

## **Microbiotica Announces Clinical Trial Collaboration with MSD to Evaluate MB097 in Combination with KEYTRUDA® (pembrolizumab) in a Phase 1b Clinical Trial in Melanoma**

**Cambridge, UK, 12 April 2023** – Microbiotica, a leader in discovering and developing microbiome-based therapeutics and biomarkers, today announces it has entered into a clinical trial collaboration with MSD (Merck & Co., Inc., Rahway, NJ, USA).

Under the terms of the agreement, Microbiotica will conduct a phase 1b clinical trial to evaluate the safety and tolerability, and initial signs of clinical activity of its live biotherapeutic product, MB097, in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in melanoma patients with primary resistance to an anti-PD-1-containing immunotherapy. Microbiotica will be the study sponsor and MSD will supply KEYTRUDA®.

MB097 is an orally administered live biotherapeutic product consisting of a defined consortium of nine bacterial strains designed to enhance the efficacy of immune checkpoint inhibitors (ICIs) such as KEYTRUDA®.

The bacterial strains in MB097 were identified by analysing the microbiome of patients in multiple studies of ICIs in melanoma. Microbiotica's discovery platform facilitates precise, strain-level identification of bacterial signatures associated with clinical response. Moreover, MB097 displayed potent anti-tumour efficacy in combination with ICIs in *in vivo* tumour models and demonstrated multiple immuno-stimulatory mechanisms in primary human immune cell assays including Cytotoxic T Lymphocyte activation and tumour cell killing *in vitro*.

**Tim Sharpington, CEO of Microbiotica, said:** "We are delighted to be working with MSD, a world leader in immuno-oncology. The treatment of patients with advanced melanoma has been revolutionised by ICIs such as KEYTRUDA® and there is an opportunity to increase the number of patients who can benefit from these treatments. There is growing evidence that the gut microbiome plays a critical role in determining a patient's response to ICIs and we believe that MB097, in combination with KEYTRUDA®, has the potential to enhance the benefit for patients with advanced melanoma and other difficult-to-treat cancers."

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

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**Contact:**

**Microbiotica:**  
Ro Gardner

T: +44 1223 869302 / M: +44 7801 480569  
E: [rgardner@microbiotica.com](mailto:rgardner@microbiotica.com)

**Microbiotica (Media relations):**  
Melanie Toyne-Sewell / Agnes Stephens  
/ Giulia Lasagni / Batoul Ali

T: +44 20 7457 2020  
E: [microbiotica@instinctif.com](mailto:microbiotica@instinctif.com)

**NOTES TO EDITORS**

**About Microbiotica**

Microbiotica is a leading player in the field of microbiome-based therapeutics, biomarkers and targets. The Company is building a growing pipeline of differentiated products based on high quality clinical datasets and unique bacterial signatures that drive biology, identified by its proprietary platform.

Consisting of a leading microbiome Reference Genome Database, Culture Collection, mass culturing technology (Personalised Bacterial Bank) and proprietary AI tools, Microbiotica's platform enables unrivalled strain-level microbiome analysis linked to patient phenotypes. The Company's current therapeutic areas of focus are immuno-oncology and IBD and it has established major clinical and academic partnerships in these areas.

Spun out of the Sanger Institute in 2016, the Company is based at Chesterford Research Park near Cambridge, UK. Microbiotica's investor syndicate includes British Patient Capital, Cambridge Innovation Capital, Flerie Invest, IP Group plc, Seventure Partners, and Tencent. In 2022, Microbiotica raised £50m Series B fund raising, the largest such fund raising for a microbiome company in Europe.

For more information, please visit [www.microbiotica.com](http://www.microbiotica.com), [LinkedIn](#), and [Twitter](#).