ASX Release

Anatara Lifesciences to commence recruitment for Stage 2 of its Pivotal Phase II Irritable Bowel Syndrome (IBS) Clinical Trial

Highlights

- **Phase II GaRP-IBS (Irritable Bowel Syndrome) trial will begin recruiting at 5 sites situated in Melbourne, Sydney and Brisbane in March.**
- **Stage 2 of the IBS trial of GaRP is an extension of the positive Stage 1 Clinical Trial of 61 patients whereby patients safely reported a 50% reduction in IBS symptoms.**
- **Stage 2 of the GaRP-IBS Phase II trial for final clinical validation will involve 60-100 patients, in a randomised, placebo controlled, double blind clinical trial:**
  - **Patients will be randomised into two groups and given the optimum dose from Stage 1 or the Placebo.**
  - **Trial data includes the placebo and optimum dose patients from Stage 1, increasing total patients to 100-140.**
- **Continuation of appraisal of other opportunities for the Company in healthcare.**

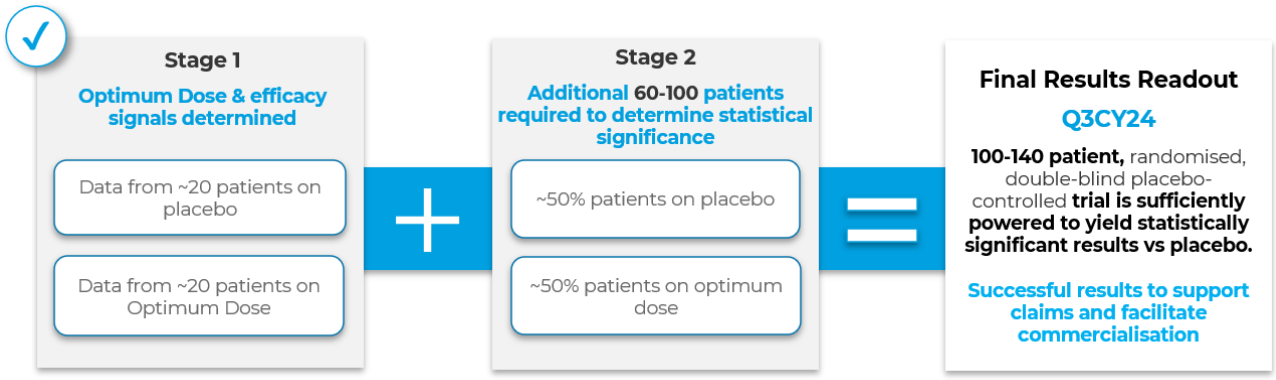
ADELAIDE, 29 February 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans and animals, is pleased to confirm that Stage 2 of the Company's Phase II GaRP-IBS trial will begin recruiting at 5 sites situated in Melbourne, Sydney and Brisbane, Australia in March following final ethics approval of protocols.

This follows the announcements in late 2023 (ASX: 28 September 2023 & 17 October 2023) of the highly encouraging and clinically meaningful findings from Stage 1 of its GaRP Irritable Bowel Syndrome (IBS) clinical trial. The interim analysis following Stage 1 successfully met all endpoints and signalled a promising new era in the quest to alleviate the burdens of IBS and related disorders.

Five sites in three capital cities onboard

The RMH (Royal Melbourne Hospital) remains an important trial site in the GaRP-IBS trial and is joined by the AusTrials site at Sunshine as the second Melbourne trial location. AusTrials will have 3 sites involved in Stage 2, with their other sites involved in this trial being St Leonards in Sydney and Wellers Hill in Brisbane. The fifth site for the GaRP-IBS trial is an additional Sydney site to be run by OzTrials in Drummoyne.

GaRP-IBS Clinical Trial Design



Bowel Syndrome (IBS) - Phase II Trial Update

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.

The Company announced in October 2023 a positive analysis of the secondary endpoints of Quality of Life (QoL) and the Hospital Anxiety and depression Score (HADS). The improvement of the QoL scores was anticipated to reflect the trend of improvement in the primary endpoint of IBS-SSS (IBS-Severity Scoring System) announced in September 2023. Analysis of improvement in HADS revealed highly significant improvement in anxiety and depression scores on Low Dose ($p < 0.05$, the actual being <0.001) for the overall treatment. The Company considered this a remarkable result while cautioning on the low numbers involved to this stage of the trial.

Stage 2 of the trial is to confirm/establish statistical significance for primary and secondary endpoints through greater numbers.

Phase II Clinical Trial Stage 2 – Overview

The 5 trial sites for Stage 2 expect to begin recruitment of patients in early March. Anatara and some of the trial sites have received considerable interest from IBS sufferers wishing to participate in Stage 2, which gives the Company confidence that recruitment will be enhanced by the interest generated from Stage 1 of the trial.

In total 60-100 additional participants are expected to be recruited for Stage 2. These participants will be randomised and blinded into two groups to receive either the optimal dose chosen from Stage 1 or the placebo. Approximately 40 patients from Stage 1 Cohorts 1 & 2 will be added to the 60-100 new Stage 2 patients bringing the total number for the GaRP-IBS trial to 100-140. The Company's statistician will refine the final numbers in due course with the expectation that this participant

number range will be able to yield a positive p-value for the primary endpoint of a reduction in the IBS-SSS, especially in light of the Stage 1 success.

The analysis of these GaRP-IBS trial Stage 1 primary and secondary endpoints furthers a belief that GaRP as a complementary medicine with rejuvenating gastrointestinal tract (GIT) effects will provide relief for sufferers of non-specific GIT symptoms and be an important adjunctive therapy in mainstream medical indications, such as IBS and IBD (Inflammatory Bowel Disease. Furthermore, the Company is very encouraged that the results support the method of action (MOA) for GaRP as a product designed with the potential to improve quality of life for patients with gastrointestinal disorders by influencing the complexities of the gut-brain axis through restoration and maintenance of the integrity of the GIT lining and assisting the homeostasis of the microbiome.

The Company previously announced, on the 28th of September 2023, the interim futility statistical analysis of Stage 1 of the GaRP-IBS trial had been reviewed by the DSMB (Data Safety Monitoring Board) on 27 September 2023 and concluded that Stage 1 successfully met the study objectives of confirming safety and the optimum dose for the single dose expanded Stage 2 of the trial, with a preliminary indication of meaningful efficacy. The data from 61 participants over 3 arms (placebo, low and high dose) strongly supported continuing the trial using the Low Dose. There were no concerning safety signals and the DSMB were satisfied that continuation of the current trial protocol was supported. The Low Dose was actually the predicted dose from Anatara's pre-clinical work in the GaRP project. Not surprisingly, the High Dose arm also delivered a significant reduction in the primary endpoint and met safety criteria, with the statistician commenting at the interim analysis that both the "Low" and "High" dose cohorts met criteria for ongoing trial activity.

Ongoing corporate initiatives

Following the GaRP interim trial results, Anatara continues to engage with global pharma companies interested in expanding their portfolio of complementary medicines. The trial is garnering interest from global leaders in the gastroenterology field due to the strong evidence-based design of the GaRP trial.

The Company continues to actively assess other opportunities in the human healthcare space and is appraising projects suitable to add to the Company's portfolio. There are also ongoing discussions for potential uses of Anatara's established products and know-how for animal health indications.

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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.