

## ASX ANNOUNCEMENT

30 January 2025

### Positive Results on Clinical Development of BMB18

- Biome has received positive results of core functional characterisation studies of its strain BMB18
- The strain demonstrated an ability to effectively modulate immune responses and inflammation, reduce oxidative stress, and maintain intestinal barrier integrity.
- This report will be used to help inform future clinical research opportunities and potential health applications and targets for this strain.

Microbiome health company *Biome Australia Limited* (ASX: BIO) ('Biome' or 'the company') is pleased to provide an update on the strain development program, which was last updated on the 14th November 2024 following the successful completion of the initial phase of the program, including initial validation of the strain and transfer of the intellectual property to *Biome*.

*Biome* has now received the positive results of the core functional characterisation studies conducted by the cell culture lab of one of Biome's key research partners. These in vitro studies investigated several functional characteristics of Biome's *Lactobacillus plantarum* BMB18 using two types of cell cultures: Caco-2 cell assays (a model of the intestinal epithelial barrier) and peripheral blood mononuclear cells (PBMCs) (used to study the stimulation of immune responses).

The report's findings showcase this probiotic strain's functional potential, which demonstrated an ability to effectively modulate immune responses and inflammation, reduce oxidative stress, and maintain intestinal barrier integrity.

#### Clinical applications identified by the researchers

Importantly, this report will be used to help inform future clinical research opportunities and potential health applications and targets for this strain.

The researchers indicated various aspects of health which may be positively impacted by the identified functional characteristics.

It was suggested that the ability for BMB18 to reduce inflammation and enhance immune responses in these studies may provide benefit in conditions with immune dysregulation, such as chronic intestinal diseases or food intolerances.

It was also indicated that modulation of oxidative stress, which was demonstrated by BMB18, is a critical factor in conditions such as cardiovascular diseases, neurodegenerative disorders, and other chronic inflammatory diseases.

As this study also demonstrated that stimulation with BMB18 enhances epithelial barrier integrity and reduces permeability, an ability to counter dysfunctions seen in various intestinal disorders was also suggested by the researchers.

An overview of the study findings can be found on the following page in Appendix 1.

**Biome Australia's Managing Director and Founder, Blair Vega Norfolk commented:**

*"I am very pleased with this significant development and positive results in the BMB18 program. This new data provides Biome with critical insights into the functional characteristics and potential downstream applications for the novel strain. As Biome continues the development of BMB18, as a key component of Vision 27, there is a significant potential commercial pipeline for the strain for new product development and also broadening the use of existing products."*



## Appendix 1. Overview of study findings

### **Caco-2 cell culture studies**

The Caco-2 epithelial cell model was used to study the ability of BMB18 to repair and prevent intestinal tissue damage. Transepithelial electrical resistance (TEER) and fluorescein isothiocyanate (FITC)-dextran 4 (FD-4) assays were used to assess the influence of BMB18 on the integrity of tight junctions among intestinal epithelial cells and cellular permeability respectively. Indirect assessment of superoxide anion production was also performed by analysing reactive oxygen species (ROS) production after cellular damage.

BMB18 was found to improve barrier function by restoring membrane integrity and permeability in a statistically significant manner ( $p < 0.05$ ). BMB18 was also found to be capable of reducing oxygen free radical levels, thus demonstrating antioxidant activity ( $p < 0.05$ ) and an ability to modulate oxidative stress.

### **Peripheral blood mononuclear cell (PBMCs) culture study**

Quantitative PCR (qPCR) was used to analyze the expression of various inflammatory cytokines: interferon- $\gamma$  (IFN- $\gamma$ ) and tumour necrosis factor- $\alpha$  (TNF- $\alpha$ ) (representing the main cytokines with pro-inflammatory actions), and interleukin-10 (IL-10) and interleukin-4 (IL-4) (representing the main cytokines with immune-regulating actions) in response to the presence of BMB18.

BMB18 was found to induce statistically significant ( $p < 0.001$ ) cytokine modulation in PBMCs with and without an inflammatory stimulus. This probiotic strain can therefore act as an immune activator or, if there is an inflammatory stimulus, it can help to reduce the immune system's inflammatory response. These observations are in line with the understanding of certain strains of probiotics being able to modulate the immune system in different ways depending on the conditions.

-ENDS-

Approved for release by the Biome Australia board of directors.



## About Biome Australia Limited

Biome Australia develops, licences, commercialises and markets innovative, evidence-based live biotherapeutics (probiotics) and complementary medicines, many of which are supported by clinical research. Biome aims to improve health outcomes and quality of life, and make its products accessible to all.

Incorporated in Australia in 2018, Biome distributes locally and abroad. In partnership with some of the world's leading organisations in microbiome research and development, Biome produced several unique live biotherapeutic (probiotic) products with innovative delivery technologies that improve their stability and efficacy to create its flagship range of complementary medicines: Activated Probiotics®.

Supported by clinical research, including randomised double-blind placebo-controlled trials, Activated Probiotics help prevent and support the management of various health concerns, including low mood and sleep, bone health, iron malabsorption, mild eczema and IBS. Through practitioner-only distribution, Biome is committed to educating health professionals on the newfound systemic health effects of the gut microbiota, helping them to provide innovative, evidence-based natural medicines for the management of some of humanity's most prevalent and chronic health concerns.

For more information visit: [www.biomeaustralia.com](http://www.biomeaustralia.com)

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