



MaaT Pharma Announces First Patient Dosed in Phase 2b Randomized Clinical Trial Evaluating MaaT033 in Patients Receiving Allo-HSCT

- PHOEBUS is a Phase 2b randomized placebo-controlled trial investigating MaaT033 as an adjunctive therapy to improve 12-month overall survival rates for allogeneic hematopoietic stem cell transplant (allo-HSCT) patients
- MaaT033, the Company's second drug candidate, is a donor-derived full microbiome ecosystem capsule applicable for ambulatory care

Lyon, France, November 06, 2023, 7:30 am 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, announced today that the first patient has been treated as part of its Phase 2b trial, called PHOEBUS, investigating the efficacy of MaaT033 in improving overall survival (OS) at 12 months for patients with blood cancer receiving allo-HSCT. The trial is an international, multi-center, randomized, double-blind, placebo-control study ([NCT05762211](#)), which will be conducted in up to 56 clinical investigation sites and is expected to enroll 387 patients. It is to date the largest randomized controlled trial assessing a microbiome therapy in oncology.

“Today marks a significant milestone for us as our second product, MaaT033, enters Phase 2b clinical trials in allo-HSCT. The opportunity to offer patients a capsule that can be taken at home not only furthers our overall mission to improve patient survival in multiple situations, but also reinforces our leadership in the field, as we believe this program is currently the most advanced in the microbiome/hemato-oncology field,” **said Hervé Affagard, CEO and co-founder of MaaT Pharma.**

Prof. Florent Malard, Professor of Hematology at the Saint-Antoine Hospital and Sorbonne University, and principal investigator of the study added, *“A growing body of evidence indicates that gut imbalance leads to higher mortality in our field. By directly targeting to restore the gut microbiome richness in patients receiving harsh and deleterious treatments, our goal is to ensure optimal microbiome functions that can potentially lead to improved hematopoietic and immune recovery as well as overall survival.”*

To date, the Company has received regulatory approvals from France and Germany, and the clinical trial will be expanded to sites in additional countries subject to regulatory approval.

Study objectives:

- Primary endpoint: Overall Survival, evaluated in late 2026.
- Secondary endpoints include evaluation of safety and tolerability before and after allo-HSCT, and evaluation of the engraftment of beneficial microbial species from MaaT033.

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) in August 2023.

About Allogeneic hematopoietic stem cell transplantation (allo-HSCT)

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) for liquid tumors can replace cancerous cells, but the harsh conditioning treatments damage the gut microbiome, which has been linked to decreased survival, increased risk of graft-vs-host disease, and infections due to impaired immune function. Nearly 20,000 allo-HSCT transplantations per year in Europe were reported in 2021 by the European Society for Blood and Marrow Transplantation (EBMT) and continue to increase.

About MaaT Pharma

MaaT Pharma, a clinical-stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has launched, in March 2022, an open-label, single-arm Phase 3 clinical trial in patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of biomarkers for microbiome-related conditions. The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice. MaaT Pharma is listed on Euronext Paris (ticker: MAAT).



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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