ASX Release

Anatara Lifesciences provides Clinical Trial and Operational update

- **Ethics approval to expand eligibility criteria for Irritable Bowel Syndrome (IBS) trial**
- **Ethics approval to expand eligibility criteria for psychological functioning trial on track for site initiation of Melbourne based site for IBS trial in late June**
- **Operational update**

MELBOURNE, 20 May 2022: 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 progress of clinical trials in psychological functioning and irritable bowel syndrome, diarrhoea subtype (IBS-D). The Company also provides a brief operational update.

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 and 3FDC complementary medicines provide a significant market opportunity to address these considerations whilst improving individuals' quality of life.

CEO Steve Lydeamore commented: "We are pleased that interest in participating in both trials has been very high however the screening failure rate has been significant due to strict eligibility criteria. On 31 March 2022, the Company advised that it was working with the usual regulatory authorities to allow broadening of eligibility to enhance enrolment.

We are pleased to report that the revised eligibility criteria have been approved by ethics committees for both trials. In addition, an ethics committee in Melbourne has approved the revised protocol for the IBS trial. This is an important first step to initiation of a respected Melbourne based trial site; anticipated to commence recruiting after the end of June.

The revised protocol for the IBS trial expands eligibility to all IBS subtypes other than IBS-C (constipation subtype). It required minor adjustments to the primary and secondary endpoints. With this change, we will be able to re-screen more than 300 potential participants who were unable to enrol due to not having diarrhoea predominant IBS. The changed protocol will be updated in the recruitment website and the Obvio Health ClaimIt online portal and mobile app by 27 June. The revised protocol for the psychological functioning expands eligibility to participants with scores in the moderate range on a minimum of one of the DASS[1]-21 subscales to also include participants with scores in the mild range on a minimum of two of the DASS-21 subscales.

We remain hopeful that there will be no significant change to the anticipated dates for the IBS results and continue to take actions to deliver the reporting dates for this trial. There is, however, a revised timeline for the psychological functioning (3FDC) study with reporting now anticipated in early 2023 rather than late 2022."

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The commercial opportunity for non-prescription gastrointestinal disorders and IBS is US$8 billion in the US[2], whilst the non-prescription mood and mental health category is a substantial opportunity with annual growth of 30% in the US[3].

Operational update

Anatara's chair, Dr. David Brookes added: "We continue to be buoyed by the interest from mainstream specialists in these trials and the potential for the broader use of the GaRP products for other indications in the fields of gastroenterology and paediatrics .The delays have been frustrating for all concerned including our shareholders and these should represent the final modifications. We look forward to the progression of the trials and the momentum that confirmation of safety and tolerance will bring to the Company, including the commercial opportunities.

I am delighted to advise that Mr. John Michailidis will join the Anatara team as an executive consultant in the role of the Chief Operations Officer (COO) from mid-June. John is an extremely experienced and respected leader in business transformation and commercialisation across pharmaceutical and technology companies. The transition and handover of roles is already well underway for the departure of the CEO in late June, at which time I will formally begin as executive chair as previously announced.

I will also take this opportunity to briefly update the animal health products. Essentially, there is commercial interest in the poultry product (ANR-pf) with Anatara collaborating with a leading producer to conduct confidential trials and there are ongoing discussions on the use of the BONIFF feed supplement for piglets as an alternative to using zinc oxide (plus commercial additives) with associated environmental and antimicrobial resistance concerns. While the focus is on our human health projects, we remain committed to endeavouring to realise value from the animal health assets."

Background information

"GaRP" is the working name for Anatara's evidence-based complementary medicine that includes unique formulations of bromelain, an enzyme extracted from pineapple stems, along with other synergistic GRAS[4] 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. The DASS is a quantitative measure of distress along the three axes of depression, anxiety[a] and stress[b]. It is not a categorical measure of clinical diagnoses; a. Symptoms of psychological arousal; b. The more cognitive, subjective symptoms of anxiety.
2. Mintel's 2018 Digestive Health U.S. – July
3. NBJ Nutrition Business Journal Feb 22, M.Juntti, A.Wong, Stressed and Sleepless. Page 11-14
4. Generally Recognised As Safe – US FDA designation that a substance is considered safe for use in food

Authorised by: The Board of Anatara Lifesciences Ltd.

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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.