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 30 participants enrolled and approximately 20 potential participants currently in final screening to determine suitability for enrolment.**
- **2 additional sites are being added in new geographical areas of Adelaide and the Sunshine Coast. The sites will be disclosed after the ethics approval process is completed and are anticipated to commence recruitment in early September.**
- **High levels of interest are still being shown at existing sites in Melbourne, Sydney and Brisbane with satisfactory numbers of potentially eligible candidates identified for consideration into the formal enrolment process.**
- **Headline Results readout anticipated late Q4 CY2024.**

ADELAIDE, 30 August 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. The Company remains focused on completing Stage 2 in Q4 CY2024 and has added two additional sites with recruitment expected to open in Adelaide and on Queensland's Sunshine Coast in September. This extends the reach of the trial by providing access to participation in new locations and has been done to ensure the momentum of the trial continues through to target recruitment. Strong interest is being shown across sites situated in Melbourne, Sydney and Brisbane with over 1,400 Expressions of Interest (EoI) to date, with the expectation of a similar level of community interest around the new sites in Adelaide and Queensland.

Anatara's Executive Chair Dr. David Brookes commented "*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 have reached 30 participants in Stage 2 of the trial, 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.

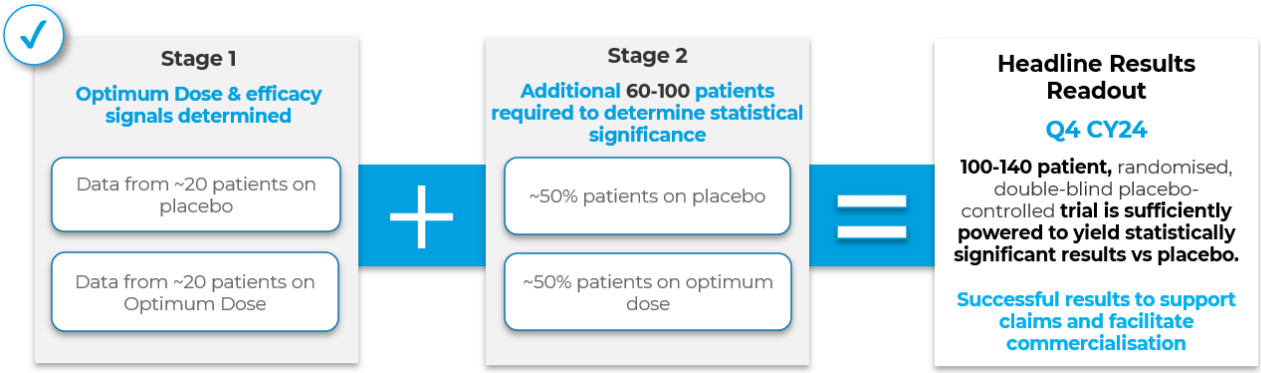
The target participant number is 60-100 for Stage 2 of the Trial. With the additional measures taken the Company still anticipates a Headline Results readout late Q4 CY2024, in line with previous guidance.

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 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.

GaRP-IBS Clinical Trial Design



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 **Ga**strointestinal **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 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.

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