

ASX Release

GaRP-IBS (Irritable Bowel Syndrome) clinical trial update

Highlights

- **Recruitment pause confirmed from today following pleasing enrolments beyond the anticipated minimum target for Stage 2 of Anatara's pivotal GaRP-IBS trial.**
- **Enrolled participants and ongoing screening numbers for finalisation next week have the trial participant number moving toward the middle of the suggested range for Stage 2.**
- **Guidance for likelihood of pivotal readout of Headline Results confirmed as March 2025.**
- **SPP (Share Purchase Plan) for eligible shareholders closes Wednesday 18th December 2024 at 5.00PM (AEDT).**

ADELAIDE, 13th December 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to provide a further update on 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 and, as previously advised, the intent was to pause recruitment from the 13th of December 2024 as enrolment numbers appear adequate and exceed the anticipated minimum requirement from the trial design of Stage 2. The trial sites will continue to process a group of more than 10 potential participants, already in the most advanced phase of screening, for enrolment and randomisation during the next week only. Following that, the trial sites will be monitoring and supporting all active participants in the usual manner.

The Company is extremely appreciative of the effort across the trial sites and to the many participants involved in the screening processes. The Company had previously advised that recruitment may be halted towards the mid-range of the trial design for participant numbers, being a minimum of 60 and up to a maximum of 100 for Stage 2. Following the trial protocol screening processes that are consistent with Stage 1 of the trial, enrolments had reached 63 participants yesterday in Stage 2 of the trial and, of those, over 30 participants have already completed the treatment phase. A further group of more than 10 potential participants are currently in final screening to determine suitability to enter the trial next week.

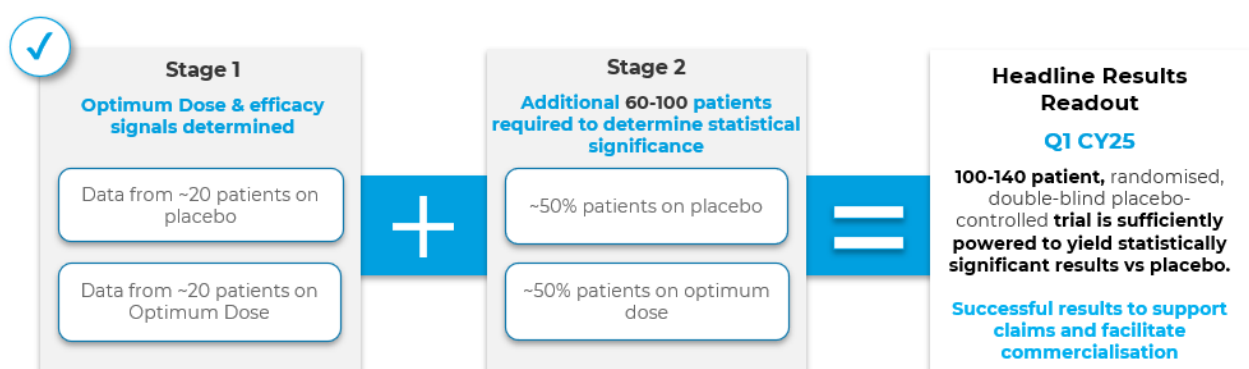


Other potential participants have been advised that currently screening cannot be offered as the recruitment process is paused from the 13th of December 2024. The Company will review the overall progress of the trial early in the New Year and confirm the status of the recruitment pause with consideration of an official halt at that time. It is likely, and preferred, that recruitment will not recommence which means the trial will progress to analysis in March 2025, following completion by all the enrolled participants.

Anatara announced a placement and an SPP on the 15th of November 2024. Eligible shareholders on the 14th of November can purchase shares at 0.05 cents in amounts from a minimum of \$2,000 to a maximum \$30,000 to support the Company with no fees or transaction costs. Please refer to the Shareholder letter and SPP Booklet released on the 27th of November 2024 for full details. This offer to shareholders closes at 5PM AEDT on Wednesday the 18th of December 2024.

As stated previously, the funds raised from the Placement and the SPP will be used to finish the pivotal Phase II clinical study of Anatara's GaRP (Gastrointestinal ReProgramming) complementary medication for irritable bowel syndrome (IBS) and to further readiness for manufacturing. There will also be approximately \$250,000 allocated to an anti-obesity proof of concept project. The anti-obesity project has been designed to develop an oral medication to assist weight reduction and sustaining weight control in conjunction with other contemporary treatments and approaches.

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 has been completed in Q4 CY2024 as outlined, with the Headline Results readout later in 1Q CY2025.

Those interested as potential participants should recruitment not be halted, or for future reference, can find 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.

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



This announcement was authorised for release by Anatara Lifesciences Ltd Executive Chair, Dr. David Brookes, with Board approval.

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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.

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