

ASX Release

Phase II GaRP-IBS (Irritable Bowel Syndrome) trial nearing completion of Stage 2 & Anti-Obesity Project ethics approval

Highlights

- The remaining participants in GaRP-IBS (Irritable Bowel Syndrome) clinical trial are now completing the follow up period with Headline analysis expected in March 2025
- Trial participant numbers are in line with Company expectations with final patient number considerations to be assessed in analysis. The trial will remain in “pause” status at least until the initial analysis following Stage 2 has been assessed and partnering discussions progressed.
- Ethics approval has been received for the “Anti-Obesity Project” *in-vivo* proof-of-concept pre-clinical studies.

ADELAIDE, 20 February 2025: Anatara Lifesciences (ASX: ANR or “the Company”), a developer of evidence-based, innovative products to address significant unmet need in human health, with a particular focus on conditions that involve the complexity of the gastrointestinal tract (GIT), is pleased to provide an update on the Company’s GaRP-IBS trial and the anti-obesity project.

The recruitment for the GaRP-IBS trial has been paused since mid-December 2024 and those last enrolled and participating have now entered the mandatory final 2 week follow up period after being randomised to receive either placebo or the GaRP product. This is consistent with previous guidance and the usual processes of data lock through to analysis will ensue in coming weeks leading to the analysis of Headline endpoints in March.

On the 14th January in the Quarterly Activities Report, the Company announced the Stage 2 enrolment number in the GaRP-IBS trial being confirmed as 71 Intent-To-Treat participants. The trial participant numbers are in line with Company expectations and the usual activities to finalise Stage 2 are occurring at the trial sites. Trial recruitment remains paused and the Company will decide on any change to that status based on the initial analysis of Headline endpoints following Stage 2 and feedback from those with corporate interest.

Stage 2 of the GaRP-IBS trial is the planned extension of the Phase II trial that follows the successful completion of Stage 1 which reported on 61 patients with a greater than a 50% reduction in IBS symptoms and with safety profile confirmed. The target participant number was 60-100 for Stage 2 of the trial with 71 now confirmed as participating, and the Headline Results analysis is expected in



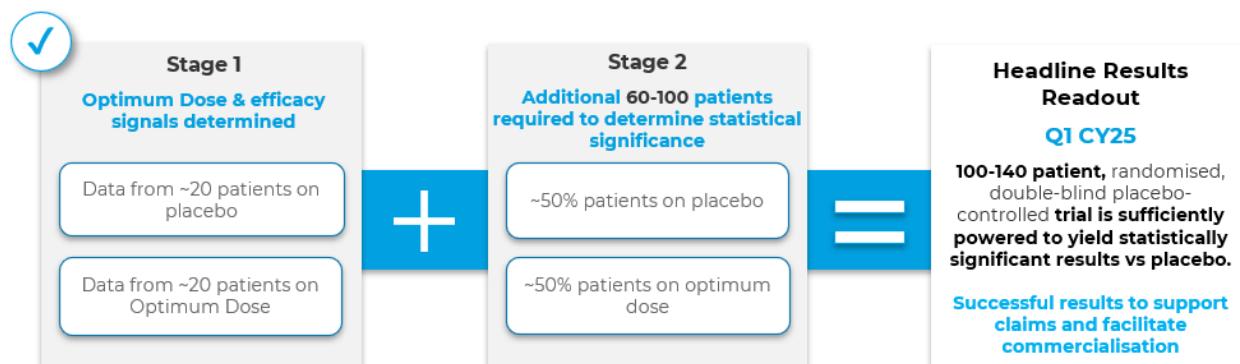
March 2025. Stage 2 aims to confirm the highly encouraging and clinically meaningful interim results from Stage 1 of the GaRP-IBS clinical trial.

The data from both Stages of the trial will form the basis of the final analysis. The sub-groups of participants from Stage 1 on either the placebo or the selected product dose are included with eligible participants from Stage 2 for the final analysis, which will result in a total of over 100. The trial was designed to be sufficiently powered to deliver statistically significant results versus placebo, and final patient number considerations are currently being assessed. (*Please see further detail on the Trial Design and GaRP below*)

Progress of Anti-Obesity Project

The planned *in-vivo* pre-clinical experiments have been approved following ethics submission and these studies are anticipated to take approximately 6 months through to completion. 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. The Company has allocated more than \$250,000 to proof-of-concept studies for the anti-obesity project.

GaRP-IBS Clinical Trial Design



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 IBS treatments underscores the clear unmet need for a health product that assists both the GIT lining as a barrier and the homeostasis of the microbiome. The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the USA.¹

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



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 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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