Successful IBD Phase I Clinical Trial

- Lead drug candidate MAP 315, demonstrated it is safe and well tolerated at both low and high doses in the Phase 1, healthy volunteer clinical trial
- MAP 315 is a novel live biotherapeutic product being developed for the treatment of ulcerative colitis and was discovered and developed using Microba's data-driven therapeutics platform
- The Phase 1 study enrolled 2 cohorts of 16 participants each, who were randomised 3:1 to receive MAP 315 or its matching placebo for 14 consecutive days (2 weeks). Unblinded analysis of trial data demonstrated no clinically significant safety signals from assessments including ECGs and laboratory analysis of haematology, coagulation, clinical chemistry, urinalysis parameters, or impact on inflammatory biomarkers
- Faecal kinetics assessed by metagenomic analysis indicated presence of MAP 315 at the terminal 28-day analysis timepoint, 14 days after the completion of dosing, confirming the ability to successfully deliver live MAP315 into the gastrointestinal tract

Microba Life Sciences Limited (ASX: MAP)("Microba" or the "Company") today announces initial unblinded data from the Phase 1 Clinical Trial of lead drug candidate MAP 315, in Microba's Inflammatory Bowel Disease (IBD) Therapeutic Program. These results demonstrate a strong safety and tolerability profile for MAP 315, and support the continued clinical development of the lead drug candidate. This is an important clinical development milestone for MAP 315 as a potential new treatment option for the millions of people suffering from ulcerative colitis.

Summary of Key MAP315-001 Study Results:

- MAP 315 had a favourable safety and tolerability profile across both low and high dose cohorts.
- There were no clinically significant safety signals from safety assessments including ECGs and laboratory analysis of haematology, coagulation, clinical chemistry or urinalysis parameters.
- There was no evidence of translocation of MAP 315 into the bloodstream.
- There was no impact on inflammatory biomarkers.
- All participants completed the study and all dosing.
- All reported adverse events (AEs) were mild (e.g. headache), with a higher proportion reported in the placebo group and there were no AEs that lead to study discontinuation or drug withdrawal.
- Treatment related AEs were minimal, transient and comparable between the MAP 315 and placebo treatment groups.
- Ongoing assessment of faecal kinetics by metagenomic analysis detects the presence of MAP 315 at the terminal 28-day analysis timepoint, 14 days after the completion of dosing, indicating the ability to successfully deliver live MAP315 into the gastrointestinal tract.

Recent preclinical characterisation data, together with these Phase 1 clinical study results provide strong positive support for continuing to advance the clinical development of MAP 315 for the treatment of Ulcerative Colitis. Data from the trial is expected to be formulated and submitted for peer review publication.

Professor Trent Munro, SVP of Therapeutics at Microba said: *"We are very pleased with the results from this clinical study which provide the foundation for further clinical development of MAP 315 in patients with Ulcerative Colitis. Microbiome based live biotherapeutics have the potential to be a revolutionary new therapeutic modality and this is exemplified by the observed safety profile in this study."*

Microba Life Sciences Ltd ABN 82 617 096 652
Level 10, 324 Queen Street, Brisbane QLD 4000 Australia
T: 1300 974 621 **E:** investor@microba.com **W:** microba.com

MAP 315 Phase 1 Clinical Trial Details

The clinical trial was titled "A Phase 1, Randomised, Double-Blind, Placebo- Controlled, Study to Evaluate the Safety, Tolerability and Pharmacokinetics of MAP 315 in Healthy Adults". The study enrolled 2 cohorts of 16 participants each, who were randomised 3:1 to receive MAP 315 or its matching placebo for 14 consecutive days (2 weeks). Cohort 1 received a low dose of 1 capsule/day of MAP 315 while Cohort 2 received a high dose of 8 capsules/day of MAP 315. The trial was conducted by Nucleus Network in Melbourne, Australia, under the Company's Human Research Ethics Committee (HREC) approval and in alignment with formal feedback received from an FDA pre-IND engagement. Full study details can also be found in the Australian New Zealand Clinical Trials Registry (ANZCTR) under study ID: ACTRN12623000291684.

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 uncharacterised and novel bacterial species is commonly observed in healthy individuals but consistently deficient in individuals with IBD. 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 critical for sustained disease remission but not adequately addressed through existing therapy.

MAP 315 is a live biotherapeutic product (LBP) consisting of lyophilised bacteria in an enteric coated capsule which is orally administered and being developed as an investigational product for the treatment of ulcerative colitis (UC). Microba worked in partnership with leading microbiome contract drug manufacturer Bacthera to produce GMP compliant MAP 315 at large-scale in their state-of-the-art facilities in Europe to supply material for the MAP 315 clinical trial.

Inflammatory Bowel Disease – Large unmet need & commercial opportunity

IBD causes 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 UC 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 MAP 315 presents an opportunity to improve the current standard of care and treatment for millions of people suffering from the debilitating effects of UC.

Therapeutic Platform & Programs

There is a growing body of evidence that the gut microbiome plays a central role in the maintenance of health and the development of chronic disease. With microbiome-based therapeutics now in clinical development and the first FDA approvals, these novel drugs represent an exciting new opportunity for the treatment of chronic diseases that are underserved by current pharmaceuticals.

Microba is at the forefront of this field using its advanced proprietary metagenomics technology developed by leading Australian researchers in the top 1% of cited researchers globally. Using this technology, 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 Inflammatory Bowel Disease (IBD), Immuno-Oncology and Autoimmune Diseases, with lead candidate MAP 315 under the Company's IBD program the first program to enter human clinical trials.

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

This announcement has been authorised for release by the Board.

For further information, please contact:

Dr Luke Reid
Chief Executive Officer
E: Luke.Reid@microba.com

Investor / Media Relations
E: investor@microba.com
W: https://ir.microba.com/
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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.