MaaT Pharma Announces Positive Safety Interim Analysis from DSMB for Phase 2b Trial Evaluating MaaT033 for Patients Receiving Allo-HSCT

- Following a milestone unblinded interim safety review, the independent Data Safety Monitoring Board (DSMB) has recommended that the study proceed without modification.
- MaaT033, a pooled donor-derived oral drug candidate developed for ambulatory use, continues to demonstrate a favorable safety profile and tolerability.

Lyon, France, April 8, 2025 – 7.30am 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 positive outcome of a key DSMB safety interim analysis for the Phase 2b trial PHOEBUS, the world's largest randomized controlled trial evaluating microbiome therapy in oncology to date. The study compares the efficacy and safety of MaaT033 (experimental arm) to placebo in patients undergoing an Allogeneic Hematopoietic Stem Cell Transplantation (allo-HSCT).

Early after allo-HSCT, patients are highly vulnerable and face a significant risk of non-relapse mortality. Therefore, the study protocol includes a specific safety analysis that would trigger a stopping rule in case a pre-defined mortality excess in the experimental arm would be identified after 30 patients have been randomized to receive MaaT033 (approximately 60 enrolled in the study) and monitored for 90 days after allo-HSCT. This analysis is distinct from the ongoing safety assessments conducted every six months, whose positive outcomes have last been communicated on January 21, 2025. As a result of their unblinded analysis, the DSMB recommended the trial to proceed as planned, showing no excessive mortality related to MaaT033 as of today. This additional positive outcome further reinforces MaaT033's safety profile and supports MaaT033's integration in the allo-HSCT setting without significant risks of severe adverse events.

"We are pleased to report that MaaT033's safety profile continues to be positive. The confirmed absence of a pre-specified mortality excess in patients receiving MaaT033 is of critical relevance", **said Gianfranco Pittari, MD, PhD, Chief Medical Officer of MaaT Pharma.** *"These patients would enormously benefit from innovative therapies enhancing hematopoietic stem cell transplantation outcomes while avoiding toxic effects."*

Patient enrollment is ongoing in France, Germany, Belgium, Spain, Netherlands and the United Kingdom. The Phoebus trial is an international, multi-center, randomized, double-blinded study comparing MaaT033 (a standardized, oral, freeze-dried, multi-donor microbiotherapy) to placebo in patients receiving an allo-HSCT. The trial is expected to enroll 387 patients and is set to be conducted in up to 60 clinical investigational sites (NCT05762211).

Building on the demonstrated safety and efficacy profile of MaaT013, the capsule formulation MaaT033, a high-value asset and the second candidate from MaaT Pharma's native ecosystem platform, is designed to reach a larger patient population through its oral administration. By enabling outpatient use, MaaT033 also supports optimized patient care.

Next steps:

- The next DSMB unblinded interim analysis with mortality monitoring is scheduled for Q3 2025 at the 120-patient mark.
- The routine DSMB review for ongoing safety, conducted every six months, is also expected for Q3 2025.

About MaaT033

MaaT033, a 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 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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