

Anatara Lifesciences – 3FDC Clinical Trial update

- The psychological functioning study being conducted by the CSIRO using 3FDC components of the GaRP (“Gastrointestinal Reprogramming” coated multicomponent complementary medicine) has been halted
- Anatara was the sponsor for the CSIRO trial supported by grant funding to assess 3FDC effect on mild to moderate levels of depression, anxiety or stress related symptoms in participants without a gastrointestinal disorder
- During a review of all aspects of Anatara’s clinical trials, it became apparent that the sample size required to detect a signal in this 3FDC study may be higher than initially proposed. This reinforced the focus on GaRP as a total complementary medicine for gastrointestinal disorders and related considerations such as the relationship to the gut-brain axis.
- No concerns around safety or tolerance with 3FDC components have been detected
- GaRP – Irritable Bowel Syndrome (IBS) 200 patient clinical trial remains the Company’s priority with interim results expected Q1CY2023. 3FDC is contained within the total GaRP formulation and psychological functioning is being assessed in the GaRP -IBS trial

MELBOURNE, 3 October 2022: Anatara Lifesciences (ASX: ANR or “the Company”), a developer of evidence-based solutions for gastrointestinal diseases in humans and animals, is provides an important operational update regarding the psychological functioning study being conducted by the CSIRO using 3FDC.

3FDC - Psychological functioning trial

The psychological functioning study being conducted by the CSIRO using 3FDC was in the process of recruiting ~100 patients with mild to moderate levels of depression, anxiety, or stress symptoms indicated by the Depression, Anxiety and Stress Scale (DASS-21).

During review of all Anatara clinical trials, it became apparent that the sample size required to detect a signal in this study may be higher than initially proposed to reach a reliable outcome. Whilst it is common for anxiety and depression trials to have high placebo responses, the Board of Anatara have elected to halt the study on the balance of outcome probability rather than considering a commitment to significant future costs.

Importantly, there were no concerns around safety or tolerance with 3FDC components to date and none are anticipated. The GaRP complementary medicine includes a subset of 3 components formulated for release in the lower large intestinal tract which have been labelled “3FDC”.

Whilst there remains a strong rationale regarding the influence on the “gut-brain” axis and the homeostasis of the microbiome, Anatara remains focused on the GaRP Irritable Bowel Syndrome (IBS) 200 patient clinical trial which the Company continues to prioritise, striving to achieve interim results by Q1CY2023. In line with the Company’s vision, the IBS trial delivers on our strategic imperative to develop and commercialise innovative, evidence-based products for gastrointestinal health.

In addition, the Hospital Anxiety and Depression Scale (HADS) and Quality of Life (QOL) assessments within the questionnaire of the GaRP clinical trial will allow for preliminary analyses of the influence of the total GaRP components, in participants with gastrointestinal symptoms, on depression and anxiety.

GaRP potentially has broad indications for use in conditions requiring a product to restore and maintain both the gastrointestinal tract lining and function, and the homeostasis of the microbiome. The GaRP-IBS trial data is anticipated to provide insight regarding the relationship of anxiety and depressive symptoms with gut disorders (which is in keeping with the general interest in the gut-brain axis) and provide preliminary information about progressing the use of the full GaRP complementary medicine, including the 3FDC components, for the indication of mild depression and/or anxiety in the future.

For more information please contact:

Dr. David Brookes

Chair, Anatara Lifesciences Ltd

+61 (0) 411 712 579

dbrookes@anatara.com

Dirk van Dissel

Candour Advisory – Investor Relations

+61 (0) 408 326 367

dirk@candouradvisory.com.au

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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Anatara Lifesciences Limited

Registered Office

Level 3, 62 Lygon Street, Carlton South, VIC, 3053, Australia

Administration and R&D

Suite 101, 55 Flemington Rd, North Melbourne, VIC 3051, Australia

Email info@anatara.com | Website anatarylifesciences.com

