



## Anatara Lifesciences clinical trials update

MELBOURNE, 31 March 2022: Anatara Lifesciences (ASX: ANR or “the Company” ), a developer of evidence-based solutions for gastrointestinal diseases is pleased to provide an update on progress of clinical trials in psychological functioning and irritable bowel syndrome, diarrhoea subtype (IBS-D).

- **Continuing recruitment for two human clinical trials with ethics approval**
  - **GaRP in Irritable Bowel Syndrome – diarrhoea subtype (IBS-D)**
    - **Trial sites: Paratus Clinical Research (Brisbane, Canberra, Central Coast NSW, Western Sydney); CSIRO Nutrition and Health Research Clinic (Adelaide)**
    - **Anticipated results: Interim August 2022; Final January 2023**
  - **3FDC in psychological functioning (anxiety, depression, stress)**
    - **Trial site: CSIRO Nutrition and Health Research Clinic (Adelaide)**
    - **Anticipated results: Final late 2022**
- **Exploring opportunities to bring forward anticipated dates for results**
  - **Further expansion of eligibility criteria for both trials**
  - **Anticipated addition of Melbourne site for IBS-D trial in May 2022**

### Human clinical trials for IBS-D (GaRP) and psychological functioning (3FDC)

Globally there is a high prevalence of digestive disorders requiring relief from both symptoms and the disease process, including irritable bowel syndrome (IBS). There is also increasing interest in the “gut-brain” axis and the influences of the microbiome. The GaRP complementary medicine provides a significant market opportunity to address these considerations whilst improving individuals’ quality of life.

### **Commenting on outlook, CEO Steve Lydeamore said:**

“We are pleased to confirm that interest in participating in both trials has been very high and the Company is working with the usual regulatory authorities to allow broadening of eligibility to enhance enrolment. We report no change to anticipated dates for results and continue to take actions to deliver the reporting dates for these trials and remain optimistic about the potential outcomes of these trials. The commercial opportunity for non-prescription gastrointestinal disorders and IBS is US\$8 billion in the US<sup>2</sup>, whilst the non-prescription mood and mental health category is a substantial opportunity with annual growth of 30% in the US<sup>3</sup>.”

“Our exploration of additional opportunities to broaden our gastrointestinal health pipeline has yielded a number of attractive opportunities, which are presently under evaluation.”

“We look forward to progressing these human clinical trials and progressing opportunities to broaden our gastrointestinal health pipeline, while continuing to advance commercialisation discussions for both our human and animal gut health portfolio,” concluded Mr. Lydeamore.



“GaRP” is the working name for Anatarata’s evidence-based complementary medicine that includes unique formulations of bromelain, an enzyme extracted from pineapple stems, along with other synergistic GRAS<sup>1</sup> components. The combination and coating of these GaRP components have a beneficial effect on the physiology of the gastrointestinal lining, a positive influence on the microbiome (homeostasis & metabolites) and allow absorption of beneficial components in targeted areas of the gastrointestinal tract.

“3FDC” is the Company’s working reference to specific components from the overall GaRP product. The 3FDC components are coated for targeted release predominately beyond the small intestine to allow delivery and influence in the large intestine. The 3FDC components are anticipated to have direct and indirect effects including assisting the homeostasis of a healthy microbiome. The delivery of these components and the microbiome influences are considered important for gut-brain axis balance, hence the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

1. Generally Recognised As Safe – US FDA designation that a substance is considered safe for use in food

2. Mintel’s 2018 Digestive Health U.S. – July, 16

3. NBJ Nutrition Business Journal Feb 22, M.Juntti, A.Wong, Stressed and Sleepless. Page 11-14

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### About Anatarata Lifesciences Ltd

Anatarata Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based products for gastrointestinal health where there is significant unmet need. Anatarata is a life sciences company with expertise in developing products for human and animal health. Anatarata 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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