



## MaaT Pharma Provides Second Quarter 2023 Business Update and Reports Financial Results

- Data presented at 49th Annual Meeting of EBMT 2023 confirms clinical benefit of MaaT013 in Acute Graft-versus-Host Disease (aGvHD) in the early access program
- Clearing of the IND for MaaT013 by the FDA in patients with aGvHD
- PHOEBUS, a Phase 2b randomized placebo-controlled trial assessing MaaT033's impact on overall survival in allo-HSCT patients is now anticipated to start in H2 2023
- As of June 30, 2023, cash and cash equivalents were EUR 35.1 million<sup>1</sup>
- Revenues of EUR 0.7 million<sup>1</sup> in Q2 2023

**Lyon, France, July 27<sup>th</sup>, 2023 – 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 provided a business update and reported its cash position as of June 30, 2023 and its revenues for the second quarter of 2023.

*"As a leading microbiome company in oncology, we are proud of the progress made in the second quarter of 2023. We are particularly pleased with positive interactions with international regulatory agencies, such as the FDA's clearance of the IND application, which paves the way for bringing MaaT013 to patients. We remain aligned with our strategy to pursue the development of MaaT013 towards its registration in the treatment of aGvHD. Additionally, we are on the brink of launching the largest, to our knowledge, randomized study in hemato-oncology with a microbiome therapy, as we finalize preparation for the Phase 2 trial of MaaT033,"* **commented Hervé Affagard, CEO and co-founder of MaaT Pharma.** *"In the upcoming months, we will continue to deliver on the plans presented during our IPO to investors, patients, and the global community."*

### Pipeline highlights

#### MaaT013

- **In onco-hematology:**
  - [In April 2023](#), MaaT013 clinical results in its early access program for 81 patients, previously announced at American Society of Hematology (ASH), were presented during the 49<sup>th</sup> Annual Meeting of the European Society for Blood and Marrow Transplantation

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<sup>1</sup> Unaudited data

(EBMT 2023). Clinical results showed a GI-Overall Response Rate (GI-ORR) of 56% with a 12-month overall survival (OS) of 59% in patients responding to MaaT013 treatment. A 65% ORR was observed in 31 patients being a similar population to those treated in MaaT Pharma's ongoing pivotal Phase 3 [ARES clinical trial](#) (3rd-line therapy after failure to 2nd-line ruxolitinib treatment); 12-month OS in this group responding to MaaT013 treatment was 74%. As a reminder, overall survival in ruxolitinib-resistant patients at 2 months is 22% (REACH1 study).

- In [April 2023](#), the U.S. Food and Drug Administration (FDA) lifted the clinical hold and cleared the Investigational New Drug (IND) application for MaaT013 in patients with aGvHD. MaaT Pharma intends to consult with the FDA on the next steps of the regulatory process to bring MaaT013 to US patients in the most expeditious way possible while the Company continues the late-stage clinical development of MaaT013 in Europe with the ongoing international multicenter, open-label, single arm, pivotal Phase 3 trial (ARES).
  - The Company announces that the independent data safety and monitoring board (DSMB) meeting, after enrollment of half of the patients in the ARES study evaluating MaaT013 in aGvHD, is expected in H2 2023, as opposed to H1 2023, while the ORR is expected mid-2024.
  - In parallel to the ARES trial, the European Early Access Program (EAP) continues to gather significant interest from healthcare professionals with the number of patients treated in H1.2023, significantly higher than that of H1.2022.
  - As a post-period event, 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's journals. The data includes results from 24 patients in a Phase 2 clinical trial and 52 patients enrolled in the EAP in France. The article can be accessed [here](#).
- **In immuno-oncology:**
    - The [PICASSO](#) study, sponsored by APHP, is on track for data readout expected in H2 2024. This is the only double-blind randomized clinical trial in the field evaluating a microbiome approach (MaaT013) to enhance the efficacy of immune checkpoints inhibitors (ICI) treatments in patients with metastatic melanoma.
    - With more than half of the patients now having completed their week 9 visit, the Company is in a position to receive biological biomarker data from its partner.

### **MaaT033**

- **In onco-hematology:**
  - [In April 2023](#), MaaT033 data of Phase 1b study CIMON, previously presented at ASH 2022 annual meeting, were also shared at the EBMT 2023. The Company's second drug candidate was shown to be safe and tolerable in 21 patients. This is an important milestone prior to embarking on subsequent clinical development of MaaT033 and for establishing the dose determination for the Phase 2b PHOEBUS.
  - During the period, and following the positive feedback received from the FDA in April 2023 clearing the IND for MaaT013, the Company incorporated learnings related to its proprietary pooling technology into its clinical development plan envisaged for its

second clinical-stage product MaaT033. In parallel, the clinical protocol of the Phase 2b randomized placebo-controlled PHOEBUS trial was reviewed in a Scientific Advice with EMA, with a positive outcome and no consequences on the authorizations already received in France and Germany [in March 2023](#). Consequently, the start of the PHOEBUS trial, initially planned to start in Q2 2023 is now expected in H2 2023. This trial will assess MaaT033's impact on overall survival in allo-HSCT patients.

- **In neurodegenerative diseases:**

- The IASO Phase 1b pilot study ([NCT05889572](#)) in ALS (also known as Lou Gehrig's disease in the US and Charcot's disease in French-speaking country) is active and ready for the first patient to be dosed.

## Corporate update

- On June 19, 2023, all resolutions presented during the AGM were adopted in line with Board recommendations. For further information, please visit: <https://www.maatpharma.com/investors/#GM>
- [In June 2023](#), MaaT Pharma announced new appointments to the Board of Directors and Executive team, to align with the Company's long-term vision and goals:
  - Karim Dabbagh as Chairman and Nadia Kamal as Director, both independent.
  - Pr. Gervais Tougas, acting Chief Medical Officer and Philippe Moyen, Chief Operating Officer.
- [In June 2023](#), MaaT Pharma announced the appointment of Guillaume Debroas as Head of Investor Relations.
- As a post period event, [in July 2023](#), MaaT Pharma announced having joined the Microbiome Therapeutics Innovation Group (MTIG). MTIG is a coalition of companies leading the research and development of FDA-approved microbiome therapeutic drugs and microbiome-based products to address unmet medical needs, improve clinical outcomes, and reduce health care costs.

## Cash position<sup>1</sup>

- As of June 30, 2023, total cash and cash equivalents were EUR 35.1 million, as compared to EUR 40.7 million as of March 31, 2023, and EUR 35.2 million as of December 31, 2022. The net decrease in cash of EUR 5.6 million during the second quarter 2023 reflecting the continued investment in R&D activities across the pipeline and includes partial reimbursement of the 2022 R&D tax credit for EUR 2.3 million. The Company believes it has sufficient cash to cover needs of the development programs into the second quarter of 2024.

## Revenues in Q2 2023<sup>1</sup>

- MaaT Pharma reported revenues<sup>2</sup> from its compassionate access program of EUR 0.7 million for the quarter ended June 30, 2023, comparable with EUR 0.7 million for the first quarter of 2023. Total revenues for the first half of 2023 amount to EUR 1.4 million compared with EUR 0.9 million for the first half of 2022. This trend is a direct reflection of the continued demand from the medical community for drug candidate MaaT013.

## Upcoming financial communication and investor conference participation

- September 26, 2023 – Half-year Results 2023\*
- September 27, 2023 – 6th edition - Forum LPB Valeurs Régionales
- October 4, 2023 – KBC Securities Life Sciences Conference
- October 4-5, 2023 – Portzamparc Seminar Biotech & Health
- October 9-10, 2023 – Investor Access Event

*\*Indicative calendar that may be subject to change.*

### 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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<sup>2</sup> Revenues correspond to compensation invoiced in relation to the compassionate access program, as approved by the French National Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM).