ASX Release

Phase II GaRP-IBS (Irritable Bowel Syndrome) trial Stage 2 in datalock that precedes result analysis & Anti-Obesity Project mice studies to commence

Highlights

- **Stage 2 of Anatara's GaRP-IBS (Irritable Bowel Syndrome) Phase II trial has moved into the database lock process following all participants having completed the mandatory 2 week follow up period. Headline results analysis anticipated this month (March)**
- **Following an in-depth assessment of participant numbers for both compliance and entry criteria, the final fully assessable number of participants has been reduced from 71 to 62. The trial will remain in "pause" status at least until the initial analysis of Stage 2 has been reviewed and any partnering discussions progressed.**
- **The Company's expectation and guidance, from a preliminary review of non-finalised data of Stage 2, is that the primary efficacy endpoint for IBS-SSS reduction versus placebo is unlikely to be met. There remain no safety concerns and a number of secondary endpoints will be included in the headline result analysis.**
- **Workflow contracts for the GLP-1 agonism focused "Anti-Obesity Project" *in-vivo* proof-of-concept pre-clinical mice studies have been commenced following the previously announced ethics approval.**

ADELAIDE, 10 March 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), provides 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 all participants have completed the mandatory 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 now occurs leading to the announcement of headline results later in March. The endpoints will include the primary endpoints of IBS-SSS ("SSS" being Severity Scoring System) reduction and safety (adverse events) and a number of secondary endpoints including Adequate Relief, Anxiety and Quality of Life.

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 (ITT) participants. The trial participant numbers remain in line with Company expectations even after determining the fully assessable data set of 62 participants following the removal of those not meeting minimal compliance requirements and those with an unacceptably low IBS-SSS at baseline.

The Company's guidance from the preliminary analysis is that the primary endpoint, a statistically significant improvement (meaning reduction) in IBS-SSS when compared to placebo, is unlikely to be achieved. The secondary endpoint of >20% improvement in IBS-SSS from baseline appears highly likely to be achieved.

Anatara's Executive Chair commented : " The Company is obviously extremely disappointed that the preliminary analysis we have reviewed has left little doubt that the statistically significant primary efficacy endpoint that had been our focus from Stage 2 will not be achieved. The final headline results with some secondary endpoints that are expected later in the month will still be of interest , especially as the IBS-SSS is a subjective measure and the trial has the expected high placebo response. Anatara will be endeavouring to maximise the value of the GaRP project, while progressing our exciting anti-obesity concept work."

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 20 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 62 now confirmed as fully assessable participants 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 which created partnering interest.

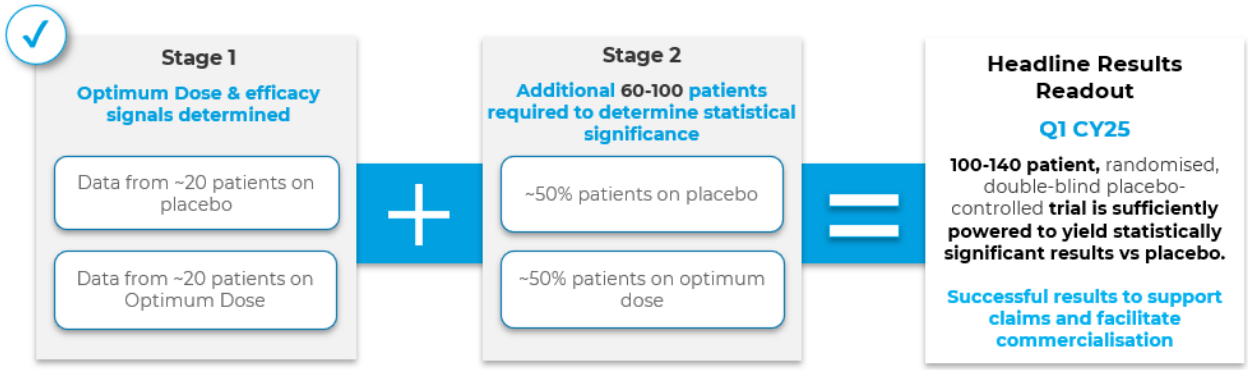
The data from both Stages of the trial will form the basis of the final analysis. The sub-groups of participants from Stage 1 are included with eligible participants from Stage 2 for the final analysis, which will result in a total of approximately 100 participants. The trial was designed to be sufficiently 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 that have been approved following ethics submission are now underway following agreements with the University of Newcastle, who will conduct the studies. The studies are anticipated to take approximately 6-9 months through to completion, depending on the extent to which weight control is sustained in the animal model.
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. Specifically, the product is being developed with the target of assisting the maintenance of weight loss and limiting rebound weight gain following cessation of contemporary weight loss

medications. While the Company needs to protect the project at this early stage, the mechanism of action involves the stimulation of endogenous GLP-1. The Company will assess several compounds of interest (that have been sourced/manufactured) in the pre-clinical studies to determine the best candidate/s going forward. The Company has allocated more than $250,000 to proof-of-concept studies for the anti-obesity project.

GaRP-IBS Clinical Trial Design



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 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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