MaaT Pharma Announces Positive Outcomes from Final DSMB Meeting for Pivotal Phase 3 Clinical Trial Evaluating MaaT013 in Acute Graft-versus-Host Disease

- The Independent Data Safety and Monitoring Board (DSMB) confirmed the remarkable efficacy results and a positive benefit/risk profile of MaaT013 in this patient population
- The Company plans for submission with the European Medicines Agency in June 2025, targeting a potential approval in mid-2026

Lyon, France, March 18th, 2025 – 6:00 PM 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, after recently receiving the approval of its Pediatric Investigation Plan (PIP) by the EMA Pediatric Committee, that the DSMB completed its final safety assessment of the pivotal Phase 3 trial ARES, a single-arm, open-label, multicenter European study evaluating the efficacy and safety of MaaT013 in acute Graft-versus-Host Disease patients with gastrointestinal involvement (GI-aGvHD) in third-line treatment, refractory to steroids and refractory or intolerant to ruxolitinib.

"This DSMB's positive review is another key milestone for MaaT Pharma, further validating MaaT013's consistently favorable clinical profile, demonstrated over the years in clinical development in a highly fragile patient population," **stated Gianfranco Pittari, MD, PhD, Chief Medical Officer of MaaT Pharma.** *"It underscores our determination to enhance outcomes in patients with aGvHD through innovative therapies."*

The Phase 3 study met its primary endpoint, and positive topline results (full details here) were reported in January 2025, demonstrating high efficacy for MaaT013 with a significant gastrointestinal overall response rate at Day 28 of 62%, exceeding the initially expected response rate of 38%. The DSMB, composed of 4 independent experts, had previously reviewed data on 30 patients in October 2023 and had concluded that MaaT013 demonstrated a positive benefit/risk ratio based on a good safety profile and positive preliminary efficacy results. The experts completed their review during the last meeting and reviewed safety data from 66 patients up to the data cut-off of the primary analysis. The DSMB confirmed that *"given the remarkable efficacy results, the study results show an*

acceptable safety profile and a favorable benefit /risk ratio". The DSMB members will continue to review safety on an ongoing basis until the 1-year follow-up.

"*With both the Pediatric Investigation Plan approved by the EMA Pediatric Committee and now positive DSMB confirmation, we continue to build a strong momentum toward a potential market approval, with the opportunity to have the first-approved microbiome-based drug in Europe,*" **concluded Hervé Affagard, co-founder and CEO and of MaaT Pharma.**

Next Steps for MaaT013 in aGvHD:

- Submission of a Centralized Marketing Authorization Application (MAA) to the EMA is expected in June 2025.
- Evaluation of the One-year Overall Survival (secondary endpoint evaluation) is expected in Q4 2025.
- The Company is actively engaging with investors and potential partners to advance toward the regulatory phase and commercialization.

About acute Graft-versus-Host Disease

Acute Graft-versus-Host Disease occurs in patients within 100 days of undergoing a stem cell or bone marrow transplant, where the transplanted cells initiate an immune response and attack the transplant recipient's organs, causing inflammation of the skin, liver and/or gastro-intestinal tract and leading to significant morbidity and mortality. GI involvement is associated with severe complications such as profound diarrhea, abdominal pain, intestinal bleeding, and death. These complications are often life-threatening, with increased mortality risk, due to the challenges of managing severe GI inflammation and the associated risks of infection, malnutrition, and organ failure. The standard first line therapy for treating aGvHD is the use of systemic steroids. If patients do not respond to steroids, they are considered Steroid Resistant (SR) and other agents can be administered. Currently, the second-line treatment for steroid-refractory acute graft-versus-host disease (SR aGvHD) is ruxolitinib. Recently, remestemcel—L-rknd was approved in December 2024 in the US specifically for use in the paediatric population as a second-line treatment.

About MaaT013

MaaT Pharma's Microbiome Ecosystem Therapies™ (MET) are designed to leverage a full microbiome ecosystem to restore balance and maximize clinical benefits for patients with severe, treatment-induced dysbiosis in acute diseases. MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, enema Microbiome Ecosystem Therapy™ for acute, hospital use. It is characterized by a consistently high diversity and richness of microbial species and the presence of Butycore™ (a group of bacterial species known to produce anti-inflammatory metabolites). MaaT013 aims to restore the symbiotic relationship between the patient's functional gut microbiome and their immune system to correct the responsiveness and tolerance of immune functions and thus reduce steroid-resistant, gastrointestinal (GI)-aGvHD. MaaT013 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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

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Contacts

MaaT Pharma – Investor Relations
Guilhaume DEBROAS, Ph.D.
Head of Investor Relations
+33 6 16 48 92 50
invest@maat-pharma.com

MaaT Pharma – Media Relations
Pauline RICHAUD
Senior PR & Corporate Communications Manager
+33 6 14 06 45 92
media@maat-pharma.com

Rx Communications Group – U.S. Investor Relations
Michael Miller
Managing Director
+1-917-633-6086
mmiller@rxir.com

Catalytic Agency – U.S. Media Relations
Heather Shea
Media relations for MaaT Pharma
+1 617-286-2013
heather.shea@catalyticagency.com