MaaT Pharma Presents Positive 18-month Data for MaaT013 Showing a Clear Overall Survival Advantage in aGvHD from the Early Access Program at the 2024 EBMT Event

- Positive efficacy and safety results in 140 patients treated with MaaT013 in acute graft-versus-host disease (aGvHD) as part of the MaaT Pharma Early Access Program (EAP).
- Gastrointestinal overall response rate (GI-ORR) of 52% observed at Day (D) 28.
- Long-term survival data at 18 months with 42% overall survival (OS) in all patients and 58% in responder patients to MaaT013.
- Used in 3rd line, MaaT013 exhibits a high and durable response rate (with 63% GI-ORR at D28 and 53% at D56), translating to the highest overall survival in this population of patients when compared to reported evidence in the literature (Abedin et al., 2021).
- A pivotal Phase 3 trial evaluating MaaT013 (ARES trial - NCT04769895; n=75) in patients with corticosteroid and ruxolitinib-refractory GI-aGvHD is currently ongoing with primary endpoint expected in mid Q4-2024.

Lyon, France, April 15th, 2024 – 7.30 am 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, presents a summary of its oral presentation at the 50th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) currently being hosted in Glasgow, Scotland from 14-17 April 2024. The presentation is scheduled for April 17th by Dr. Malard, Professor of Hematology at Saint-Antoine Hospital and Sorbonne University in Paris and is based on the abstract made available on the website of the event.

This presentation will unveil promising extended outcomes from the EAP in Europe, involving 140 patients with steroid-refractory (SR) or steroid-dependent (SD) gastrointestinal acute graft-versus-host disease (GI-aGvHD) treated with MaaT013. Prof. Malard will emphasize a significantly high response rate (Complete Response [CR] and Very Good Partial Response [VGPR]) to MaaT013, demonstrating a clear reduction in disease burden and improved Overall Survival (OS) at 18 months compared to published data.

Prof. Malard commented: *"MaaT013 shows remarkable efficacy at 18 months, yielding more complete responses in aGvHD patients who have shown resistance to current treatments, as compared to other available therapies. This effect is coupled with reduced toxicity compared to standard immunosuppressive drugs. Notably, these results are achieved with just 3 doses in less than 2 weeks of treatment initiation. This would not only improve patient outcomes, but also significantly enhance their quality of life."*

Echoing this feedback, **Dr. Jaime Sanz Caballer, Hematologist and coordinator of the Bone Marrow Transplant Unit at the University Hospital La Fe in Valencia, Spain, also commented:** *"there is a persistent unmet medical need in aGvHD with consistently reported poor survival outcomes. This is particularly noticeable for patients in third-line treatment options where only 15% of patients survive at 12 months*[1]*. This underscores the urgent demand for innovative solutions such as MaaT013, presenting a promising immuno-restorative approach."*

The data presented highlights the strong safety profile of MaaT013 (full details here) and translates into increased OS. In this heavily pre-treated population (n=140), the following results were observed:

- GI-ORR of 52% at D28, with CR observed in 28% of patients; ORR considering all organs was 52% with 24% CR.
- OS was 54% at 6 months, 47% at 12 months, 42% at 18 months.
- OS was significantly higher in patients who responded to MaaT013 compared to non-responders (68% versus 24% at 12 months, and 58% versus 24% at 18 months).

A subset of the 140 patients (n=49) that is a similar population to that of the ongoing Phase 3 ARES clinical trial (NCT04769895): steroid- and ruxolitinib- refractory corresponding to the third-line treatment demonstrated even better efficacy:

- GI-ORR of 63% at D28, with almost half of patients demonstrating a CR (49%); global ORR was 61% with 43% with a CR.
- OS was 52% at 6 months, 49% at 12 months, 42% at 18 months.
- OS was significantly higher in patients who responded to MaaT013 compared to non-responders (76% versus 6% at 12 months, and 64% versus 6% at 18 months).

A pivotal Phase 3 trial (n=75) evaluating MaaT013 (ARES trial - NCT04769895) in patients with corticosteroid and ruxolitinib-refractory GI-aGvHD is currently ongoing to confirm the results from the EAP. The Company previously shared the positive review by the Data Safety Monitoring Board (DSMB) for the Phase 3 ARES trial, including a favorable benefit/risk ratio, with "*high efficacy and low toxicity.*"

"The confirmation of an improvement in 18-month survival, compared to the data already presented, by the company, at 12 months, reinforces our confidence in the ongoing development, notably the results of the current Phase 3 trial," **stated Hervé Affagard, CEO and co-founder of MaaT Pharma.** *"Beyond the significant impact for patients, this advancement distinguishes our treatment in a context where current options offer only limited benefits and lead to severe complications. Anticipating a positive Phase 3 outcome and a potential commercial launch in 2026,*

[1] *Abedin et al, 2021*

we aim to capture a substantial share of the market for third-line patients, thereby marking a turning point in the management of this condition."

MaaT013, a pooled-donor microbiome ecosystem therapy, has been awarded Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) due to the rarity of the disease, underscoring the need for therapeutic advances.

MaaT Pharma also presented its ongoing Phase 2b trial design for MaaT033 developed as an adjunctive therapy to enhance OS in allogeneic hematopoietic stem cell transplantation. This international, multi-center trial (NCT05762211) is the largest randomized controlled study to date of a microbiome-based therapy in oncology, spanning up to 56 sites and aiming to enroll 387 patients.

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 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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