Microbiotica's Microbiome Medicines in Melanoma and Ulcerative Colitis Gain Regulatory Approvals in EU and UK for Phase 1b Studies

Microbiotica (a Flerie Portfolio Company) Secures Additional Financing to Advance Clinical Programmes in Immuno-Oncology and Inflammatory Bowel Disease Through to Data Readout

Cambridge, UK – 27 August 2024: Microbiotica, a biopharma company developing a pipeline of oral precision microbiome medicines called live biotherapeutic products (LBPs), is pleased to announce that it has received regulatory approvals to initiate clinical studies for its first two programmes in advanced melanoma (MELODY-1) and ulcerative colitis (COMPOSER-1) in selected EU countries and the UK. Both studies are due to start shortly, with initial data readouts expected by the end of 2025.

As it transitions to a clinic-stage company, Microbiotica is also pleased to have secured additional funding from existing investors, giving the Company the financial runway to complete these clinical trials.

MELODY-1 study – MB097 – Advanced melanoma

The MELODY-1 study will evaluate safety and initial signals of efficacy of MB097 in advanced melanoma, in combination with KEYTRUDA® (pembrolizumab), MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy. MSD will supply KEYTRUDA (study identifiers NCT06540391; MSD KEYNOTE-E75; 023-507377-17).

MB097 is a once daily, orally administered LBP consisting of a defined consortium of nine bacterial strains designed to enhance the efficacy of ICIs. The bacterial strains in MB097 were identified by analysing the microbiome of patients in multiple studies of ICIs in melanoma, including the MELRESIST study carried out with the company's collaborators at Cambridge University Hospitals. Collectively, the MB097 bacterial consortium provides microbiome signalling needed for ICI response. Preclinical studies demonstrate that MB097 stimulates core pathways of the immune system to activate Cytotoxic T Lymphocytes, and Natural Killer cells to enable them to kill tumour cells.

COMPOSER-1 study – MB310 – Ulcerative colitis

The COMPOSER-1 study will investigate the safety and initial signals of efficacy of a once-daily oral dose of MB310 for the treatment of ulcerative colitis, an inflammatory bowel disease. MB310 is a defined microbial consortium identified from healthy donors, which induced disease remission in patients with UC who participated in a clinical trial at the University of Adelaide.
Preclinical studies have demonstrated that MB310 acts via at least three independent mechanisms that are central to UC pathology: promoting the healing of the damaged gut epithelial barrier; regulating the balance of inflammatory and immune-modulatory cytokines; and inducing a regulatory T-cell response. (Study identifiers 2023-507376-50 (EudraCT)).

Claire Birrell, Microbiotica's VP Clinical Development, said, "The treatment of patients with

advanced melanoma has been revolutionised by ICIs. By optimising the patient's gut microbiome there is an opportunity to increase the number of patients who can benefit from these treatments. We believe that MB097, in combination with ICIs, has the potential to enhance the therapeutic benefit for patients with advanced melanoma. Similarly, with MB310, we see great potential in treating ulcerative colitis, where there remains significant unmet medical need."

Tim Sharpington, Microbiotica's CEO, said, "Starting our first clinical trials is a major milestone for the Company. We are delighted to have been given two regulatory approvals in quick succession and to have completed the manufacture of our clinical trial supplies batches. Working closely with our collaborators and clinical sites, we will initiate both trials in the coming weeks and look forward to treating patients with these promising new medicines."

– ENDS –

Notes to Editors
KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Microbiotica
Microbiotica is a private, clinic-ready, biopharma company developing a pipeline of oral precision microbiome medicines called live biotherapeutic products (LBPs) with lead programmes in immuno-oncology and inflammatory bowel disease. The company has a clinic-led, purpose-built, proprietary, microbiome profiling platform to support drug discovery based on clinical data, which enables precision identification of bacteria associated with favourable clinical trial outcomes in specific patient populations. The company has significant expertise in microbiology, bioinformatics, translational biology and LBP manufacturing and development.

The Company is creating a novel pipeline of programmes in immuno-oncology (MB097 for advanced melanoma), and inflammatory bowel disease (MB310 for ulcerative colitis). It has a major partnership with Cancer Research UK and Cambridge University Hospitals in Immuno-oncology. The company has a supply agreement with MSD (Merck & Co., Inc., Rahway, NJ, USA) for use of KEYTRUDA in evaluating MB097 in melanoma patients with primary resistance to anti-PD-1 immunotherapy. MB310 was developed in collaboration with the University of Adelaide. Both programmes have data read-outs in 2025.

Spun out of the Wellcome Sanger Institute in 2016, the Company is based in purpose-built facilities at the Chesterford Research Park near Cambridge, UK. Microbiotica has raised £62 million equity investment, including a £50 million Series B in 2022, with venture investors including British Patient Capital, Cambridge Innovation Capital, Flerie Invest, IP Group plc, Seventure Partners and Tencent. The company has also received financial support from the US-based Crohn's and Colitis Foundation.

For more information, please visit www.microbiotica.com, and follow us on LinkedIn.

Media contacts
Microbiotica
Ro Gardner, rgardner@microbiotica.com, +44 7801 480569

Scius Communications
Sue Charles, sue@sciuscommunications.com, +44 7968726585
Katja Stout, katja@sciuscommunications.com, +44 7789435990
Daniel Gooch, daniel@sciuscommunications.com, +44 7747875479

Flerie in brief
Flerie is an active long-term life science investor, with a broad and diversified portfolio of innovative companies based on pioneering science. We invest in product development and commercial growth opportunities globally alongside other leading investors, focusing predominantly on private companies that are otherwise difficult to access. Flerie's active ownership model, broad network and resources support and accelerate the development of the portfolio projects, creating value for shareholders. Flerie AB's ordinary share is listed on Nasdaq Stockholm with the ticker FLERIE. For further information please visit www.flerie.com

Attachments
Microbiotica's Microbiome Medicines in Melanoma and Ulcerative Colitis Gain Regulatory Approvals in EU and UK for Phase 1b Studies