ASX Announcement
29 March 2023

Microba Receives Ethics Approval for Phase 1 Clinical Trial

- **Microba has received formal Human Research Ethics Committee (HREC) approval for its planned first in human clinical trial of Microba's novel drug candidate MAP 315**
- **The trial will be conducted at Nucleus Network in Melbourne as a Randomised, Double-Blind, Placebo-Controlled Study to evaluate the Safety, Tolerability and Pharmacokinetics of MAP 315 in healthy adults**
- **MAP 315 is a novel live biotherapeutic being developed for the treatment of Ulcerative Colitis and was discovered and developed using Microba's Data-Driven Therapeutics Platform**

Microba Life Sciences Limited (ASX: MAP) ("Microba" or the "Company") is pleased to announce that it has received formal Human Research Ethics Committee (HREC) approval for its upcoming Phase 1 clinical trial of novel drug candidate MAP 315. MAP 315 is a novel live biotherapeutic that has been discovered and developed for the treatment of ulcerative colitis, using Microba's data-driven Therapeutics Platform.

The planned Phase 1 clinical trial will involve 32 healthy participants and be conducted by Nucleus Network utilising their world class clinical trial facilities in Melbourne. Microba has appointed Beyond Drug Development as the contract research organisation to support the study. The clinical trial is structured as a randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of MAP 315 in healthy adults.

Professor Trent Munro, SVP of Therapeutics at Microba said: *"This is an important milestone as we take the next step in maturity for our therapeutic development activities here at Microba. Our ability to use human-data guided drug discovery sets us apart as a global leader in the microbiome sector. We are excited to move MAP 315 into the clinic as a novel therapeutic targeting a major unmet clinical need for Inflammatory Bowel Disease sufferers."*

Inflammatory Bowel Disease (IBD) – Large unmet need & commercial opportunity

IBD is a term for conditions that cause prolonged inflammation of the digestive tract and now affects more than 7 million people globally, with this number increasing each year[1]. Ulcerative colitis (UC) is one of the two major forms of IBD which results in inflammation and ulcers (sores) in the digestive tract, causing a debilitating chronic condition. Patients are currently treated with anti-inflammatory and immunomodulatory medication to dampen the disease and control symptoms, often with significant side effects. These available treatment options commonly fail, with more than 50% of patients unable to achieve sustained remission[2], which sees them experiencing regular episodes of inflammation, diarrhoea, bleeding and abdominal pain[3], with as many as 25% of patients requiring hospitalisation[4]. The market for ulcerative colitis treatment was valued at US$7.5 billion in 2020 and is forecast to grow to US$10.8 billion by 2030[5]. Microba's novel drug candidate MAP315 presents an opportunity to fill a key gap in the current standard of care for ulcerative colitis treatment, representing a novel treatment paradigm for patients living with this debilitating disease.

Microba's Novel Drug Candidate MAP 315

MAP 315 was identified using Microba's unique analysis of its large proprietary human databank, demonstrating that this previously unidentified novel bacterial species is commonly observed in healthy individuals but consistently deficient in individuals with Inflammatory Bowel Disease. Subsequent pre-clinical investigation of MAP 315 through both *in vitro* and *in vivo* models demonstrated that MAP 315 promotes epithelial restitution and mucosal healing - biological activities that are associated with disease remission but not adequately addressed through existing therapy.

1 https://www.thelancet.com/journals/langas/article/PIIS2468-1253(19)30333-4/fulltext
2 https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf
3 Scribano, M.L. Adverse events of IBD therapies. Inflamm Bowel Dis. (2008). https://doi.org/10.1002/ibd.20702.
4 Pola, S. et al. Strategies for the care of adults hospitalized for active ulcerative colitis. Clin Gastroenterol Hepatol. (2012). https://doi.org/10.1016/j.cgh.2012.07.006.
5 https://www.nature.com/articles/d41573-021-00194-5 , https://www.alliedmarketresearch.com/ulcerative-colitis-market

Therapeutic Platform & Programs

Microba has established a data-driven platform for drug discovery and development from the human gut microbiome. This platform leverages a large, growing, proprietary databank collected through the Company's Microbiome Testing Services, and is generating multiple potent therapeutic candidates to address chronic diseases. Microba has established three therapeutic programs spanning IBD, Immuno-Oncology and Autoimmune Diseases, with lead candidate MAP 315 under the Company's IBD program scheduled to be the first program to enter human clinical trials.

This announcement has been authorised for release by the Board.

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About Microba Life Sciences Limited

Microba Life Sciences is a precision microbiome company driven to improve human health. With world-leading technology for measuring the human gut microbiome, Microba is driving the discovery and development of novel therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers. Through partnerships with leading organisations, Microba is powering the discovery of new relationships between the microbiome, health and disease for the development of new health solutions.

For more information visit: www.microba.com

Microba encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.