



MaaT Pharma Announces Upcoming Pre-IND Meeting with the FDA and Advances MaaT034 Toward Clinical Development in Solid Tumors

- Pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA), focused on CMC (Chemistry, Manufacturing, and Controls), is scheduled for October 2026, representing the next key regulatory milestone for MaaT034
- A First-in-Human study has been designed to determine the optimal dosing and pre-treatment regimen and generate initial clinical proof-of-concept data
- Initial clinical development planned in combination with PD-(L)1 inhibitors in solid tumors with high unmet medical needs and limited treatment options, including second-line advanced non-small cell lung cancer (NSCLC), refractory advanced melanoma and other solid tumors
- The First-in-Human study could be initiated in late 2027, subject to obtaining the appropriate funding and necessary regulatory clearance

Lyon, France, September 21, 2026 – 7.00pm CET - MaaT Pharma (EURONEXT: MAAT – the “Company”), a clinical-stage biotechnology company and a leader in the development of Microbiome Ecosystem Therapies™ (MET), dedicated to enhancing survival for patients with cancer through immune modulation, today announced the next clinical development steps for MaaT034, the first functionally-selected, co-cultured microbial ecosystem from the Company’s innovative donor-independent MET-C platform, to be evaluated in combination with PD-(L)1 inhibitors in advanced solid tumors.

The MET-C platform combines rational candidate design, artificial intelligence-enabled computational tools for functional feature selection and unique co-culture technology to produce functionally selected microbial ecosystems at an industrial scale. MaaT034 is the first candidate to emerge from this platform and is specifically designed with the objective of optimizing intestinal microbiome functions and to support antitumor immune responses in combination with immune checkpoint inhibitors.

MaaT Pharma has scheduled a Pre-IND CMC-focused meeting with the FDA in October 2026, the next regulatory milestone toward clinical development of MaaT034. The program's progression toward clinical development is based on a series of preclinical findings presented at the [AACR](#) and [SITC](#) Annual Meetings¹.

MaaT034 is expected to be developed in combination with PD-(L)1 inhibitors in selected advanced solid tumors, including second-line NSCLC and refractory advanced melanoma, as well as in other solid tumors characterized by significant unmet medical needs and limited treatment options. By modulating the gut microbiome, MaaT034 is designed to help restore anti-tumor immunity and sensitivity to PD-(L)1 inhibitors, with the aim of overcoming acquired resistance and improving outcomes beyond current standard of care benchmarks.

Subject to obtaining the necessary regulatory clearances and the availability of appropriate funding, MaaT Pharma could initiate a First-in-Human study evaluating MaaT034 in late 2027. To support the clinical development of MaaT034, the Company is exploring financing opportunities from investors and strategic partnerships with pharmaceutical companies.

About MaaT Pharma

MaaT Pharma is a leading, late-stage clinical company focused on developing innovative gut microbiome-driven therapies to modulate the immune system and enhance cancer patient survival. Supported by a talented team committed to making a difference for patients worldwide, the Company was founded in 2014 and is based in Lyon, France. As a pioneer, MaaT Pharma is leading the way in bringing the first microbiome-driven immunomodulator in oncology. Using its proprietary pooling and co-cultivation technologies, MaaT Pharma develops high diversity, standardized drug candidates, aiming at extending life of cancer patients. MaaT Pharma has been listed on Euronext Paris (ticker: MAAT) since 2021.



About MaaT034

MaaT034, currently in preclinical development, is a next-generation donor-independent functionally selected, co-cultured microbial ecosystem, designed to improve patient responses to immunotherapy in combination with Immune Checkpoint Inhibitors (ICIs). Developed using MaaT Pharma's proprietary MET-C co-culturing platform, MaaT034 is optimized for large-scale manufacturing and designed to deliver key microbial functions associated with anti-tumor immune responses.

Preclinical data presented at the AACR and at SITC annual meetings demonstrated that MaaT034 produced key metabolites, recognized as promoting gut barrier restoration and modulating immune responses, such as Short-Chain Fatty Acids (SCFA), secondary bile acids, and tryptophan derivatives. These data support the potential of MaaT034 to promote gut barrier restoration, enhance T-cell activation, and increase anti-tumor activity when combined with anti-PD-1 or anti-PD-L1 therapies.

By restoring microbiome-mediated functions and modulating immune responses, MaaT034 is designed to complement the mechanism of action of immune checkpoint inhibitors and has the potential to improve treatment outcomes in patients with advanced solid tumors.

¹ Preclinical data for MaaT034 have been presented at AACR and SITC annual meetings since 2023. Posters are available in the [dedicated section of the Company's website](#).

Forward-looking Statements

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "target," "believe," "expect," "aim", "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements.

Contacts

MaaT Pharma – Investor Relations

Eric Soyer
Chief Financial Officer
+33 4 28 29 14 00
invest@maat-pharma.com

MaaT Pharma – Media Relations

Pauline Richaud
Head of Communication
+33 6 14 06 45 92
media@maat-pharma.com