

ASX Release

GaRP-IBS (Irritable Bowel Syndrome) clinical trial update

Highlights

- **Recruitment continues to progress pleasingly for Stage 2 of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial with enrolled participants now totalling approximately 60 and with more than 25 high potential participants in final screening.**
- **Enrolled participants and ongoing screening numbers have the trial moving beyond the minimum anticipated requirement for Stage 2, hence recruitment is to be paused from 13 December 2024.**
- **Headline Results readout anticipated in Q1 CY2025.**

ADELAIDE, 4th December 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to update the progress of recruitment for Stage 2 of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial.

The Company's focus has been on completing the recruitment for Stage 2 in Q4 CY2024, as previously advised. The recent steady recruitment momentum has participant level at the anticipated minimum requirement from the trial design of Stage 2. The trial sites will continue to process participants in screening with no new enrolments to occur beyond the week ending the 13th of December .

The Company is extremely appreciative of the effort across the trial sites and to the many participants involved in the screening processes. Anatara has continued to support all four sites via the Company's website and with social media promotions in the push to ensure numbers through to the target recruitment levels that allow statistical analysis. The minimum target participant number for Stage 2 is 60 and, while the upper limit of the trial design is 100, the Company anticipates that recruitment will be able to be ceased towards the mid-range of the designed 60 to 100 participants in Stage 2.

Anatara's Executive Chair Dr. David Brookes commented: *" Progress has continued at a satisfactory rate and the Company is extremely pleased to progress towards and beyond the minimum number of 60 participants sought for Stage 2. We intend to pause recruitment at the end of next week and will decide about any need for resumption early in the New Year . This only leaves a short window of days for any new participants to be involved in the screening process. I really encourage any IBS sufferers considering involvement, and who meet the criteria sub-types of IBS-Diarrhoeal predominant or IBS-Mixed pattern, to submit their expression of interest within the next few days otherwise any opportunity for recruitment may have lapsed. It is simply a matter of going to the*

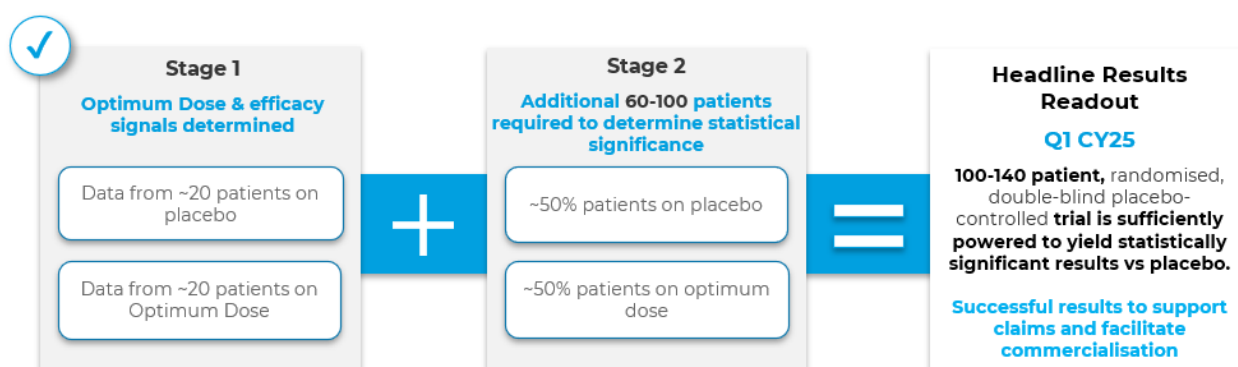


Anatara website or by using ibstrial.au to find the link to the clinic in their geographical zone to register an interest. From there, the next step is an online questionnaire before deciding on consent and a clinic visit. The trial of our GaRP product as potentially an emerging treatment for a difficult medical condition is a significant commitment and we appreciate the contribution of the participants to selflessly consider and comply with the trial conditions.

On behalf of the Company, the investigators and staff of the trial sites, I again take the opportunity to thank all those who have expressed interest to be involved including those that 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 59 participants yesterday in Stage 2 of the trial, many of whom have completed the treatment phase. A further group of more than 25 participants are currently in final screening to determine suitability to enter the trial. The larger group of potential participants, identifiable as potentially eligible from the initial questionnaires, may now not be offered enrolment screening until further notice as the recruitment process pauses from the 13th of December 2024.

GaRP-IBS Clinical Trial Design



To ensure ongoing overall trial efficiencies, the focus on recruitment has been prioritised to 4 sites recruiting across the Eastern mainland states and Adelaide, SA. The other 3 sites are no longer involved in recruitment and continue to process enrolled participants per usual.

With the additional measures taken the Company anticipates that recruitment will be completed in Q4 CY2024 as outlined, with the Headline Results readout later in 1Q CY2025.

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



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.

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