



MaaT Pharma Announces Positive Interim Engraftment Data for Oral Formulation MaaT033 Allowing Early Termination of Phase 1b CIMON Study

- MaaT033 is a high-richness, high-diversity, donor-derived Microbiome Ecosystem Therapy for oral administration
- Four cohorts have completed the study in the dose-ranging Phase 1b CIMON trial with MaaT033 in patients with acute myeloid leukemia
- Proof-of-engraftment: MaaT033 achieves a good microbiome engraftment and engraftment persistence, together with a satisfactory safety profile
- Complete results for the trial are expected in the first half of 2022, and are expected to support the initiation of a Phase 2/3 trial planned in the second half of 2022

Lyon, France, January 24, 2022 – 7:30 am CET – [MaaT Pharma \(EURONEXT: MAAT - the “Company”\)](#), a French clinical-stage biotech and a pioneer in the development of microbiome-based ecosystem therapies dedicated to improving survival outcomes for patients with cancer, announced today positive interim engraftment data from the first four cohorts of the CIMON trial with MaaT033, the Company’s high-richness, high-diversity, Microbiome Ecosystem Therapy for oral administration. These results represent the first confirmation of MaaT033’s mechanism of action in humans. MaaT033 is the company’s second product in clinical development and is intended to improve survival in patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT), which represents approximately 22,000 patients every year in the 7 major markets. Its oral formulation, designed for targeted delivery in the intestine, may support long-term, ambulatory use.

In this dose-ranging study, data from four out of five intended cohorts showed satisfactory safety and good microbiome engraftment, which is characterized by the presence of microbial OTUs¹ in the gut as a result of product administration and that were not present at treatment start.

¹ 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.

Based on this positive data, the Company will close the CIMON trial to enable faster than planned completion and evaluation of the full data from the trial, in order to advance MaaT033 towards a planned Phase 2/3 trial, which could start in the second half of 2022. Complete results from the Phase 1b CIMON trial are expected in the first half of 2022.

“These interim results are an important milestone for MaaT Pharma as MaaT033 is our second drug candidate and our first oral formulation, to demonstrate proof of engraftment in humans,” said Hervé Affagard, CEO and co-founder of MaaT Pharma. “This expands the potential of our proprietary Microbiome Ecosystem Therapy (MET) platform to the ambulatory setting, after positive data achieved in aGvHD with MaaT013, an enema product for acute, hospital use. This is the first step towards treating larger patient populations that may benefit from orally-administered microbiome therapies, including patients receiving allo-HSCT, and also patients with solid tumors.”

MaaT033 is intended to improve survival outcomes in hemato-oncology patients receiving allo-HSCT by protecting and restoring their gut microbiome. In these patients, intensive chemotherapy and antibiotic treatments that are administered to prepare for the allo-HSCT procedure result in a severely damaged gut microbiome. Importantly, higher gut microbiome diversity at the time of allo-HSCT has been correlated to higher survival and lower risks of complications, including incidence of graft-vs-host-disease and multi-resistant infections².

“With a very satisfactory safety profile and very promising engraftment data in the first four cohorts of this trial, we believe we have the appropriate amount of data in hand to confidently move forward with MaaT033’s clinical development, without testing the highest planned dose of nine capsules a day,” added John Weinberg, MD, Chief Medical Officer at MaaT Pharma. “We look forward to further exploring the data from CIMON and preparing for a Phase 2/3 trial start.”

The CIMON Phase 1b trial ([NCT04150393](#)) is an open-label, dose-ranging study and has enrolled to date a total of 21 patients in four cohorts (up to three capsules a day for 14 days) across six sites in France. CIMON is designed to investigate the maximum tolerated dose of MaaT033, over 7 or 14 days of therapy, that supports optimal gut microbiome colonization in patients with acute myeloid leukemia or high-risk myelodysplastic syndrome who have undergone intensive chemotherapy. Overall, four Data and Safety Monitoring Board meetings have been conducted evaluating the safety of the trial. All concluded in support of the continuation of the study with the latest taking place in December 2021. Complete results from the trial will be submitted for a presentation at an upcoming key major conference in hemato-oncology as well as for peer-reviewed publication.

About MaaT033

MaaT033 is an oral, full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness Microbiome Ecosystem Therapy. It is manufactured at MaaT Pharma’s centralized European cGMP production facility. MaaT033 is designed to restore the gut ecosystem to full functionality to improve

² Peled, J.U. & al N Engl J Med 2020;382:822-34

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, which characterize MaaT Pharma's Microbiome Ecosystem Therapies.

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 already achieved proof of concept in a Phase II clinical trial in acute GvHD. Our powerful discovery and analysis platform, gutPrint®, supports the development and expansion of our 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).



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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