MaaT Pharma Provides a Business Update and Highlights Key Milestones Expected in 2025

- Marketing Authorization application of Xervyteg® (MaaT013) in acute graft-versus-host-disease submitted to the European Medicines Agency (EMA) in June 2025
- MAA could be expected in H2 2026 allowing, if approved, for commercialization of Xervyteg® in Europe
- As part of a strategic focus on Xervyteg®'s registration activities in Europe, the Phase 3 dedicated trial launch in the U.S is now expected in 2026
- The Company's General Meeting will take place on June 20, 2025, at 9.30am CET at the Company's headquarter in France located at 70 avenue Tony Garnier, 69007 Lyon and will also be broadcasted live

Lyon, France, June 19, 2025, 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 provides a business update and highlights its key milestones expected for the second half of 2025.

"Following the submission of the Marketing Authorization Application to the EMA for our lead asset, Xervyteg®, earlier this month, we are excited to advance Xervyteg® toward commercialization — a potential world first for a microbiota therapeutic in oncology — and are now fully focused on progressing registration activities across Europe", **said Hervé Affagard, CEO and co-founder of MaaT Pharma.** *"This marks a major step in confirming our commitment to address high unmet medical needs and, importantly, it serves as a stepping stone toward international expansion, as we aim to bring our therapies to patients worldwide."*

Pipeline highlights

In Hemato-Oncology

Acute Graft-versus-Host Disease (aGvHD) – Xervyteg® (MaaT013)

- In January 2025, the Company announced positive topline results from the pivotal Phase 3 ARES Study evaluating Xervyteg® (MaaT013) in aGvHD. The study met its primary endpoint with a significant gastrointestinal overall response rate at Day 28 of 62% and demonstrates the unprecedented efficacy of Xervyteg® as third-line treatment of aGvHD with gastrointestinal involvement (GI-aGvHD) consistent with communicated Early Access Program results.
- On June 02, 2025, the Company announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its lead drug candidate MaaT013, under the registered brand name of Xervyteg®. If approved, the Marketing Authorization would establish Xervyteg® as the first microbiota therapeutic approved by the EMA, the first one in hemato-oncology worldwide and the first approved therapy in third-line GI-aGvHD.
- On June 13, 2025, the Company presented positive updated data in Early Access Program for 173 patients at the 2025 annual EHA Congress supporting the high efficacy and good safety profile of Xervyteg®. This dataset confirms the breakthrough potential of Xervyteg® for aGvHD patients with limited treatment options.
- Final results from the pivotal ARES study, including 12-month overall survival data, are expected before the end of 2025 and will be incorporated into the filing dossier.
- The potential marketing authorization could be delivered around mid-2026, enabling the start of the commercialization of Xervyteg® in Europe.
- MaaT Pharma is advancing discussions with potential partners to accelerate the commercialization plan across Europe.
- MaaT Pharma primarily focuses on the commercialization of its most advanced asset with the completion of regulatory steps in Europe, and dedicated preparation activities for the European launch of Xervyteg®.
- In parallel, the Company continues discussions with the FDA to optimize a dedicated pivotal study in the U.S., with the objective of enabling the earliest possible access to Xervyteg® for U.S. patients. Such a study could be initiated in 2026 (instead of Q4 2025), subject to regulatory confirmation as MaaT Pharma continues watching the evolving regulatory policies and process in the United States.
- The Company continues the ongoing Early Access Program in the United States, initiated in December 2024.

Allogenic Hematopoietic Stem Cell Transplant (allo-HSCT) - MaaT033

- Over the past 12 months, three DSMB safety assessments were conducted for MaaT033 in the Phase 2b PHOEBUS randomized trial designed to be pivotal: two routine evaluations and one interim analysis focused on excess mortality. All confirmed a favorable safety profile and recommended continuation of the trial without modifications.
- The last patient enrollment in the trial is anticipated for mid-2026 while the 1-year OS results are expected in H2 2027.

In Immuno-Oncology

Xervyteg® and MaaT033 – Proof-of-Concept trials using the MET-N platform (donor derived conducted as Investigator-Sponsored Trials (ISTs).

- In March 2024, the Company completed patient recruitment for the Phase 2a randomized clinical trial (NCT04988841) (PICASSO) sponsored by AP-HP in Paris and in collaboration with INRAE and Institut Gustave Roussy, evaluating Xervyteg® in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®), in metastatic melanoma patients. The Company provided its Xervyteg® drug candidate and placebo and contributes to the microbiome profiling of patients using its proprietary gutPrint® AI research engine, while the trial investigator-sponsor handled recruitment, treatment and is overseeing data collection and analysis. Data readout is expected in H2 2025 as previously announced.
- In May 2024, the Company announced its participation in the IMMUNOLIFE 'RHU' (university hospital trial) program, a consortium including academic partners, such as Institut Gustave Roussy (IGR), a world-renowned center in the field of cancer treatment, and biotech companies. MaaT033 will be tested as a concomitant treatment to cemiplimab (Regeneron), an anti-PD1 therapy, to assess the potential increase in response rate in patients having received antibiotics. This investigator-sponsored, randomized, multicenter Phase 2 trial will evaluate MaaT033 in patients with advanced non-small cell lung cancer (NSCLC), with MaaT Pharma supplying the investigational product. The trial is expected by the sponsor to start mid-2025.

MaaT034 – Next-generation drug candidates with co-cultured technology (MET-C platform)

- In April 2025, the Company presented new preclinical data for MaaT034, its next generation product, showing compelling anti-tumor efficacy results in germ-free mice at the American Association for Cancer Research (AACR) Annual Meeting 2025. Key results included:
  - Metagenomic analysis shows that MaaT034 reproduces the microbial functions of Xervyteg®
  - MaaT034 improves DC-mediated T cell activation and potentiates anti-tumor effects mediated by anti-PD-1 checkpoint blockade in vitro.
  - 70% of MaaT034 microbial species engraft in mice, ensuring an enduring presence of beneficial bacteria in the gut environment.
  - MaaT034 increases the production of key microbial-derived metabolites such as short-chain fatty acids in germ-free mice. This translates into an improved gastrointestinal physiology as evidenced by gut mucosal restoration.
  - MaaT034 optimizes anti-PD1 mediated activity in tumor-bearing, germ-free mice. While anti-PD1 alone reduced tumor growth by 10%, the combination of anti-PD1 and MaaT034 resulted in a 83.7% tumor growth reduction (compared to a 24.2% reduction when using a single strain of *Akkermansia muciniphila* bacteria).

In Neurodegenerative Diseases

- In May 2025, MaaT Pharma announced positive final Phase 1b results for MaaT033 in Amyotrophic Lateral Sclerosis (ALS), showing a favorable safety and tolerability profile supported by biomarker and microbiome analyses. Moving forward, the Company is seeking a partner to further advance clinical evaluation in ALS.

As a reminder, the Company's Annual General Meeting will take place on Friday, June 20, 2025, at 9:30am CET at the Company's headquarter in France located at 70 avenue Tony Garnier, 69007 Lyon and will also be broadcasted live. A presentation by the management team on recent developments and perspectives will take place from 9:00 to 9:30 a.m. CET, prior to the General Meeting. For more information, please visit the investors section on the Company's website.

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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