ASX ANNOUNCEMENT

24 February 2022

Ethics approval received for Biome Daily Kids™ clinical trial; recruitment begins

- Ethics approval from the Federation University School of Health has been received for Biome's *Biome Daily Kids™* clinical trial
- The trial will be led by Dr Blake Peck and will immediately begin recruiting 192 children 2 – 5 years old
- Children will be dosed once per day and the trial will last six months
- Trial to assess the effect of *Biome Daily Kids™* probiotic on immune health and absenteeism from childcare centres

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Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to announce that it has received ethics approval at the Federation University School of Health to commence a clinical trial for its *Biome Daily Kids™* probiotic for paediatric immune health. Ethics approval was granted on 22nd February 2022.

Recruitment, which will be led by Dr Blake Peck at Federation University's School of Health, will now commence and a total of 192 children aged between 2 and 5 years old will be recruited.

Product	Ethics Approval	Recruitment and trial commence	Completion of recruitment	Preliminary results	Final results
PAEDIATRIC IMMUNE HEALTH Biome Kids Probiotic	✓	✓	**TBA**	**TBA**	**TBA**

✓ Complete Scheduled

The primary aim of the trial is to examine the influence of the use of *Biome Daily Kids™* probiotic on absenteeism and immune health among children aged 2-5 years attending childcare centres.

The 192 children will be dosed once per day over six months.

The study will be investigating:

- The duration of symptoms of common infections (gastrointestinal and respiratory infections etc)
- The number of children with different varieties of infectious diseases (gastrointestinal infections; respiratory infections; hand foot and mouth disease etc)
- Use of antibiotics or other medication related to infectious diseases
- Changes in mood and behaviour (secondary outcome)

Biome Daily Kids™ was developed to support children and their families by helping to reduce the transmission of respiratory and gastrointestinal infections, and the subsequent burden they place on families by reducing symptoms and severity.

The aim of this new trial is to strengthen the market positioning and the evidence of efficacy of *Biome Daily Kids™* probiotic in this important area of community health.

Biome Daily Kids™ launched in November 2019 and contributed $279,246 in revenue in FY21.

There is existing evidence of efficacy of a key probiotic ingredient in *Biome Daily Kids™* improving immune and gastrointestinal health; however, this new trial aims to assess the efficacy of the end *Biome Daily Kids™* product.

Positive results in this trial will enable Biome to strengthen and expand the health claims that can be made on its product and will increase the number of Biome's clinically proven live biotherapeutic products.

A key active probiotic ingredient in *Biome Daily Kids™* Probiotic has been previously widely tested and featured in a number of published peer reviewed research papers including three referenced below.



Biome Daily Kids™ Probiotic

To help reduce the occurrence and duration of common colds

Publication:
Gawrońska A, Dziechciarz P, Horvath A, Szajewska H. A randomized double-blind placebo-controlled trial of Lactobacillus GG for abdominal pain disorders in children. Aliment Pharmacol Ther. 2007;25(2):177–84

Publication:
Liu S, Hu P, Du X, Zhou T, Pei X. Lactobacillus rhamnosus GG supplementation for preventing respiratory infections in children: A Meta-analysis of Randomized, Placebo-controlled Trials. Indian Pediatr [Internet]. 2013 Apr 25;50(4):377–81, 3.

Publication:
Szajewska H, Canani RB, Guarino A, Hojsak I, Indrio F, Kolacek S, et al. Probiotics for the Prevention of Antibiotic-Associated Diarrhea in Children. J Pediatr Gastroenterol Nutr. 2016 Mar;62(3):495–506.

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Certified B Corporation

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Approved for release by the Biome Australia board of directors.

About Biome Australia Limited

Biome Australia develops, licenses, 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.

Biome also develops, licenses and distributes a scientifically formulated, organic nutraceutical range, Activated Nutrients® and a sports performance and recovery range, Activated X Performance®, which is made exclusively for professional athletes.

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