



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

- The DSMB conducted an unblinded safety review of data from the first 120 enrolled patients and identified no safety concerns and no excessive mortality related to MaaT033 as of today.
- The DSMB recommended that the study continue as planned.
- MaaT033 continues to demonstrate a favorable safety profile and tolerability.

Lyon, France, October 7, 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, announced that the independent Data Safety Monitoring Board (DSMB) has completed the second pre-planned safety interim analysis of the ongoing PHOEBUS trial, a Phase 2b randomized controlled trial designed to be pivotal, evaluate the efficacy and safety of MaaT033 versus placebo in patients undergoing an Allogeneic Hematopoietic Stem Cell Transplantation (allo-HSCT). The PHOEBUS trial is the world’s largest randomized controlled trial evaluating microbiome therapy in oncology to date.

“We are pleased to report another positive safety review for MaaT033 with the DSMB’s recommendation to continue the trial without modification marking a key milestone in its development. We remain fully committed to advancing this Phase 2b trial and to delivering a much-needed therapeutic option for patients fighting blood cancers and undergoing allo-HSCT and to shaping a future where microbiome-based therapies become an integral part of hematology-oncology treatment,” **said Hervé Affagard, Chief Executive Officer and co-founder of MaaT Pharma.**

The DSMB reviewed unblinded safety data on 120 enrolled patients (including 60 patients randomized to receive MaaT033) and monitored patients for 90 days after allo-HSCT as per the trial protocol. Patients are especially vulnerable in the early phase after allo-HSCT, with a heightened risk of non-relapse mortality. To ensure patient safety, the study protocol includes a predefined safety review, with a stopping rule if an excess of mortality is detected in the experimental group.

Following its review, the DSMB recommended that the study continue as planned, having identified no safety concerns and no excessive mortality related to MaaT033 as of today.

In addition to this specific safety analysis, routine safety assessments are conducted every six months. All assessments to date have confirmed a favorable safety profile for MaaT033, and recommended continuation of the trial without modifications. These regular safety reviews further support MaaT033's integration in the allo-HSCT treatment setting, without significant added risk of severe adverse events.

Patient enrollment for the PHOEBUS trial is ongoing in France, Germany, Belgium, Spain, Netherlands and the United Kingdom. The trial is expected to enroll 387 patients and is set to be conducted in up to 60 clinical investigational sites ([NCT05762211](#)). Next steps include the routine DSMB review for ongoing safety for MaaT033, conducted every six months, with the next analysis expected for the first quarter of 2026.

MaaT033 is designed to reach an expanded patient population through its oral capsule administration that could address approximately 6,000 patients per year, with an estimated potential market of €500 million (EU5, US). By enabling outpatient use, MaaT033 also supports optimized patient care.

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 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.



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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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