

# **Microba Continues to Advance its Therapeutic Programs**

- Pre-clinical package and manufacturing strategy for lead Inflammatory Bowel Disease program asset
  MAP 315 has advanced, to support the Phase I clinical trial
- Microba has two recently discovered oncology leads in culture in the laboratory, and pre-clinical work commenced with a global CRO to demonstrate efficacy
- Autoimmune disease program characterisation and screening activities now active with strategic shareholder and partner, Ginkgo Bioworks (NYSE: DNA)
- Second data package delivered in research partnership with International Flavors & Fragrances Inc. (NYSE:
  IFF) delivering therapy leads for food allergy and atopic dermatitis

**Microba Life Sciences Limited** (ASX: MAP) ("Microba" or the "Company") is pleased to provide an update on the continued advancement of its therapeutic programs covering Inflammatory Bowel Disease, Immuno-oncology, Autoimmune diseases, and allergy treatment.

#### **Inflammatory Bowel Disease Program**

Microba has advanced the pre-clinical program for MAP 315, working to achieve readiness for an upcoming human ethics submission and clinical testing under the TGA clinical trials notification scheme. Microba will also submit a request for a pre-IND meeting with the FDA to support rapid advancement of the clinical program.

MAP 315 is being developed for the treatment of Ulcerative Colitis, a debilitating form of Inflammatory Bowel Disease with >50% of patients unable to achieve sustained remission. Existing therapeutics fail to adequately address epithelial and mucosal healing which is linked to disease remission and reduced risk of surgery. In pre-clinical models MAP 315 delivers potent epithelial and mucosal healing which represents a potential novel treatment paradigm for the millions of patients suffering from Ulcerative Colitis globally. The global market for Ulcerative Colitis treatments was valued at \$7.5B in 2020<sup>1</sup>.

Manufacturing of MAP 315 with Microba's partner in Europe continues to make progress, however issues with a piece of processing equipment required for cGMP production of clinical material have resulted in some minor delays. A complete solution is being deployed by the Company's partner but requires additional time for implementation and cGMP qualification. This extends the timeline to receive cGMP material to initiate dosing for Microba's Phase I clinical trial from December 2022, into April 2023. The additional time will also be leveraged to gather additional supporting data and conduct further process development activities to advance manufacturing efficiency.

# **Immuno-oncology Program**

Following the recent discovery of multiple therapeutic leads from a comprehensive microbiome meta-analysis, the team now has two novel lead assets growing in culture in the laboratory. Aligned to this Microba has commenced a program of work with Eurofins in Taiwan, which will provide important pre-clinical efficacy data on the potential of these organism to increase response to immune checkpoint inhibitor (ICI) therapy.

This program continues to advance ahead of schedule and initial results are expected later this calendar year. Global checkpoint inhibitor sales have grown substantially since Microba has commenced the program, with Merck announcing sales

Microba Life Sciences Ltd ABN 82 617 096 652

 $<sup>^{1}\</sup> https://www.nature.com/articles/d41573-021-00194-5\ ,\ https://www.alliedmarketresearch.com/ulcerative-colitis-marketresearch.com/ulcerati$ 

31 Aug 2022



of lead drug Keytruda in excess of \$5bn USD in Q2 2022<sup>2</sup>. Microba has had pleasing engagement with several pharmaceutical companies that are monitoring the progress of this program.

#### **Autoimmune Disease Program**

Microba has now supplied multiple batches of bacterial strains from the Company's biobank to strategic shareholder and partner Ginkgo Bioworks (NYSE: DNA) for assessment, with characterisation and screening activities now active at their laboratories in Boston, USA. A further update on the program will be received during a progress meeting scheduled in mid-October.

Senior Vice President of Therapeutics, Prof Trent Munro said, "I am pleased by our progress on all programs. We are well prepared for our impending pre-IND meeting with the FDA, which will further support rapid advancement of our clinical program for MAP 315. The challenges experienced by our manufacturing partner has caused a small shift in the timing of our Phase I trial, but importantly this is a resolvable equipment issue and unrelated to our lead asset MAP 315. MAP 315 continues to deliver exciting biological activity which we are hoping to translate into a novel effective drug that can treat millions of patients globally suffering with Ulcerative Colitis."

"The ongoing interest from clinicians, pharmaceutical companies, and researchers in microbiome modulation for checkpoint response is very strong. Oncology presents a compelling opportunity for the company and the recent progress in the programs are an important step."

# **Allergy Treatment Program**

A second data package has been delivered to International Flavors & Fragrances Inc. ("IFF") (NYSE: IFF) in a research partnership to discover and develop microbiome-based solutions for multiple forms of allergy. The new data package identified multiple microbial therapy leads for food allergy and atopic dermatitis.

This builds on the first data package delivered in June 2022 for asthma and allergic rhinitis and marks a step towards a potential longer-term commercial relationship between the parties, leveraging Microba's Therapeutic Platform to develop novel allergy treatments. This program further demonstrates Microba's repeatable, scalable data-driven Therapeutic Platform with the ability to partner with large multinational health and pharmaceutical companies to discover and develop novel monoclonal microbial cell therapies.

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 Simon Hinsley

Investor / Media Relations E: simon@nwrcommunications.com.au T: +61 401 809 653

# **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.

<sup>&</sup>lt;sup>2</sup> https://s21.q4cdn.com/488056881/files/doc\_financials/2022/q2/v2/Q2-2022-Merck-Earnings-Deck-(update-8.9.2022).pdf