



MaaT Pharma Confirms Positive Results from Completed Phase 1b CIMON Study Evaluating MaaT033 in Blood Cancer Patients

- Data describe rapid, safe and robust microbiome engraftment¹ of MaaT033 in the gut of patients with acute myeloid leukemia or high-risk myelodysplastic syndrome undergoing intensive chemotherapy and support the selection of a recommended dose for further development
- MaaT033 is an orally-administered high-richness, high-diversity, standardized, off-the-shelf, healthy-donors-derived Microbiome Ecosystem Therapy
- Company is on track with preparations for upcoming Phase 2/3 trial to evaluate MaaT033's efficacy in improving overall survival and preventing complications in patients with blood cancers receiving allogeneic hematopoietic stem cell transplantation

Lyon, France, June 2, 2022, 6:00 pm CET – [MaaT Pharma \(EURONEXT: MAAT – the “Company”\)](#), a French clinical-stage biotech and a pioneer in the development of Microbiome Ecosystem Therapies™ (MET) dedicated to improving survival outcomes for patients with cancer, today announced completion of its Phase 1b CIMON trial evaluating the safety and tolerability of MaaT033, the Company's high-richness, high-diversity MET for oral administration, in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (HRMS) having received intensive chemotherapy. In this study, performed in an immuno-compromised patient population, MaaT033 presented a good safety and tolerability profile, evaluated as the primary endpoint. The topline results also show rapid and persistent engraftment of MaaT033 in the patients' gut. The study data support the Company's preparation to initiate a Phase 2/3 trial later this year to evaluate MaaT033's ability to improve survival and prevent complications after allogeneic hematopoietic stem cell transplantation (allo-HSCT) in patients with blood cancers. Every year, approximately 22,000 patients require allo-HSCT in the seven major markets². MaaT033's oral formulation is designed to support long-term, ambulatory use, opening up new potential development opportunities for the Company. Today's announcement confirms previously-announced promising [interim results](#) of the trial, which allowed early completion of the study.

¹ Engraftment: Percentage of OTUs from the product that are detected in the patient's gut after treatment, and were not present before treatment.

² Seven major markets: USA, France, Germany, Italy, Spain, UK, Japan.

*“Parallel to the clinical successes of our lead candidate MaaT013, we developed MaaT033 as our first oral formulation, and the strength of the engraftment we have seen in these cohorts exceeds our expectations. Together with a good safety profile, this solid evidence for our first oral candidate is a crucial milestone for MaaT Pharma,” commented **Hervé Affagard, CEO and co-founder of MaaT Pharma.** “Allo-HSCT is a curative treatment of liquid tumors, that is unfortunately negatively impacted by two primary complications, graft-versus-host disease and severe infections, which hinder overall survival. We view the prevention of these adverse effects as the key to a better prognosis for these patients.”*

MaaT033 is designed to restore and maintain a healthy gut microbiome in patients with severe dysbiosis³ as a result of intensive chemotherapy and antibiotic treatment. Developed as an oral formulation in lyophilized capsules, its proprietary targeted-delivery design is conceived to optimize the product’s engraftment in the patient’s gut and its interaction with the immune system. Thanks to its high bacterial richness and Butycore™⁴ content, the product aims to reorient the gut microbial network towards immune homeostasis and restore the microbiome’s intestinal barrier function against infections.

*“We know from previous studies that AML patients are highly dysbiotic as a result of intensive chemotherapy and antibiotic therapy. From the CIMON trial data, we can be confident that MaaT033 results in robust levels of engraftment in the gut of AML patients at the targeted dose,” said **Prof. Christian Recher, Professor of Hematology at the Toulouse University Hospital/IUCT-Oncopole (France) and Principal Investigator of the study.** “This strong foundational data supports the launch of the next phase evaluating MaaT033 in preventing allo-HSCT complications in this patient population.”*

The CIMON Phase 1b trial ([NCT04150393](#)) was an open-label, dose-ranging study investigating the maximum tolerated dose of MaaT033 in patients with acute myeloid leukemia or high-risk myelodysplastic syndrome who have undergone intensive chemotherapy. The trial enrolled 21 patients in four dose escalation cohorts (up to three capsules a day for 14 days) across six sites in France. The trial allowed to select the recommended dose for MaaT033, which remains confidential at this stage. MaaT033 showed rapid and persistent engraftment with the detection of more than 60% of the MaaT033 microbial communities (OTUs⁵) in the patient’s gut post-exposure at the selected dose. Substantial engraftment was maintained during the treatment period and for at least three weeks after the end of treatment (last measure). Good tolerability of the candidate was also observed in this immunocompromised population, with only four serious adverse events (SAE) considered as unrelated to the treatment and one possibly related SAE (an infectious diarrhea event with no detection of the causal pathogen in the administered MaaT033 and patient recovery within four days). This is in line with the expected AE profile with standard of care treatments in this fragile population.

MaaT Pharma has performed a Scientific Advice procedure with the European Medicine Agency and will move forward with preparations for a Phase 2/3 randomized, double-blind, placebo-

³ Dysbiosis: disruption of the healthy relationship and balance between a person’s immune system and their gut microbiome. The gut microbiome is known to educate, modulate and reinforce our immunity throughout life.

⁴ Butycore™: a group of 15 bacterial genera known to produce immuno-modulatory short-chain fatty acids.

⁵ OTU or Operational Taxonomic Unit is used to classify bacteria at the genus level, based on sequence similarity of the 16S marker gene. An OTU consists of a group of bacteria whose 16S marker gene shows a sequence identity of 97 percent and above.

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controlled study in 340 patients, that will assess safety and tolerability of MaaT033 before and after allo-HSCT, as well as the efficacy of the candidate in improving overall survival and prevention of allo-HSCT complications. The trial initiation is planned by end of 2022. This is in line with the program announced during the Company's IPO in November 2021, and part of the funding raised during the IPO is allocated to the clinical development of MaaT033.

The Phase 1b CIMON topline data will be presented and discussed by Prof. Mohamad Mohty (Professor at Sorbonne University and Head of the Clinical Hematology and Cellular Therapy Department, Saint-Antoine Hospital, AP-HP, France) during the Company's upcoming Virtual R&D Day, which will be held on Tuesday June 7, 2022 ([register here](#)).

Complete trial results will be submitted for presentation and/or publication in a peer-reviewed forum.

About MaaT033

MaaT033 is an oral, full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness Microbiome Ecosystem Therapy™. MaaT033 is designed to restore the gut ecosystem to full functionality to improve clinical outcomes as well as to control adverse events related to conventional treatments for liquid tumors. The capsule formulation facilitates administration while maintaining the high and consistent richness and diversity of microbial species, including anti-inflammatory Butycore™ species.

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, a Phase 3 clinical trial for patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, supports the development and expansion of its pipeline by determining novel disease targets, evaluating drug candidates, and identifying 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).



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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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