ASX Release

Anatara Lifesciences provides clinical trials update

MELBOURNE, 16 December 2021: Anatara Lifesciences (ASX: ANR), a developer of evidence based solutions for gastrointestinal diseases in humans and animals, provides an update on progress of clinical trials in psychological functioning and irritable bowel syndrome, diarrhoea subtype (IBS-D).

On 16 November at the AGM, Anatara anticipated commencing recruitment for the psychological functioning trial by the end of November and interim results for the IBS-D trial in April 2022.

Commenting on progress made towards the human clinical studies, CEO Steve Lydeamore said, "We are about a month behind where we expected to be with both trials. While we always anticipated a pause in recruiting over the Christmas break, as well as the potential impact of diet and lifestyle during that period, investigational product was not received from India in time to commence recruitment for the psychological functioning trial prior to Christmas. We now anticipate commencing recruitment for that trial to be in mid-January 2022".

"We are taking actions to recover trial participants in the IBS-D trial. Potential trial participants were excluded as their IBS Symptom Severity Scores (IBS-SSS) were marginally higher than the trial inclusion criteria. In the field of IBS clinical research severity is identified using the IBS-SSS questionnaire. For moderate sufferers the cut off score is below 300. In our screening we have identified a sizeable cohort with scores of 300-350 who have been excluded to date. Anatara applied for and received ethics approval to modify the criteria which has now expanded the pool of potential patients".

Anatara is adding an additional site in Adelaide for the IBS-D trial which will target recruitment of up to 50 participants and has engaged Evrima, a specialist in patient identification and recruitment. Evrima will support Anatara's IBS-D trial by both direct-to-patient and direct-to-clinician channels. Direct-to-patient will increase community awareness via social media, digital marketing campaigns and radio advertising. Direct-to-clinician will generate awareness within the GP community, as well as through the use of their proprietary software to identify potentially eligible patients via electronic health records in Australia.

3FDC trial in psychological functioning

3FDC is one of the components of Anatara's GaRP (Gastrointestinal reprogramming) complementary medicine. GaRP is a combination of two different minitablets, which is under investigation in another study focused on diarrhoea predominant Irritable bowel syndrome (IBS-D). The different minitablets in the formulation target different parts of the gastrointestinal tract. 3FDC is targeted to release at the junction between the small and large intestine (ileocecal junction) and exert its effects on the microbiome in the large intestine. Since restoration of a healthy microbiome is considered important for gut-brain axis balance, the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

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This randomised, double-blinded, placebo-controlled study into the effects of 3FDC in adults with moderate anxiety, stress or depression will be conducted at CSIRO's Nutrition and Health Research Clinic in Adelaide. Approximately 100 participants will be randomised in a 1:1 manner to treatment with 3FDC or placebo which is dosed twice a day for 6 weeks.

CEO Steve Lydeamore commented, "There is a major unmet need and significant market opportunity for an evidence-based complementary medicine for stress, anxiety and depression. According to Beyond Blue a quarter of Australians will experience an anxiety condition in their lifetime. I am excited that Anatara's 3FDC dietary supplement may be of benefit to some of the many who experience these conditions. It is gratifying that Anatara's focus on gut health and integrity has allowed us to capitalise on our research in IBS with the potential to address other microbiome centric conditions. The current study has the potential, not only to help those suffering mood disorders, but to significantly add to our understanding of GaRP in non-IBS participants. "

GaRP trial in IBS-D (irritable bowel syndrome)

This study consists of two stages (Stage 1, Stage 2), with an interim analysis between stages. Stage 1 will assess the safety, tolerability and efficacy of two different strengths of GaRP against placebo in a 1:1:1 randomisation protocol. Following interim analysis, one dose will be selected, and the remaining participants recruited in a 1:1 randomisation protocol. Of the 200 planned participants, at least 90 will enrol in stage 1, and 110 participants will enrol in stage 2. For each participant in each stage, the study will last for 12 weeks; including 8 weeks of treatment, preceded by a 2-week screening/baseline period and followed by a 2-week washout period. Measurements will include a number of surveys including the IBS specific surveys: IBS-SSS (severity scoring system), IBS QoL (quality of life) and IBS-AR (adequate relief) and Bristol Stool Form Scale.
CEO Steve Lydeamore commented, "There is a major unmet need and significant market opportunity for an evidence-based complementary medicine for IBS. Anatara's GaRP has demonstrated that it has the potential to manage the devastating symptoms experienced by IBD and IBS patients, by addressing processes that contribute to the pathophysiology of these chronic bowel conditions."

For more information please contact:

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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.