

# MaaT Pharma Provides a Business Update and Highlights Key Milestones Expected in 2024

- Positive efficacy and safety data of MaaT013 in aGvHD in the Early Access Program
  presented at the EBMT 2024 annual meeting with 63% GI-ORR at D28, a 49% one year and
  42% 18 months Overall Survival (OS) in patients similar to those included in the ARES Phase
  3 clinical trial.
- Primary endpoint readout, GI-ORR at D28, of the ARES Phase 3 clinical trial in aGvHD expected for mid Q4-2024.
- Production of batches of MaaT013 destined for clinical supply in the US.
- Participation in a randomized multicenter investigator-sponsored Phase 2 trial evaluating MaaT033 concomitant to anti-PDI treatment in advanced lung cancer patients. This trial is sponsored by Institut Gustave Roussy, steering cutting-edge research in the microbiome field, as part of the IMMUNOLIFE program, a consortium including researchers and biotech companies.
- Completion of patient recruitment for the Phase 1 clinical trial IASO, evaluating MaaT033 for patients with Amyotrophic Lateral Sclerosis.

Lyon, France, May 07, 2024 - 6:30 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 highlights its key milestones for 2024.

Hervé Affagard, CEO and co-founder of MaaT Pharma said: "We're confidently advancing towards Phase 3 results for MaaT013, meeting milestones and delivering value for shareholders. Recent data at the EBMT annual congress underscores MaaT013's potential in aGvHD where therapeutic options are insufficient. We are also thrilled to partner with Institut Gustave Roussy (IGR), a world-renowned center in cancer treatment to explore MaaT033's impact on immune checkpoint inhibitors' response in non-small cell lung cancer patients, and therefore deepening our development in immuno-oncology. This collaboration further strengthens MaaT Pharma's leading position in oncology and the medical community's interest in microbiome drug candidates."

# **Pipeline highlights**

### **MET-N**

### MaaT013

# • In hemato-oncology:

- o In March 2024, the Company announced the launch of a retrospective multicenter trial called CHRONOS in Europe. Its objective is to provide the Company efficacy data for 3rd-line therapies for patients not receiving MaaT013 or any microbiome intervention. This study was not requested by regulatory authorities and does not impact cash projections as funding has already been secured.
- o In April 2024, at the 50<sup>th</sup> annual meeting of the European Society for Blood and Marrow Transplantation (EBMT), the Company presented positive efficacy and safety results in 140 patients treated with MaaT013 in acute graft-versus-host disease (aGvHD) as part of the Early Access Program (EAP). The data presented demonstrates a clear reduction in disease burden and an improved Overall Survival (OS), and highlighted MaaT013's good safety profile. The results in the 49-patient "ARES-like" subgroup, with the same characteristics as those of the Phase 3 ARES trial (NCT04769895) demonstrated 63% GI-ORR at D28 and Overall Survival (OS) of 49% at one year and 42% at 18 months. This represents a significant increase when compared with the historical data published by Abedin et al. (used by the medical community as the most recent reference) which showed a limited 15% OS at one year in a similar population.
- o Primary endpoint readout, GI-ORR at D28, of the ARES Phase 3 clinical trial in aGvHD is expected for mid Q4-2024.

# • In immuno-oncology:

o In March 2024, the Company informed on the completion of patient recruitment for the Phase 2a clinical trial PICASSO (NCT04988841) sponsored by AP-HP and in collaboration with INRAE and Institut Gustave Roussy, evaluating MaaT013 in combination with Immune Checkpoint Inhibitors (ICI). Topline results expected in Q4 2024/Q1 2025.

# MaaT033

# • In immuno-oncology:

o MaaT Pharma announces its participation in the IMMUNOLIFE RHU1 program, a consortium including academic partners, such as Institut Gustave Roussy (IGR), a world-renowned center in the field of cancer treatment, and biotech companies. IMMUNOLIFE aims to solve the significant problem of primary resistance to immune checkpoint inhibitors (ICI) observed in advanced non-small cell lung cancer (NSCLC) patients following antibiotic uptake. MaaT033, an oral, pooled fecal microbiotherapy, developed

Contract No ANR-21-RHUS-0017 - RHU stands for Recherche Hospitalo-Universitaire - University Hospital Research

by MaaT Pharma will be tested as a concomitant treatment to anti-PD1 therapy to increase the ICI response rate in this Phase 2 randomized multicenter clinical trial including advanced NSCLC patients. Participation in this program will also grant access to clinical and metagenomic data from a large cohort of cancer patients (bladder, lung and renal) which will be used to improve MaaT Pharma's artificial intelligence (AI) gutPrint® platform. The related costs for MaaT Pharma are limited to clinical product supply in line with previous cash projections.

# In neurodegenerative diseases:

- o In <u>February 2024</u>, the Company announced that the Data Safety and Monitoring Board (DSMB) reviewed safety data in the first 8 patients with Amyotrophic Lateral Sclerosis (ALS) treated with MaaT033 in the Phase I clinical trial IASO (NCT05889572). The DSMB, composed of 4 independent experts, including an ALS patient association representative, concluded that safety was good and recommended that the trial continue without modifications.
- o MaaT Pharma announces the completion of patient recruitment for IASO.

# **MET-C**

### MaaT034

# • In immuno-oncology:

o In April 2024, at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego, California, the Company presented <a href="new in vitro data">new in vitro data</a> characterizing the metabolites produced by MaaT034 and their impact on immune modulation. MaaT034 may be the first full-co-cultivated ecosystem therapy for immuno-oncology, combining a diverse array of supportive species with functional networks of interest to improve the response to immune checkpoint inhibitors. The results demonstrate that MaaT034 produced key metabolites, recognized as promoting gut barrier restoration and modulating immune responses. This represents a significant advancement in understanding the mechanism of action (MoA) of co-cultured microbiome therapies developed by MaaT Pharma marking a major step towards clinical evaluation.

# **Corporate update**

- In March 2024, the Company announced the appointment of Jonathan Chriqui, PharmD, as Chief Business Officer and member of the executive management team. Jonathan will be responsible for MaaT Pharma's business development and partnering strategies, increasing the Company's ability to secure partnership deals, in line with its strategic objectives.
- MaaT Pharma has engaged in active discussions with prominent US clinicians in the field of stem cell transplantation to explore the most efficient path forward to introduce MaaT013 to patients in the United States. The Company is pleased to announce the production of batches of MaaT013 destined for clinical supply in the US as the Company pursues the readiness phase in advance of clinical study initiation.

The Company believes it has sufficient cash to finance operations to the end of Q3 2024.
 While the Company does not have sufficient cash to finance its operations for the next twelve months, it has active ongoing discussions to finance operations beyond the end of Q3 2024 and remains confident in extending its cash runway.

# **Key value creation milestones in 2024**

### MaaT013

- Mid-Q4: Primary endpoint readout (GI-ORR at D28) from the ARES Phase 3 clinical trial in aGvHD
- Q4 2024/Q1 2025: Topline results of the PICASSO Phase 2a clinical trial in metastatic melanoma

#### MaaT033

- o H2 2024: First DSMB<sup>2</sup> of the PHOEBUS Phase 2b clinical trial in allo-HSCT
- o H2 2024: Results of the IASO Phase 1 clinical trial in ALS

### MaaT034

- o H1 2024: Candidate selection
- o H2 2024: Start of the production of the first cGMP batch

# **Upcoming investor and business conferences participation**

- June 3-6, 2024 BIO 2024
- June 11-12, 2024 Portzamparc Mid & Small Caps 2024 Conference
- June 25-27, 2024 Stifel European Healthcare Summit Lyon
- July 10-12, 2024 Microbiome Movement Drug Development Summit

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#### **About MaaT Pharma**

MaaT Pharma, a leading 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 initiated an open-label, single-arm Phase 3 clinical trial in patients with acute GvHD, building on the positive results of its Phase 2 proof-of-concept study. 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

<sup>&</sup>lt;sup>2</sup> at the recruitment of 60 patients

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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