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ASIA EDITION

Australia's BiomeBank to commercialize world-first microbial therapy across APAC

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BiomeBank will be the first in the world to have an approved microbial therapy for recurrent Clostridioides difficile (C-diff) and Ulcerative Colitis diseases

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, Australia's regulatory authority, 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 treatmentoption 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 like-minded 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 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. In addition to our existing syringe-based therapy, we are also developing capsule based-products that will allow improved patient access to our therapies." Dr Costello said.