ASX Release

Irritable Bowel Syndrome (IBS) clinical trial Stage 1 patients finalised

Highlights

- **The Stage 1 patient group has been finalised in the GaRP Irritable Bowel Syndrome (IBS) trial with all participants having completed dosing.**
- **Stage 1 of the GaRP-IBS Phase I/II Trial consisted of 3 cohorts (Placebo, Low Dose & High Dose) in a randomised, double blind, placebo-controlled study.**
- **Interim results from approximately 70 Stage 1 patients are expected to be released in late September 2023.**
- **No safety concerns across the participant groups, in line with the Company's expectations.**
- **Statistical analysis of the first 31 ITT participants in early June encouraged Anatara to continue with the completion of Stage 1 and consider preparations for Stage 2 of the GaRP-IBS trial.**
- **The primary endpoint of the GaRP-IBS Trial is a clinically meaningful reduction in the internationally recognised IBS-SSS (Irritable Bowel Severity Scoring System) and secondary endpoints include improvements in quality of life, anxiety and depression as well as pain.**
- **The Company anticipates strong commercial interest, in the event of interim results success, given the clear unmet need for non-prescription products to relieve and modify gastrointestinal disorders such as IBS.**

MELBOURNE, 31 August 2023: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans and animals, is pleased to provide an update on the Gastrointestinal ReProgramming (GaRP) trial for IBS.

GaRP – Irritable Bowel Syndrome (IBS) – Last Patient Dosed

Anatara's GaRP product is a multi-component, coated complementary medicine designed to address underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD. The product is made of GRAS (Generally Regarded As Safe) components and is designed to assist restoration and maintenance of the gastrointestinal tract (GIT) lining and the homeostasis of the microbiome.

As announced on the 6th June, 2023, a preliminary statistical analysis of the cohort of the initial 31 patients in the GaRP-IBS trial was conducted. The DSMB (Data Safety Monitoring Board) reviewed the preliminary data and were satisfied that the continuation of the current trial protocol was supported, noting the small data set. Importantly, there were no safety concerns across the participant groups.

This feedback encouraged the Company to proceed with the ongoing Stage 1 of the trial and commence planning for Stage 2.

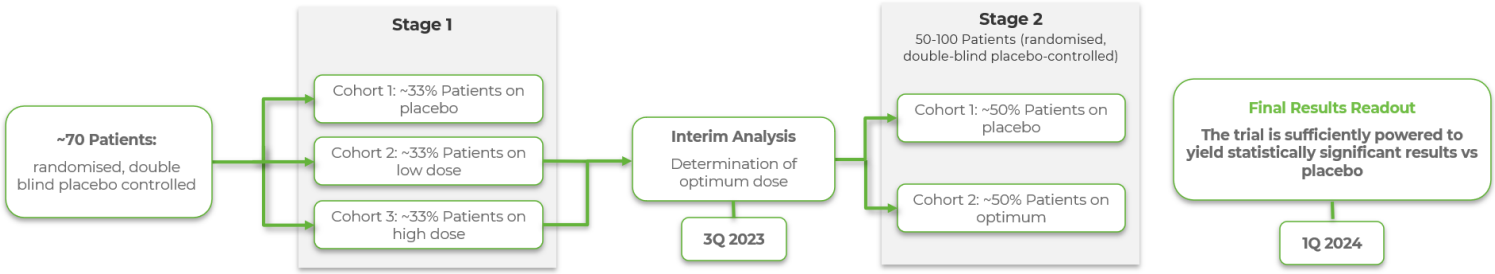
Recruitment for Stage 1 was finalised in June with approximately 70 patients from the more than 2,700 applicants screened for enrolment. The GaRP-IBS trial is powered to deliver results that will validate and support efficacy claims.

The trial enrolled males and females 18-65 years of age with irritable bowel syndrome (IBS-SSS score of 175-350) for 12 weeks within which the patients were dosed orally twice daily for 8 weeks.

The trial has been designed to return, if successful, a clinically meaningful and statistically significant result, with primary endpoints of a reduction in the IBS-SSS (Irritable Bowel Severity Scoring System) and safety. Secondary endpoints include quality of life, anxiety and depression and pain improvements.

Anatara's executive Chair, Dr David Brookes commented that "*The Company is very pleased to have reached the analysis step following the protracted circumstances completing Stage 1. The trial was more challenging than anticipated for many reasons and highlighted the difficulties that sufferers of IBS deal with from day to day. The trial design will deliver an evidence-based result and the criteria excluded "milder" IBS sufferers (IBS-SSS<175) which meant all participants were IBS patients with significant symptoms to manage and cope with, yet they accepted the challenge of potentially being randomised to a placebo. I take this opportunity on behalf of the Company to thank all those who were involved in the trial process.*"

GaRP-IBS Clinical Trial Design



Key endpoints

Primary Endpoints	Secondary endpoints
• Change in IBS-Severity Scoring System (IBS-SSS) between test and placebo groups compared to baseline • Treatment-Related Adverse Events	• IBS Adequate Relief (IBS-AR) compared to baseline • Hospital Anxiety and Depression (HAD) Scale comparing to baseline • Change in IBS quality of life (IBS QoL) points compared to baseline • Safety markers
Exploratory Endpoints	
• Plasma levels of specific inflammatory markers • Use of rescue medication across the study group	• Alterations in gut microbiota with respect diversity and balance; correlation to IBS symptoms including overall wellness

GaRP presents itself as a potential disease-modifying treatment that aims to positively impact a large proportion of the population that suffer from the debilitating symptoms of digestive disorders, including irritable bowel syndrome (IBS). The lack of efficacious digestive treatments amplifies 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]

Ongoing corporate initiatives

In preparation for the GaRP interim trial results, Anatara is engaging with global pharma companies interested in expanding their portfolio of complementary medicines. The trial is garnering interest from global leaders in the GI 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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[1] *https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market*

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.

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