



MaaT Pharma indicates completion of Patient Recruitment for the Phase 2a Investigator-Sponsored Randomized Clinical Trial Evaluating MaaT013 in Combination with Immune Checkpoint Inhibitors in Metastatic Melanoma

- Last patient randomized in Phase 2a PICASSO trial, sponsored by AP-HP in collaboration with MaaT Pharma, INRAE and Institut Gustave Roussy, evaluating MaaT013 in melanoma in combination with Immune Checkpoint Inhibitors.
- Submission of the study's findings to a scientific journal is anticipated in the last quarter of 2024 or the first quarter of 2025.
- Topline results are scheduled for communication in the last quarter of 2024 or the first quarter of 2025.

Lyon, France, March 5th, 2024, 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 of patients with cancer, informs today on the completion of patient recruitment for the [Phase 2a clinical trial](#)¹ sponsored by AP-HP² and in collaboration with INRAE and Institut Gustave Roussy, evaluating MaaT013, the Company's lead product candidate, in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®).**

A total of 70 patients have been enrolled in 5 different centers in France in the randomized controlled Phase 2a PICASSO trial, which started in April 2022. The Company provided MaaT013 drug candidate and placebo and will contribute to the microbiome profiling of patients using its proprietary gutPrint® research engine. The unblinding will be done at Week 27 (W27) to assess the primary endpoint which is safety. In parallel, the first efficacy data will be made available, assessed by the best overall response rate, rated by immunological Response Evaluation Criteria in Solid Tumors (iRECIST; 19).

Having reached this key recruitment milestone, the first publication will be submitted at the end of 2024 or in the first quarter of 2025.

¹ [NCT0498884](#): Prospective randomized clinical trial assessing the tolerance and clinical benefit of fecal transplantation in patients with melanoma treated with CTLA-4 and PD-1 inhibitors.

² AP-HP: Assistance Publique - Hôpitaux de Paris

The PICASSO trial is funded by the Directorate of Health Care Supply (DGOS: *Direction Générale de l'Offre de Soins*) and operated by the French National Cancer Institute (INCa: *Institut National du Cancer*) as part of a call for projects (project PHRC-K19-183).

About MaaT013

MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, enema Microbiome Ecosystem Therapy™ for acute, hospital use. It is characterized by a consistently high diversity and richness of microbial species and the presence of Butycore™ (group of bacterial species known to produce anti-inflammatory metabolites). MaaT013 aims to restore the symbiotic relationship between the patient's functional gut microbiome and their immune system to correct the responsiveness and tolerance of immune functions and thus reduce steroid-resistant, gastrointestinal (GI)-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 launched, in March 2022, an open-label, single arm, phase 3 clinical trial in patients with acute GvHD (aGvHD), 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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