

ASX Release

Australian patent granted for GaRP product

Highlights

- GaRP has been granted an Australian patent, expanding the intellectual property protection for the product with the title of invention being “Gastrointestinal Health Composition.”
- The granted patent is valid in Australia for 20 years from 9 October 2020. This follows a similar EU grant as announced 20th September 2024 and the usual patenting processes are ongoing in further jurisdictions.
- The Australian patent grant further consolidates the commercial proposition for the Company’s IP should the current GaRP-IBS trial confirm efficacy. Headline results from the pivotal GaRP-IBS trial are anticipated in March 2025.
- The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the US alone.¹

ADELAIDE, 28 January 2025: Anatara Lifesciences (ASX: ANR or “the Company”), a developer of evidence-based, innovative products to address significant unmet need in human health, with a particular focus on conditions that involve the complexity of the gastrointestinal tract (GIT), is pleased to report the Company has received certification of the grant of a standard patent on 23 January for the GaRP product under the invention title of “Gastrointestinal Health Composition”. The patent numbered 2020364192 was granted by the Commissioner of Patents for the Australian Patent Office and has a term of 20 years from 9 October 2020 (therefore the expiry date is 9 October 2040).

This follows a grant of a European patent from the European Patent Office (EPO) for the title and documents relating to its **Gastrointestinal ReProgramming** product (known as “GaRP”). That decision from the EPO took effect from the publication of the grant in the European Patent Bulletin 24/38 on the 18th September 2024.

Anatara’s Executive Chair Dr. David Brookes commented: *“This patent grant is further confirmation of the uniqueness of GaRP and consolidates the commercial proposition. The mechanism of action of GaRP is based on ingredients designed to restore and maintain the gastrointestinal tract lining and dynamics, using sophisticated coatings and combinations. This potentially has broad health indications and we look forward to the progress of our current Phase II GaRP-IBS trial in establishing efficacy data. A successful conclusion of the Irritable Bowel Syndrome (IBS) clinical trial is obviously a key consideration for market differentiation and commercialisation.”*

¹ <https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market>



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Patent prosecution is ongoing and advanced in many other jurisdictions and the Company will update on these when notified. Importantly, the EU application grant, as announced on 20th September 2024, extends to patent coverage in the United Kingdom and Hong Kong to further our exclusivity in key jurisdictions.

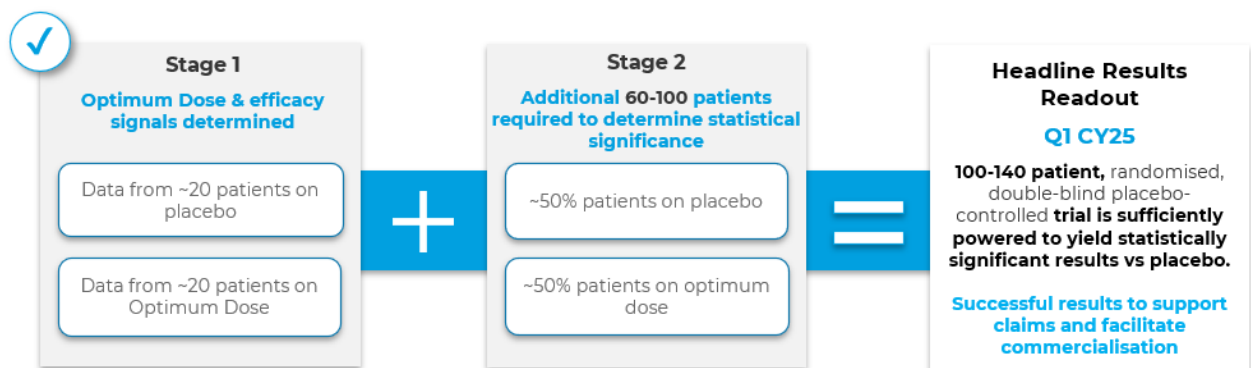
GaRP has the potential to be a disease-modifying treatment that aims to positively impact a substantial proportion of the population that suffer from the debilitating symptoms of digestive disorders, including irritable bowel syndrome (IBS). Due to the mechanism of action, GaRP is expected to be applicable to a wide range of indications in gastrointestinal health beyond IBS. The lack of efficacious IBS treatments underscores the clear unmet need for a health product that assists both the GIT lining as a barrier and the homeostasis of the microbiome. The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the USA.²

On the 14th January in the Quarterly Activities Report, the Company announced the Stage 2 enrolment number in the GaRP-IBS trial being confirmed as 71 Intent-To-Treat participants. The trial participant numbers are in line with Company expectations and the usual activities are ongoing at the trial sites. The final patient number considerations are currently being assessed, with recruitment remaining in “pause.”

Stage 2 of the GaRP-IBS trial is the planned extension of the Phase II trial that follows the successful completion of Stage 1 which reported on 61 patients with a greater than a 50% reduction in IBS symptoms and with safety profile confirmed. The target participant number was 60-100 for Stage 2 of the trial with 71 now confirmed as participating, and the Headline Results readout is anticipated in Q1 CY2025. Stage 2 aims to confirm the highly encouraging and clinically meaningful interim results from Stage 1 of the GaRP-IBS clinical trial.

The data from both Stages of the trial will form the basis of the final analysis. This will result in a total of over 100 trial participants. The trial is designed to be sufficiently powered to deliver statistically significant results versus placebo, and final patient number considerations are currently being assessed.

GaRP-IBS Clinical Trial Design



² <https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market>



About GaRP

Anatara's GaRP product is a multi-component, multi-coated complementary medicine designed to address underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD. GaRP is the working name for the product from the Company's **Gastrointestinal ReProgramming** project that was designed to assist restoration and maintenance of the gastrointestinal tract (GIT) lining as a barrier and assist the homeostasis of the microbiome. The product is made of GRAS (Generally Regarded As Safe) components.

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About Anatara Lifesciences Ltd

Anatara Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based health products where there is significant unmet need. Anatara is focused on building a pipeline of human health products with a particular focus on conditions that involve the complexity of the gastrointestinal tract. Underlying this product development program is our commitment to delivering real outcomes for patients and strong value for our shareholders.

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