MaaT Pharma Provides Corporate Update and Highlights Key Expected Milestones in 2023

Lyon, France, January 24, 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,** provides a corporate update highlighting the progress, adjustments to clinical programs and key development milestones expected in 2023.

"MaaT Pharma has delivered important clinical milestones during 2022 including the expansion of its development pipeline with the launch of two clinical trials for its lead drug candidate, MaaT013 in hemato-oncology (Phase 3) and in immuno-oncology (Phase 2a). The year 2022 also marks an important milestone for the global microbiome industry with the regulatory approvals of the first microbiome-based drugs by the FDA in the U.S. and by the TGA in Australia," **stated Hervé Affagard, CEO and co-founder of MaaT Pharma.** *"Despite difficult market conditions, we continue to advance our pioneering science and technology and we remain focused on delivering new therapeutic solutions to the benefit of patients with severe conditions as well as building value for our shareholders. 2023 will be a year with important inflection points and will require us to act decisively to reach our objectives. We thank our investors for their support throughout this year, and their confidence in our ability to achieve the next level of corporate development."*

Clinical development

Hemato-oncology

MaaT013, a full-ecosystem, standardized, pooled-donor native Microbiome Ecosystem Therapy for acute, hospital use (enema administration)

MaaT013 for the treatment of acute Graft-versus-Host Disease (aGvHD): MaaT013 has received an Orphan Drug Designation by both the U.S. Food and Drug Administration (FDA) and the European Medical Agency (EMA).

- MaaT013 is currently being evaluated in Europe in an ongoing international multicenter open-label, single arm, pivotal Phase 3 trial (ARES) in 75 patients with steroid-resistant gastrointestinal aGvHD. The Company has received full regulatory approvals in the following countries, which is more than initially envisioned: Austria, Belgium, France, Germany, Italy, and Spain. A safety and efficacy data review will be conducted by an independent data safety and monitoring board (DSMB) after enrollment of half of the

patients in the study. The review is expected in the first half of 2023 and the Company will communicate the DSMB's recommendations following the review.

- The initiation of clinical trials following the Investigational New Drug (IND) application for MaaT013 in the United States (U.S.) will depend on the outcome of ongoing exchanges with the FDA in response to the August 2022 continued clinical hold letter. The most recent communication received by the Company from the FDA stated that the complete response provided by the Company in response to the letter received in August 2022, was still under review. Feedback could be expected in the early part of 2023 and the Company will update investors accordingly. The Company understands that the FDA's Center for Biologics Evaluation and Research (CBER) that currently hosts all microbiome-based drug candidates, continues to prioritize their work to advance the nation's response to the COVID-19 public health emergency, which is creating additional delays. Despite this, the Company remains focused on achieving regulatory approval for MaaT013 in the U.S. and providing a therapeutic solution for patients in the country.
- MaaT013 has already been successfully evaluated in a Phase 2 clinical trial in patients with steroid-resistant grade III-IV gastro-intestinal (GI) aGvHD (HERACLES) 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 presented at the 2022 American Society of Hematology (ASH) conference in an oral presentation and in a poster at the 2022 edition of the International Human Microbiome Consortium (IHMC). The compelling data demonstrates that the pooled microbiota product is well tolerated and shows a good safety profile in a fragile patient population. Efficacy of MaaT013 correlates with engraftment of the product's microbial species in the gut and clinical response to MaaT013 translates to increased overall survival in patients with aGvHD.

MaaT033, a donor-derived, standardized, high-richness, high-diversity Microbiome Ecosystem Therapy for oral administration, currently being developed as an adjunctive and maintenance therapy to improve overall survival in patients receiving HSCT[1].

MaaT033 for the improved survival of patients with hematological malignancies receiving allo-HSCT

- Based on promising results following the Phase 1b trial presented at the 2022 edition of the ASH annual meeting, and learnings from this study, along with an in-depth review of the Protocol Assistance with the EMA, and discussions with potential partners showing an interest in the license and commercialization of MaaT033 in this therapeutic area, the Company has optimized and adjusted the protocol for the Phase 2b trial of MaaT033 (PHOEBUS). In this context and given the strategic importance of the trial, the Company has decided to take over the sponsorship of the clinical trial in Europe. At the time of the IPO, it was anticipated that AP-HP[2] would sponsor the trial in France as an Investigator-sponsored trial. The study is expected to start in Q2 2023 and would now be conducted in Europe in accordance with EMA recommendations. The number of patients enrolled in

[1] *HSCT= Hematopoietic stem-cell transplantation*
[2] *AP-HP = Assistance Publique - Hôpitaux de Paris*

the study would expand from 341 to 387 and the number of sites would be increased from 20 to 56, enabling the recruitment period to be reduced from 36 to 24 months.
- While the primary endpoint of the study is to evaluate the efficacy of MaaT033 in improving overall survival at 12 months, secondary endpoints would include the evaluation of safety and tolerability before and after allo-HSCT, and the evaluation of the engraftment of beneficial microbial species from MaaT033 and the activity in preventing allo-HSCT complications (infections, GvHD).
- Additional readouts have been included throughout the 24-month recruitment period, such as interim safety analysis with stopping rules[3] when the trial has enrolled and randomized, respectively, 60 and 120 patients.
- The expected timelines including the overall survival endpoint (data to be expected in H1 2026) announced by MaaT Pharma during the IPO should be confirmed based on the adjustments mentioned above.
- In parallel to starting the trial in Europe, the Company plans to discuss this program with the FDA upon conclusion of ongoing dialogues with the Agency regarding its pooling technology.

Immuno-oncology – Clinical and nonclinical programs

MaaT013 for the improvement of patients' response to Immune Checkpoint Inhibitors (ICI) – proof of concept Phase 2a clinical trial sponsored by AP-HP

- The proof-of-concept double blind randomized Phase 2a clinical trial, PICASSO (n=60), initiated in April 2022, evaluating MaaT013's impact on the efficacy of ICI treatments (ipilimumab + nivolumab) in patients with metastatic melanoma, remains on track as planned.
- This trial is an Investigator-sponsored trial by AP-HP, where MaaT Pharma supplies drug candidates and performs the microbiome profiling of patients using its proprietary gutPrint® platform.
- Key study endpoints after 23 weeks of treatment include MaaT013's safety profile and best-overall response rate *vs* placebo as an add-on treatment to ipilimumab + nivolumab.
- The Company is expected to receive biological biomarker data in H1 2023 after half of the patients have been enrolled and achieved their evaluation 9 weeks after randomization.
- Results are expected in H2 2024, as planned.

MaaT03x, a new generation high richness, co-cultured, designed Microbiome Ecosystem Therapy™ in oral formulation for the increase in the response rate to ICI in patients with solid tumors - currently in preclinical testing.

- As MaaT03x is expected to be used in large markets, MaaT Pharma has been focused on increasing the level of readiness and decided to enter a Phase 1b trial in Europe and the U.S. in the first half of 2024, as opposed to the second half of 2023 as initially announced.

[3] *A stopping rule is a set of safety criteria primarily used to determine when the study needs to be paused or halted.*

This is a result of changes and adjustments following announcements of first regulatory approvals for microbiome-based products and the Company's work for the development of its native products (MaaT013 & MaaT033) in Europe. MaaT Pharma is consolidating *in vivo*/*in vitro* data, continuing product development characterization and conducting regulatory readiness of MaaT03x. Preclinical data are expected to be shared at scientific conferences in 2023.

- MaaT Pharma has initiated early interactions with the EMA in 2022 including a meeting with the EMA's Innovation Task Force (ITF). Further interactions in Europe are expected to take place in 2023. The Company is also planning early interactions with the FDA in H1 2023 to present its MaaT03x platform and has already filed a meeting request.
- The Company will be able to strengthen its intellectual property (IP) portfolio in France and internationally thanks to the co-cultured new generation products. Currently, the Company holds the IP for 14 patent families.

Therapeutic pipeline extension

Recent studies have highlighted the importance of the microbiota-gut-brain axis and the impact of the gut microbiome in brain diseases. Interestingly, patients with neurodegenerative disorders display both central nervous system (CNS) and gastrointestinal symptoms[4]. In parallel, scientific research has started to shed light on the role of the gut microbiome, linking abnormalities to diseases such as Amyotrophic lateral sclerosis (ALS[5]). The link between gut microbiota and ALS first emerged from preclinical evidence and then from clinical observations indicating a disease-modifying role for the gut microbiome. To date, there is no effective treatment for ALS, a disease that leads to death within an average of 3-5 years after diagnosis[6]. ALS affects nerve cells in the brain and the spinal cord causing loss of muscle control. Since its inception, MaaT Pharma has been committed to restoring a microbial symbiosis in life-threatening diseases with high unmet clinical needs. Growing evidence suggests that ALS patients show increased inflammation in the gut with changes in the composition of gut microbes and low levels of beneficial bacteria.

MaaT Pharma has decided to extend its scientific research to the management of ALS, which could pave the way for the treatment of several neurodegenerative diseases. The Company is leveraging the strong safety profile of its native MET products (MaaT033/MaaT013) and their inherent product characteristics of promoting immune modulation/anti-inflammatory properties and acting as a homeostasis hub. The number of ALS cases is expected to increase substantially in the developing world over the next 25 years and could reach a total of 60,000 patients in U.S. and Europe by 2040[7]. Every year, 5,000 new patients are diagnosed in the U.S. and in Europe and the incidence of ALS ranges from 3 to 4 per 100,000 person-years[7].

[4] *Gebrayel et al, J Transl Med, 2022, Singh et al, J Clin Invest. 2021*
[5] *Rowin et al., 2017; Nicholson et al, 2021; Blacher et al, 2019, Mazzini et al, 2020*
[6] *https://tousensellescontrelasla.fr/la-sla-cest-quoi/*
[7] *Longinetti.et.al 2019, Arthur, K., Calvo, A., Price, T. et al., US Centers for disease control and prevention - National ALS Registry 2016*

Leveraging 12 months of feasibility assessment in MaaT Pharma's Discovery team, the Company expects to initiate in H1 2023 a Phase 1b pilot study in ALS evaluating MaaT033 to slow down disease progression. The study, developed with experts from the ALS network (FILSLAN and ACT4ALS-MND) and strongly supported by the French patient association *(Tous en Selles contre la SLA)*, will enroll up to 15 patients presenting initial motor deficit i.e., at least 6 months up to 24 months at the time of the screening. This pipeline expansion to a new indication demonstrates the strong potential of MaaT033 to be used in an acute or chronic setting as a standalone, adjunctive and maintenance therapy. Data readout from the pilot study is expected for the first half of 2024.

If this initial trial is successful, the Company could extend further to other chronic diseases/ immuno-inflammatory diseases as MaaT Pharma collects data and strengthens in-depth understanding of the mechanism of action. Funding for the trial is already secured and the program has been designed to minimize the risk and not impact the Company's lead programs in oncology. The key study endpoints are assessment of safety and tolerability of multiple doses of MaaT033, the assessment of gut microbiota composition evolution and the identification of biomarkers sensitive to treatment before considering a larger randomized controlled efficacy study.

cGMP manufacturing facilities

MaaT Pharma is currently building its future manufacturing facilities, in partnership with Skyepharma. The 1600m^2 facility will be able to support the needs of clinical and commercial production of its native MET (MaaT013 & MaaT033), R&D and clinical batches of cultured products, MaaT03x, up to 2034.
Funding is secured and the completion of the facility is expected in mid-2023. Under the terms of the partnership agreement, MaaT Pharma will retain the know-how of its bio-manufacturing processes and agility (full command end-to-end manufacturing processes), while leveraging Skyepharma's experience in running a cGMP facility. Having this facility is a strong competitive advantage for a late-stage company preparing for commercial phase, which MaaT Pharma believes will facilitate potential commercial partnerships. The site will be the first in France, and the largest specialized manufacturing facility for full ecosystem microbiome therapies in Europe to date. The facility will also increase potential synergies within the microbiome industry and contribute to structuring the production of microbiome-based drugs. It will provide a fully integrated manufacturing and development platform that will allow quick and efficient product development, scale-up and GMP processes.

Financing plans & update on cash runway

Following an in-depth review of its ongoing programs, in particular the deferral of the clinical study of MaaT03x from 2023 to 2024 and savings on discretionary spending, the Company has optimized and prioritized its operations, extending its cash runway to end of Q4 2023, as compared to end of Q3 2023 as previously announced. The Company is also evaluating options that will finance operations and bring its late-stage products close to commercial launch. The

focus is on both dilutive and non-dilutive financing, including business deals. The Company is confident in the continuing and longstanding support of its historical investors.

The Company has updated its corporate presentation, which can be download here: https://www.maatpharma.com/investors/

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®, supports the development and expansion of its 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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