

ASX Release

Anatara Lifesciences recruitment proceeding well for Stage 2 of its Pivotal Phase II Irritable Bowel Syndrome (IBS) Clinical Trial

Highlights

- Recruitment is proceeding well for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial at the 5 sites situated in Melbourne, Sydney and Brisbane.
- High levels of interest are being shown at all 5 sites with a number of participants having already been randomised into the trial.
- Given the unmet need for an effective treatment for IBS, Anatara anticipates strong interest in the ongoing trial of the effectiveness of the Company's patent protected product, known as "GaRP" (*Gastrointestinal ReProgramming*).
- Stage 2 of the GaRP-IBS trial is the planned extension that follows the successful completion of Stage 1 of the Phase II trial involving 61 patients with a reported greater than a 50% reduction in IBS symptoms and with safety profile confirmed.
- Anatara has continuing engagement with global pharma companies regarding its GaRP program.
- Appraisal of other opportunities for the Company in healthcare is ongoing.

ADELAIDE, 13th June 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to report that recruitment for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial is proceeding well and is on time and on budget.

There have been high levels of interest shown at all 5 sites situated in Melbourne, Sydney and Brisbane with a total of over 500 Expressions of Interest (EoI) to date. Following the trial protocol screening processes, consistent with Stage 1 of the trial, enrolments have already begun with 13 participants currently randomised. This is in line with Company expectations following a slight administrative delay at some of the new trial sites.

The target participant number is 60-100 for Stage 2 of the Trial and the Company anticipates this target number will be met in Q3 CY2024 with Headline Results readout anticipated Q4 CY2024, in line with previous guidance.

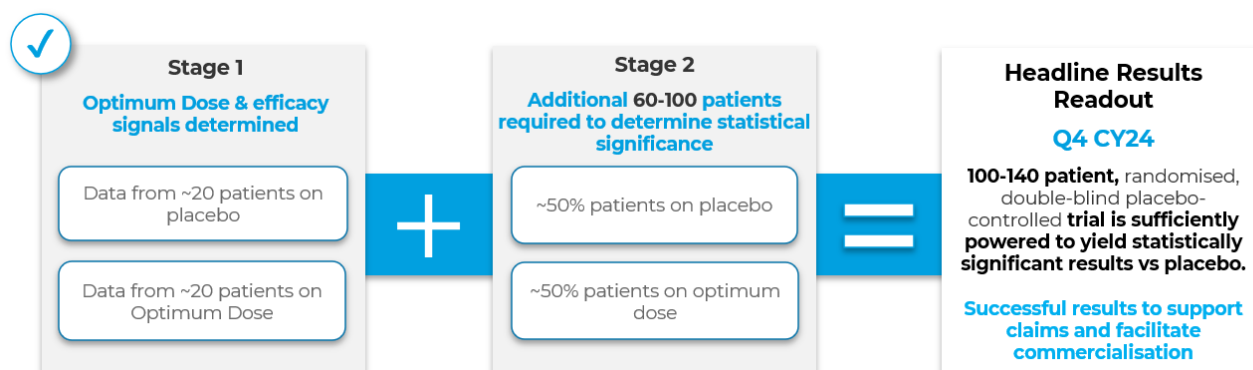


Potential participants can find the closest site to register their interest in Stage 2 of the clinical trial via the Company's website: <https://anataralifesciences.com/garp-clinical-trial/>

Participants will be randomised into one of two arms in the trial in a 1:1 ratio and receive either the optimum dose of the GaRP product selected from Stage 1 or placebo for 8 weeks plus 2 week follow-up.

Stage 2 aims to confirm the highly encouraging and clinically meaningful interim results from Stage 1 of the GaRP-IBS clinical trial. The data from Stage 1 and the 60-100 Stage 2 patients in the randomised, placebo controlled, double blind trial will form the basis of the analysis. This will result in approximately 100-140 patients in total. The trial is sufficiently powered to deliver statistically significant results versus placebo.

GaRP-IBS Clinical Trial Design



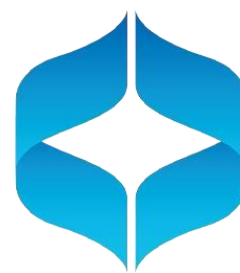
Ongoing corporate initiatives

The results to-date have signalled a promising new era in the quest to alleviate the burdens of IBS and related disorders. Confirmation of these results will provide the desired evidence-based claim to distinguish GaRP as an IBS treatment and a more valuable foundation to engage with global pharma companies interested in expanding their portfolio of complementary medicines. Discussions remain ongoing with potential partners interested in delivering a new, safe and effective treatment for IBS into a highly unsatisfied market.

Additionally, the Company continues to actively assess other opportunities in the human healthcare space and is appraising projects suitable to add to the Company's portfolio. There are also ongoing discussions for potential uses of Anatara's established products and know-how for animal health.

About GaRP

Anatara's GaRP product is a multi-component, multi-coated complementary medicine designed to address underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD. GaRP is the working name for the product from the Company's **Gastrointestinal ReProgramming** project that was designed to assist restoration and maintenance of the gastrointestinal tract (GIT) lining as a barrier and assist the homeostasis of the microbiome. The product is made of GRAS (Generally Regarded As Safe) components.



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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 human and animal 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.

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