

Successful Completion of Autoimmune Program with Ginkgo Bioworks

- Autoimmune disease therapeutic discovery program with Ginkgo Bioworks (NYSE: DNA) achieves on time and on budget completion with primary and secondary activity screening data received for all lead bacterial strains
- Delivered compelling biological activity enabling selection of 6 lead strains which demonstrate significant disease relevant activity, generating new therapeutic intellectual property assets for the Company
- The program generated more than 3 million data points, and is considered a world-first microbiome therapeutic discovery effort
- The high activity hit-rate, further validates Microba’s data driven therapeutic platform and valuation of the Microba Therapeutic business
- The successful completion of this project and the data generated provides biological validation for further investment in these assets to move into the next stage of development.

Microba Life Sciences Limited (ASX: MAP) (“Microba” or the “Company”) today announces that all screening activities for the Company’s Autoimmune disease program have been completed on schedule together with partner Ginkgo Bioworks (NYSE: DNA). From the more than 3 million data points generated, 6 therapeutic leads with compelling disease-relevant activity have been selected for further pre-clinical development. The screening identified leads which exerted potent immunomodulatory effects in multiple disease-relevant cell types.

Professor Trent Munro, SVP Therapeutics at Microba said: “Microba is at the forefront of developing precision Microbiome Therapeutics, enabled by machine learning and artificial intelligence, that have the potential to help patients in need across a number of disease indications. Over the past 2 years we have broken new technical ground with this project and probed frontier biology imparted by novel microbes derived from the human gut microbiome. This approach has now allowed selection of potent lead candidates that will be progressed as therapeutics. Autoimmune diseases represent a significant unmet need and the identification of potential live biotherapeutics is an exciting development in the creation of new modalities to improve the lives of these patients”.

Next steps for this program are to assess therapeutic efficacy of these 6 lead strains in disease relevant animal models and manufacturing for clinical trials.

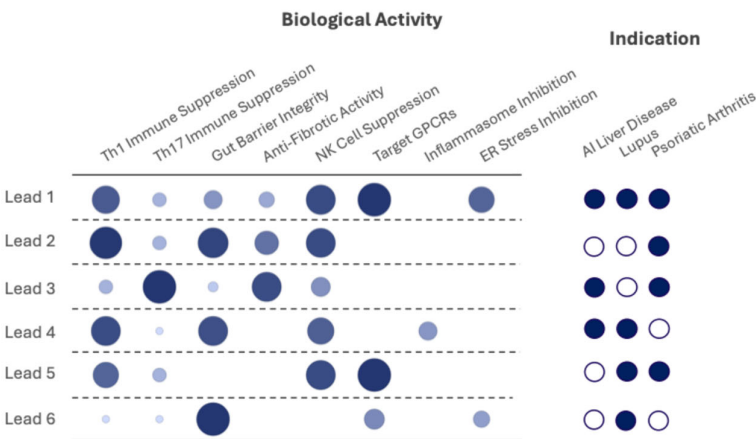


Figure 1: Activity of top 6 leads and disease indication relevance



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Autoimmune Disease Program and Ginkgo Bioworks Partnership

The goal of this program was to discover and develop novel treatments for autoimmune diseases such as lupus, psoriatic arthritis and certain autoimmune liver diseases.

- In mid-2022 Microba commenced its autoimmune disease therapeutic program in partnership with Ginkgo Bioworks.
- Microba first used its proprietary databank and advanced machine learning analytics to identify ~200 diverse gut microbiome bacterial species as therapeutic leads for target autoimmune diseases.
- Ginkgo then screened these leads for immunomodulatory activities based on a co-designed, bioanalytical assay screening cascade.

In Stage 1:

- 182¹ bacterial strains selected through Microba's data driven drug discovery platform were screened across an array of primary *in vitro* screening assays for disease relevant biological activity.
- The results demonstrated that 80% of strains exhibited activity in one or more primary screen assay, 62% demonstrated significant immunomodulatory activity, and 18% demonstrated significant inflammasome activity.
- 36 strains were selected and progressed into Stage 2 functional screening

In Stage 2:

- Screening of the 36 down selected strains was performed in disease relevant human cells including gut epithelial, liver fibroblast, synovial (joint connective) tissue and primary immune cells (directed at specific cell pathways and targets of relevance to autoimmune disease).
- Mechanism of action of select leads was characterised by multi-omics approaches including by transcriptomic analyses of host cells and secretome metabolomic analyses of lead strains.

The final data package enabled down selection to 6 strains which demonstrate compelling disease relevant activity for a range of autoimmune disorders.

Autoimmune diseases are a family of more than 80 chronic and often life-threatening illnesses, which occur when the body's own immune system attacks the body's healthy cells, tissues and organs. Autoimmune conditions now impact around 5% of the population and their prevalence is rising². In recent years, several studies have highlighted the role of the microbiome in the pathogenesis of autoimmune diseases³. The global market for autoimmune disease treatments was estimated to be US\$198b in 2023 and forecast to grow to US\$288b by 2028⁴.

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.

¹ 200 strains selected through Microba's data driven drug discovery platform were transferred to Ginkgo Bioworks of which 18 did not meet the growth specifications resulting in 182 strains progressing through primary screens

² Fugger, L et al. Challenges, Progress, and Prospects of Developing Therapies to Treat Autoimmune Diseases. Cell. (2020). <https://doi.org/10.1016/j.cell.2020.03.007><https://doi.org/10.1016/j.cell.2020.03.007>

³ De Luca, F. and Shoenfeld, Y. The microbiome in autoimmune diseases. Clin Exp Immunol. (2019). <https://doi.org/10.1111/cei.13158>

⁴ <https://www.prnewswire.com/news-releases/global-autoimmune-treatment-market-soars-to-288-32-billion-by-2028--driven-by-a-7-72-cagr-from-2023--301909189.html>



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The Company considers that these results are material and price sensitive for the following reasons:

- The delivery of 6 lead strains demonstrating significant disease relevant activities, generating new therapeutic intellectual property assets for the Company
- The successful completion of this project and the data generated provides the biological validation for further investment in these assets to move into the next stage of therapeutic development
- The high activity hit rate, further validates Microba's data driven therapeutic platform and would be expected to impact the valuation of Microba's therapeutic business
- It is estimated that the therapeutic market size in 2023 for autoimmune disease is US\$198b and forecast to grow to US\$288b by 2028, and a novel therapy for this category would be expected to be highly valued⁵.

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

View this announcement on our Investor Hub: <https://ir.microba.com/link/NPw6pr>

⁵ <https://www.prnewswire.com/news-releases/global-autoimmune-treatment-market-soars-to-288-32-billion-by-2028--driven-by-a-7-72-cagr-from-2023--301909189.html>



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