# **ASX** Release



# Anatara Lifesciences Update

# **Highlights**

- Revised protocol for Irritable Bowel Syndrome (IBS) trial of "GaRP" 200 patient trial successfully implemented and enrolment on track.
- Recruitment for Stage 1 is expected to be complete in early 2Q 2023 with approximately 50 out of 90 Stage 1 patients having now been enrolled.
- Trial is on budget with interim read-out of results anticipated early Q3 CY2023.
- Licence agreement executed with specialty junior private healthcare company,
   Mucpharm Pty Ltd, to licence technology from Anatara for use in specific fields of interest, particularly mucin producing cancers and biofilms.
- The Mucpharm agreement has potential to provide Anatara with royalties on sales and sub-licensing.

MELBOURNE, 10 March 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) - Trial Update

The Company is pleased to advise that the trial momentum and enrolment is now essentially consistent with the previous guidance after the anticipated and managed delay to recruitment and randomisation from mid-December over the Festive Season. This was somewhat protracted by further slight delays due to resolution of administrative matters at trial sites that followed from the ethics approval of the new modified protocol. Recruitment was only minimally impacted by the administrative delays and the Company is very pleased to advise that enrolment and randomisation onto product and placebo began again last week with 9 new participants subsequently in the enrolment and randomisation steps. The total of enrolled participants will now be approximately 50, influenced by an anticipated variable withdrawal rate. As per previous advice, we note there have been no significant tolerance or safety issues to date and that, with respect to the withdrawal consideration, one-third of participants are randomised to placebo.

The new "GaRP" trial criteria for IBS (Irritable Bowel Syndrome excluding only the constipation subset) and the focus on addressing screen failure inconsistencies that became apparent has led to increased interest in participation and a higher enrolment rate. From the recruiting process that resumed immediately after the Festive season break, there is a significant number of prospective participants readied for the enrolment process and the recent momentum is anticipated to be ongoing through to completion of Stage 1 recruitment.



Apart from modifying the GaRP trial criteria, the Company engaged the ProPharma Group to act as the principal clinical research organisation towards the end of CY2022. Effectively Anatara has installed a new team and internal supervisory process for the ongoing trial. The current recruitment rate and reinforcement will likely result in the interim analysis becoming available in early 3Q CY2023 when 90 participants remaining involved is reached, slightly later than previously indicated. The recruitment for Stage 1 is expected to be complete in early 2Q2023. Importantly the budget has not been significantly impacted by this time variation.

The Company takes this opportunity to thank the trial sites for the adjustments required and to confirm that the Royal Melbourne Hospital (RMH) resumed recruitment for the GaRP-IBS trial under the new protocol after final review by their ethics committee and administrators. Further participants are being enrolled to add to the 6 already contributed by the RMH under the previous protocol. The Adelaide CSIRO site has been closed for the GaRP-IBS trial. This is not anticipated to alter the guidance on the timing to interim analysis. The Company is actively engaged in seeking an appropriate site in South Australia for the GaRP-IBS trial Stage 2 for the geographical convenience of potential participants. As previously announced, the closure of the CSIRO 3FDC trial was finalised in November 2022, without any safety concerns.

The GaRP IBS trial is powered to deliver results that will validate support claims. If successful, the high prevalence of digestive disorders requiring relief from both symptoms and the disease process, including irritable bowel syndrome (IBS), present a significant market opportunity for Anatara. The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the US.<sup>1</sup>

#### **GaRP-IBS Clinical Trial Design**



### **Mucpharm Pty Ltd licence agreement**

Mucpharm have licenced technology from Anatara's portfolio for use in specific fields of interest, particularly mucin producing cancers and biofilms. The agreement provides Anatara with royalties on sales and sub-licencing.

Mucpharm is a specialised company focused on the treatment of mucin-containing and secreting conditions. It is developing the novel use of "BromAc", a combination of bromelain and acetylcysteine, in specific fields including cystic tumours.

 $<sup>^{1}\</sup> https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market$ 

#### **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 is also actively assessing other opportunities in the healthcare space.

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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.

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