

ASX Release

GaRP-IBS (Irritable Bowel Syndrome) clinical trial update

Highlights

- Recruitment continues to proceed well for Stage 2 of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial with 36 participants enrolled and with current final screening of approximately 20 potential participants.
- 2 additional trial sites were activated in late September in the new geographical areas of Adelaide and the Sunshine Coast of Queensland. The sites are the South Australian Health & Medical Research Institute (SAHMRI) located in Adelaide's CBD and Coastal Digestive Health Research Institute (CDHRI) located in Maroochydore on the Sunshine Coast.
- Expressions of interest are strong at the new sites, while high levels of activity continue at existing sites at the Royal Melbourne Hospital and Oztrials in Sydney, and with recruitment now prioritised to 4 sites overall.
- Headline Results readout anticipated late Q1 CY2025.

ADELAIDE, 8th October 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to report on the expansion of recruitment for the Stage 2 of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial to two new geographical locations and on the overall trial progress.

The Company's focus is on completing the recruitment for Stage 2 in Q4 CY2024 and, as previously advised on 30th August 2024, has added two additional locations to broaden participation reach. Recruitment has been underway since late last month (September) in Adelaide at SAHMRI located on North Terrace in the city's health precinct and on Queensland's Sunshine Coast at the CDHRI, which is a specialist centre focused on gastrointestinal health issues. This extends the trial reach by providing access to participation in new locations, which has been done to ensure the momentum of the trial continues through to target recruitment levels that allow statistical analysis. Strong interest continues across the existing sites situated at the Royal Melbourne Hospital and Oztrials in Drummoyne (Sydney) and there seems a similar level of community interest around the sites in Adelaide and Maroochydore, with participants already in screening at both new sites.

Anatara's Executive Chair Dr. David Brookes had previously commented in the ASX release on 30th August 2024 *"The additional trials sites provide the opportunity for IBS sufferers in further geographical locations to participate and will bolster enrolment to ensure adequate numbers through Stage 2 in the required time frame. We were encouraged by the eagerness of these new sites to be involved in the trial of our GaRP product as potentially an emerging treatment for a difficult medical condition and also by their empathy for the participants, given the GaRP-*

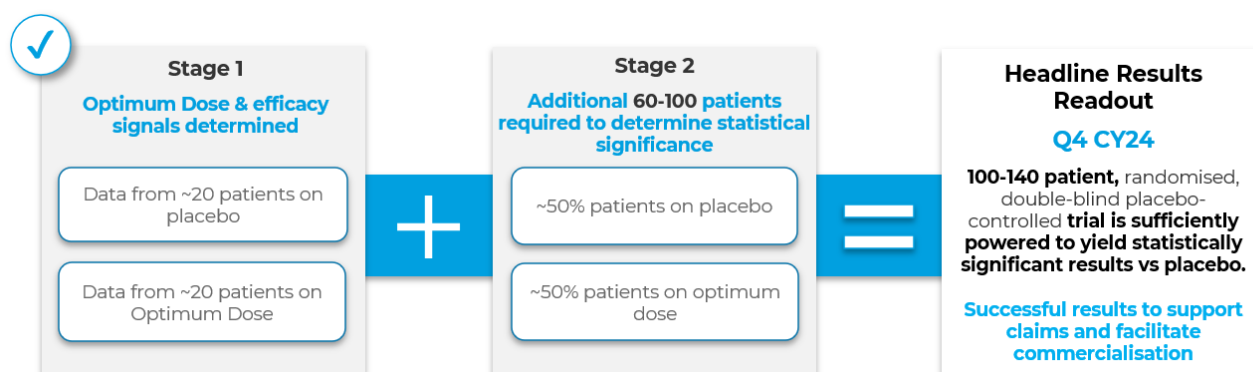


IBS trial criteria includes only moderate to moderately-severe sufferers by international classification in the IBS sub-types D (diarrhoeal predominate) and M (mixed). On behalf of the Company and the investigators and staff of the trial sites, we again take the opportunity to thank the participants and all those who expressed interest to be involved but did not meet the criteria to be enrolled."

Following the trial protocol screening processes that are consistent with Stage 1 of the trial, enrolments had reached 36 participants in Stage 2 of the trial at the end of last week, some of whom have completed the treatment phase. A further group of approximately 20 participants are currently in final screening to determine suitability to enter the trial and a much larger group of potential participants, identified as potentially eligible from the initial questionnaires, are being followed up to determine suitability to be offered enrolment screening.

The target participant number is 60-100 for Stage 2 of the GaRP-IBS trial as per the design.

GaRP-IBS Clinical Trial Design



With the additional measures taken the Company anticipates that recruitment will be completed in Q4 CY2024 with the Headline Results readout in 1Q CY2025, which stretches the timeline from the previous guidance of a results readout in late in 4Q CY2024. The process of establishing the usual administrative and ethical requirements for the new sites meant activation took place later in September than anticipated.

To ensure ongoing overall trial efficiencies, the focus on recruitment has been prioritised to the 2 new sites and the 2 existing sites that are clearly demonstrating ongoing momentum in the enrolment process. This leaves 4 sites recruiting across the Eastern mainland states and Adelaide, SA.

Potential participants can find the closest site to register their interest in Stage 2 of the IBS clinical trial at ibstrial.au or via the Company's website anataralifesciences.com with the landing page currently showing the trial details including the location links to register interest.

Participants are 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 of the trial or the placebo, for 8 weeks plus a 2-week follow-up.



Stage 2 in the trial design is 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 100-140 patients in total. The trial is sufficiently powered to deliver statistically significant results versus placebo.

Large Unmet Need for an effective IBS Treatment

GaRP has the potential to be a disease-modifying treatment that aims to positively impact a substantial proportion of the population that suffer from the debilitating symptoms of digestive disorders, including irritable bowel syndrome (IBS). Due to the mechanism of action, GaRP is expected to be applicable to a wide range of indications in gastrointestinal health beyond IBS.

The lack of efficacious digestive treatments underscores the clear unmet need and the significant market opportunity for Anatara. The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the US.¹

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 **G**astrointestinal **R**e**P**rogramming 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 health products where there is significant unmet need. Anatara is focused on building a pipeline of human health products with a particular focus on conditions that involve the complexity of the gastrointestinal tract. Underlying this product development program is our commitment to delivering real outcomes for patients and strong value for our shareholders.

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



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