MaaT Pharma Announces First Patient Randomized in IMMUNOLIFE Phase 2 Study Sponsored by Gustave Roussy, To Explore the Role of the Gut Microbiome To Overcome ICI Resistance in Advanced NSCLC Patients with Antibiotic-Induced Dysbiosis

- IMMUNOLIFE, a Phase 2 randomized exploratory study, will evaluate the potential of MaaT033 in combination with Cemiplimab versus Best Investigator Choice (i.e.: second line) in enhancing disease control rate in patients with Non-Small Cell Lung Cancer (NSCLC) who have received antibiotics
- The IMMUNOLIFE trial is sponsored by Gustave Roussy, a world-renowned center in cancer treatment and conducted within the IMMUNOLIFE consortium, which brings together leading experts in immuno-oncology including Lisa Derosa, MD, PhD
- This exploratory trial assesses the rationale for combining a full-ecosystem microbiotherapy with immune checkpoint inhibitors (ICIs) in patients presenting antibiotic-induced dysbiosis and improve clinical outcomes
- This collaboration will generate additional data to advance MaaT034 program in immuno-oncology and the Company's microbiome-informed AI platform

Lyon, France, January 20, 2026 – 6:30PM 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, announced that the first patient has been randomized in the IMMUNOLIFE Phase 2 clinical trial, a randomized multicenter study evaluating the potential of an oral pooled fecal microbiotherapy (MaaT033) in combination

with Regeneron's Cemiplimab (CB) in enhancing disease control rate versus best investigator's choice (BIC) in patients with advanced non-small cell lung cancer (NSCLC) who have developed resistance to PD-1/PD-L1 blockade following antibiotic (ATB) exposure and who present ATB-induced gut dysbiosis.

The IMMUNOLIFE trial is evaluating MaaT033 in combination with CB vs BIC in 162 patients with advanced NSCLC who are refractory to immune checkpoint inhibitors (ICIs) and have received antibiotics. Patients are randomized (1:1) to receive either MaaT033 orally for one week prior to each cycle of CB (administered every 3 weeks for 6 months), followed by CB alone, or BIC. The primary objective is to assess whether the combination is associated with an improved disease control rate at 12 weeks compared to BIC. The study includes 14 centres in France, with patient enrolment of approximately 2 years and total CB treatment duration of 2 years. Primary results after 1-year follow-up post-treatment could be expected in late 2030. An interim futility analysis around H1 2027, after the 81st randomized patient.

"Gut dysbiosis is increasingly recognized as a risk factor for immunoresistance to immunotherapy. MaaT033 is designed to restore microbiome balance and may help improve patients' response to treatment," **said Lisa Derosa, MD, PhD at Gustave Roussy and coordinating investigator of the IMMUNOLIFE trial.**

"We have built substantial evidence in our hemato-oncology programs that complex donor-derived products restore immune homeostasis in the context of pre-existing dysbiosis. This study represents an opportunity to further explore these findings in immuno-oncology in a well-defined patient population expected to show antibiotic-mediated dysbiosis," **said Hervé Affagard, CEO and co-founder of MaaT Pharma.**

This trial, sponsored by Gustave Roussy, is part of MaaT Pharma's exploratory strategy launched in 2022, which also includes the PICASSO trial, a Phase 2a randomized controlled trial sponsored by AP-HP in Paris evaluating Xervyteg® (MaaT013) in combination with ICIs, ipilimumab (Yervoy®) and nivolumab (Opdivo®) for patients with metastatic melanoma. The Company has been informed by the academic sponsor that topline results could not be available in Q4 2025 (as previously announced) and could now be expected in H1 2026. Overall, IMMUNOLIFE and PICASSO studies aim to contribute to the ongoing assessment of the Company's research strategy, including indication, treatment line, and patient population. This will also inform on the clinical development of MaaT034, a co-cultured microbiome-based therapy and the Company's next-generation drug candidate, designed to target large indications in solid tumors.

In parallel, data already generated and to be generated during the IMMUNOLIFE consortium will also fuel the Company's AI platform and support the development of all the Company's microbiome-based drug candidates.

The IMMUNOLIFE consortium includes leading academic institutions such as Gustave Roussy, INSERM, Paris Saclay University, INRAe, Hospital-University Institute (IHU) Méditerranée Infection and biotech companies. The consortium aims to address the challenge of primary resistance to ICI observed in advanced NSCLC patients following antibiotic exposure. The IMMUNOLIFE consortium receives funding from the French National Research Agency ("ANR-21-5 RHUS-0017 IMMUNOLIFE").

For more information on the IMMUNOLIFE (IMMUNOLIFE2) study: NCT07001618

About MaaT033

MaaT033, a standardized, donor-derived, high-richness, high-diversity oral Microbiome Ecosystem Therapy™ containing anti-inflammatory Butycore™ species, is currently being developed as an adjunctive therapy to improve overall survival in patients receiving HSCT and other cellular therapies. It aims to ensure optimal microbiota function and to address a larger patient population in a chronic setting. MaaT033 has been granted Orphan Drug Designation by the European Medicines Agency (EMA).

About MaaT034

MaaT034, currently in preclinical development, is a next-generation donor-independent full ecosystem synthetic microbiome therapy, dedicated to improving patient responses to immunotherapy in combination with Immune Checkpoint Inhibitors. Developed using the Company's co-culturing proprietary MET-C platform, MaaT034 is optimized for large-scale production in oncology. Previous presented preclinical data showed 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 role of MaaT034 in gut barrier repair and in T cell reactivation either in combination with anti-PD1 or with anti-PD-L1. By enhancing gut barrier repair and modulating immune responses, MaaT034 is expected to complement the action of these immunotherapeutic agents, potentially improving their efficacy in treating solid tumors cancer.

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.

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.

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