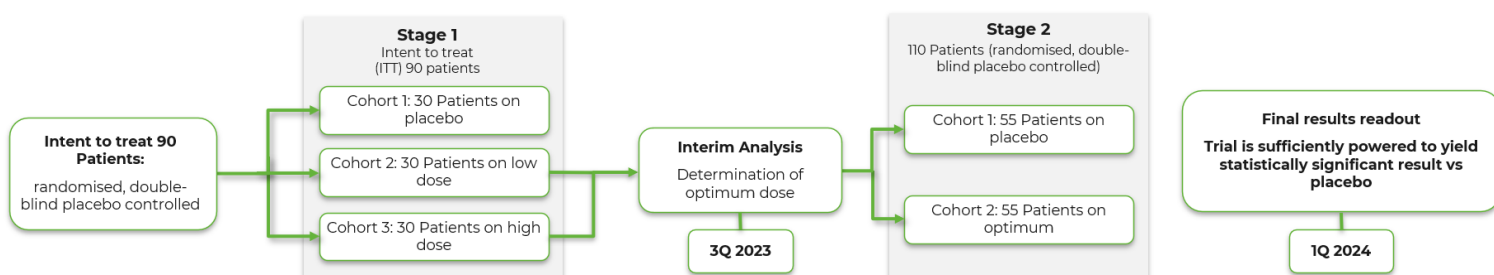
The Company takes this opportunity to again thank the participants and trial sites involved in the GaRP-IBS trial.

The Company anticipates a significant R&D tax rebate in Q3 CY 2023 with the trial funded beyond the interim analysis.

The GaRP IBS trial is powered to deliver results that will validate support claims. If successful, the high prevalence of digestive disorders requiring relief from both symptoms and the disease process, including irritable bowel syndrome (IBS), present a significant market opportunity for Anantara.

The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the US.¹

GaRP-IBS Clinical Trial Design



¹ <https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market>

Ongoing corporate initiatives

In preparation for the GaRP interim trial results, Anataara is engaging with global pharma companies interested in expanding their portfolio of complementary medicines. The trial is garnering interest from global leaders in gastrointestinal health due to the strong evidence-based design of the GaRP trial and the potential for use of the product in a number of other indications, such as inflammatory bowel disease.

The Company continues to actively assess other opportunities in the healthcare space and maintains a vision of championing evidence-based solutions for unmet health needs.

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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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