**BiomeBank submits for market authorisation of world first microbial therapy**

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The company behind Australia’s first facility for the manufacturing of microbial therapies has set its sights on global impact, applying to the Therapeutic Goods Administration for approval of their world-first biologic drug product.

South Australian based biotechnology company BiomeBank has submitted for Market Authorisation of their product for the treatment of recurrent Clostridioides difficile (C-diff) and Ulcerative Colitis in a bid to meet unmet medical need across Asia Pacific.

The drug product is already used in Australia to treat C-diff through faecal microbiota transplantation (FMT) and has been positioned as an alternative to existing biologic therapies for Ulcerative Colitis.

BiomeBank CEO Mr Thomas Mitchell said it is believed this could be one of the first microbial therapies approved in the world, alongside companies such as Ferring Pharmaceuticals and Seres Therapeutics.

“We’re positioning BiomeBank as a global leader in microbial drug development with a GMP\* facility in South Australia, a first-generation microbial therapy now submitted for approval and a rapidly growing portfolio of second-generation products in the pipeline,” Mr Mitchell said.

“Official Market Authorisation of our existing product will enable more patients in Australia to access this as a treatment option and allow our company to extend into the Asia Pacific market, highlighting Australia’s capabilities in microbial drug discovery and development.

“While there are a number of likeminded companies across the globe working on discovering and developing similar products, we believe BiomeBank will be the first in the world to have an approved microbial therapy for these diseases.”

Mr Mitchell also noted that the product’s intended use has been positioned for recurrent *Clostridioides difficile* as well as mild to moderate Ulcerative Colitis, with the intention to bring the product to patients early in the treatment of their disease.

Amid its Series-A funding round, BiomeBank’s Chair Dr Stephen Rodda said the dossier submission was an important milestone for the company and its current and future investors.

“With microbial therapies set to transform the treatment of disease globally, BiomeBank is poised to become a leading biotechnology company and is truly positioning Australia as a global leader in drug discovery,” Dr Rodda said.

“Harnessing an innovative and collaborative mindset, our leadership team is concurrently establishing critical partnerships with prominent research institutes across the country such as RMIT University and the Hudson Institute, translating world-class microbiome research into a variety of treatment options for patients across the world.

“Backed by a dedicated and passionate team, BiomeBank is already exceeding on its 2021 milestones and fast attracting both local and international interest from investors in our Series A funding round.”

With a growing number of diseases linked to a loss of gut microbes, BiomeBank’s Chief Medical Officer and Co-Founder Dr Sam Costello explained that microbial therapies are being increasingly recognised as effective treatments across the globe.

“The approval of our GMP facility will enhance BiomeBank’s ability to provide these important therapies to patients in Australia and across Asia Pacific,” Dr Costello said.

“In addition to our existing syringe-based therapy, we are also developing capsule based-products that will allow improved patient access to our therapies.

“This is particularly relevant for the treatment of Ulcerative Colitis, where the LOTUS[[1]](#footnote-1) study has demonstrated promising results.”

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**About BiomeBank**

BiomeBank is a clinical stage biotechnology company developing a pipeline of live biotherapeutic products to treat unmet medical need. BiomeBank's mission is to treat and prevent disease by replenishing gut microbial ecology.

Backed by a world-leading team of translational microbiome experts, BiomeBank’s platform uses a unique combination of machine learning and microbiology to identify bacterial strains which influence disease, leading to the discovery and development of new therapies.

[www.biomebank.com](http://www.biomebank.com)

1. *https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377325* [↑](#footnote-ref-1)