



## MaaT Pharma Provides Business Objectives and Expected Milestones for 2022

- Important clinical milestones are expected in 2022 in the Company's hemato-oncology and immuno-oncology programs.
- MaaT013, the Company's lead Microbiome Ecosystem Therapy, is ready to enter Phase 3 in the treatment of acute Graft-versus-Host Disease (aGvHD).
- Clinical results are expected in H1 2022 for MaaT033, the company's oral capsule formulation designed to prevent complications of allogeneic hematopoietic stem cell transplantation (allo-HSCT).

**Lyon, France, January 17, 2022 – 6:00 pm 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**, today provides business objectives and clinical milestones for 2022.

*"Despite the ongoing pandemic, 2021 was a turning point in MaaT Pharma history, as we became the first microbiome therapeutic company to be listed on Euronext, we established a Phase 2 proof of concept with MaaT013 in acute Graft-vs-Host-Disease, and we expanded our hemato-oncology program with the initiation of a Phase 1b trial of MaaT033, our oral formulation," stated Hervé Affagard, CEO and co-founder of MaaT Pharma. "We expect new achievements in 2022, with 3 clinical programs either ongoing or starting. This year should see key clinical milestones in hemato-oncology with MaaT013 ready to enter Phase 3 and new clinical data for MaaT033 expected in the first half of 2022. Moreover, our immuno-oncology program leveraging a new generation of products, MaaT03X to address solid tumors, is currently in nonclinical validation. Since our creation, we have been pioneering the development of Microbiome Ecosystem Therapies to bring these innovations to millions of patients fighting cancer globally."*

### Expected milestones in 2022

#### Hemato-oncology– Clinical programs:

**MaaT013 for the treatment of aGvHD** (Orphan Drug Designation by the FDA and the EMA):

- **MaaT013** is a full-ecosystem, off-the-shelf, standardized, pooled-donor Microbiome Ecosystem Therapy for enema administration.
- MaaT013 is ready to start its **pivotal Phase 3 in Europe**. MaaT Pharma has already received regulatory authorization to start this trial in France and Germany. The Company will communicate upon the inclusion of the first patient (FPI).
- The initiation of the clinical trials for MaaT013 in the United States will depend on the outcome of ongoing exchanges with the Food and Drug Administration (FDA) in response to the August 2021 clinical hold letter regarding the IND for MaaT013 in the US.
- MaaT013 has been successfully evaluated in Phase 2 clinical trial in patients with steroid-resistant grade III-IV gastro-intestinal (GI) aGvHD as well as in an ongoing compassionate use program (EAP) in France in patients with Grade II-IV GI-aGvHD having failed previous therapies, [with promising results](#).
- To date, **more than 100 patients with aGvHD** have been safely treated with MaaT013, including:
  - 24 patients in the [Phase 2 trial](#).
  - 96 patients in the Early Access Program in France (EAP). This program has also been an opportunity for the Company to strengthen its supply chain and manufacturing capacities to deliver MaaT013 regularly and safely to 18 hospital transplant centers as of today.
  - Additionally, MaaT Pharma has recently honored two requests for compassionate use of MaaT013 originating from two other European countries.

#### **MaaT033 for the prevention of complications due to allogeneic hematopoietic stem cell transplantation (allo-HSCT)**

- **MaaT033** is a donor-derived, standardized, high-richness, high-diversity Microbiome Ecosystem Therapy for oral administration.
- MaaT033, is currently being evaluated to define dose regimen in a **[Phase 1b clinical trial in patients](#)** with acute myeloid leukemia (AML) following intensive chemotherapy.
- There have been 4 meetings of an independent safety review Board (DSMB) to date evaluating the safety of the trial and that concluded in [support of the continuation](#) of the study.
- In Q1 2022, the Company will provide **interim results of engraftment data** for the Phase 1b clinical trial.
- Complete results are **expected in the first half of 2022** and a pivotal Phase 2/3 may be initiated at the end of 2022 to evaluate MaaT033 as a prophylactic treatment for blood cancer patients undergoing allo-HSCT.

#### **Immuno-oncology – Clinical and nonclinical programs**

##### **MaaT013 for the improvement of a patient's response to Immune Checkpoint Inhibitors (ICI) – proof of concept clinical trial sponsored by AP-HP**

- MaaT013 is ready to enter a randomized, placebo-controlled **Phase 2a trial** to evaluate its effect on the efficacy of ICI **treatment in patients with metastatic melanoma**. AP-HP is the sponsor of this trial. MaaT Pharma will supply the drugs and perform the microbiome profiling of patients using its proprietary gutPrint® platform.
- French regulatory authorities have approved the trial and the Company will communicate upon inclusion of the first patient.

### **MaaT03X for the increase in the response rate to Immune Checkpoint Inhibitors in patients with solid tumors**

- **MaaT03X** is a fermented, high diversity, rationally designed Microbiome Ecosystem Therapy for oral administration. MaaT03X's design is based on clinical and microbiome data analyses from hundreds of patients.
- MaaT Pharma is leveraging its proprietary **gutPrint®** computational biology platform and full ecosystem **co-fermentation technology** to develop this new generation of candidates.
- The first MaaT03X candidate is **currently in nonclinical testing** and will aim to improve the anti-cancer efficacy of ICI in patients with an undisclosed solid tumor with a high unmet need. A first clinical study is expected to start in the first half of 2023.
- In 2021, the MaaT03X program received a **€1.9M grant** to support industrialization of the manufacturing process.

### **cGMP manufacturing facilities**

- MaaT Pharma has entered negotiations with a potential partner to secure the expansion of the Company's cGMP manufacturing capacities, as stated in a letter of intent signed in November 2021. A new cGMP manufacturing plant, entirely dedicated to the Company's high-diversity and high-richness Microbiome Ecosystem Therapies, would be built in the Auvergne-Rhône-Alpes region allowing the Company to operate its own equipment and processes while benefitting from full associated cGMP services provided by the partner. **Contracting is expected to take place in H1 2022.**

### **Initiation of coverage of MaaT Pharma stock**

To date, three brokerage firms have initiated coverage of MaaT Pharma (EURONEXT: MAAT):

- Dec. 2021 - KBC Securities: research report *"More than a Gut Feeling"*
- Dec. 2021 - Kempen: research report *"No Guts no Glory"*
- Jan 2022 - Portzamparc / Groupe BNP Paribas: research report *"Échec et MaaT pour le cancer"*

### **2022 Financial calendar**

- February 28, 2022 – **Revenues and Cash Position** as of December 31<sup>st</sup>, 2021
- April 15, 2022 – **Annual Results** 2021
- May 05, 2022 – **Revenues and Cash Position Quarter 1**

- May 23, 2022 – **General Meeting**
- July 28, 2022 – **Revenues and Cash Position Quarter 2**
- September 29, 2022 – **Half-year Results** (April – September)
- November 08, 2022 – **Revenues and Cash Position Quarter 3**

## 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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