



MaaT Pharma Provides Third Quarter 2023 Business Update and Reports Financial Results

- Independent Data Safety Monitoring Board (DSMB) reviewing the Phase 3 ARES trial evaluating MaaT013 in aGvHD concluded on a positive benefit/risk ratio based on a good safety profile and positive preliminary efficacy results with an Overall Response Rate higher than pre-defined protocol assumptions
- Results from the Company's Early Access Program of MaaT013 in 111 patients with aGvHD to be presented at the 65th ASH Annual Meeting
- First patient dosed in the PHOEBUS Phase 2b randomized placebo-controlled trial evaluating MaaT033 in patients receiving allo-HSCT
- Preclinical data of MaaT034 presented at the 38th SITC Annual Meeting
- As of September 30, 2023, cash and cash equivalents were EUR 31.7 million¹
- Revenues of EUR 0.4 million in Q3 2023

Lyon, France, November 09th, 2023 – 6:00 pm 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, today provided a business update and reported its cash position as of September 30, 2023.

“The positive DSMB review of MaaT013 in its Phase 3 trial and the commencement of the MaaT033 Phase 2b trial underscores our leadership position in oncology-focused microbiome therapeutics. It also demonstrates our ability to execute our clinical plan and prepare for commercialization through expanded production capacities that were completed in Q3. We are proud to achieve these milestones and we will continue to work on generating value for our shareholders,” stated Siân Crouzet, CFO of MaaT Pharma. “Our progress and achievements put us in good stead as we look towards the months ahead and the completion of patient recruitment in the Phase 3 clinical study in 2024.”

Pipeline highlights

¹ Unaudited data

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MaaT013

- **In hemato-oncology:**
 - In July 2023, the Company announced that clinical data on MaaT013 as a treatment for aGvHD was published in [eClinicalMedicine](#), one of the Lancet Discovery Science suite of journals.
 - As a post period event, [in October 2023](#), the Company announced that the DSMB unanimously recommended that the open-label, single arm pivotal Phase 3 clinical trial evaluating MaaT013 in acute Graft-versus-Host Disease (aGvHD), named ARES, can continue without modification. The Overall Response Rate (ORR) was superior to pre-defined protocol assumptions. Therefore, the DSMB concluded that the benefit/risk ratio with “*high efficacy and low toxicity*” was favorable in this patient population.
 - As a post period event, in November 2023, the Company announced that extended results from its Early Access Program of MaaT013 in 111 patients (additional 30 patients included in the Program compared to last year) with aGvHD have been selected for poster presentations at the [65th American Society of Hematology \(ASH\) Annual Meeting](#).
- **In immuno-oncology:**
 - The Phase 2a PICASSO trial, evaluating MaaT013 in combination with immune checkpoint inhibitors in metastatic melanoma, is on schedule, and results should be available in late 2024 or early 2025.

MaaT033

- **In hemato-oncology:**
 - [In September 2023](#), the Company announced that the European Medicines Agency (EMA) had granted MaaT033 an orphan drug designation. MaaT033 aims to improve overall survival in patients undergoing hematopoietic stem cell transplantation (HSCT) and the EMA had recognized the significant benefit that MaaT033 could therefore bring to this patient population. The status offers key benefits including market exclusivity, clinical protocol assistance, waivers or reductions in regulatory fees.
 - As a post period event, [in November 2023](#), the Company announced that the first patient has been treated as part of its Phase 2b trial (PHOEBUS) investigating the efficacy of MaaT033 in improving overall survival at 12 months for patients with blood cancer receiving allo-HSCT. The international, multi-center, randomized, double-blind, placebo-control study ([NCT05762211](#)), 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.
 - As a post period event, in November 2023, the Company announced that the design of its Phase 2b study evaluating MaaT033 has been selected for a poster presentation at the [65th American Society of Hematology \(ASH\) Annual Meeting](#).
- **In neurodegenerative diseases:**

- In [September 2023](#), the Company announced that the first patient was dosed in the IASO Phase 1b pilot study ([NCT05889572](#)) in ALS (also known as Lou Gehrig's disease in the U.S. and Charcot's disease in French-speaking countries).

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MaaT034

- **In immuno-oncology:**

- As a post period event, [in November 2023](#), the Company had two presentations at the 38th Society for Immunotherapy of Cancer (SITC) Annual Meeting including in vitro results for its new Artificial Intelligence (AI)-generated lead product, MaaT034, designed to improve responses to immunotherapy for patients with solid tumors. MaaT034 is the first member of the MET-C platform. Data presented at SITC 2023 shows that MaaT034 replicates, at large industrial scale, the richness and diversity of healthy native-based microbiome ecosystems, restores the integrity of a damaged gut barrier, activates AhR pathway involved in gut homeostasis, and stimulates both myeloid and lymphoid immune cells and improves immune cell response to immune checkpoint inhibitor (ICI) therapy. The first clinical batches are expected to be produced in 2024 and the first-in-human testing is planned for 2025.

Corporate update

- [In July 2023](#), MaaT Pharma joined the Microbiome Therapeutics Innovation Group (MTIG).
- [In September 2023](#), the Company and Skyepharma announced completion of the cGMP manufacturing facility and the transfer of MaaT Pharma's Production and Development teams to the new site.

Cash position¹

- As of September 30, 2023, total cash and cash equivalents were EUR 31.7 million, as compared to EUR 35.1 million as of June 30, 2023, and EUR 35.2 million as of December 31, 2022. The net decrease in cash of EUR 3.4 million during the third quarter 2023 reflects continued investment in R&D activities across the pipeline, offset in part by partial reimbursement of the 2022 R&D tax credit of EUR 0.5 million. The Company believes it has sufficient cash to cover needs of the development programs into the second quarter of 2024.

Revenues in Q3 2023

- MaaT Pharma reported revenues from its compassionate access program of EUR 0.4 million for the quarter ended September 30, 2023 comparable with the third quarter of 2022. Total revenues for the first three quarters of 2023 amount to EUR 1.8 million compared with EUR

0.9 million for the first three quarters of 2022². This trend is a direct reflection of the continued demand from the medical community for MaaT Pharma's drug candidate MaaT013.

Upcoming investor and medical conference participation

- November 14-17, 2023 – London, UK Investor Meetings
- November 14-16, 2023 – Boston, MA – USA, Microbiome Connect
- November 15-17, 2023 – Lille, France, 22nd Société Francophone de Greffe de Moelle et de Thérapie Cellulaire (SFGM-TC) Congress - **Booth #12**
- December 9-12, 2023 – San Diego, CA – USA, 65th American Society of Hematology (ASH) Annual Meeting – **Posters presentation**
- January 8-12, 2024 – San Francisco, CA – USA, Investor Meetings

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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² The Company would like to correct a clerical error that was present in its Q2 results press release of July 27, 2023. The revenue from H1 2022 was EUR 0.5 million, and not EUR 0.9 million as reported in the press release. The EUR 0.9 million figure was the difference in revenue between H1 2023 and H1 2022 (EUR 1.4 million vs. EUR 0.5 million).