MaaT Pharma Presents Positive Results with Lead Product MaaT013 and Provides Insights on Ongoing Phase 2b Trial with MaaT033 at ASH 2023

- Positive efficacy and good safety results from 111 patients with acute graft-versus-host disease (aGvHD) treated with MaaT013 in Early Access Program presented at 2023 ASH Meeting
- Gastrointestinal overall response rate (GI-ORR) of 53% observed at day 28 positively and significantly impacted overall survival (OS) in responder patients
- OS results were even more pronounced (81% for responders and 8% for non-responders) in population matching patients in the Phase 3 ARES clinical trial (GI-ORR of 61% at day 28)
- Design of ongoing Phase 2b Trial in Europe evaluating MaaT033 in patients receiving allogeneic hematopoietic stem cell transplantation presented at 2023 ASH Meeting

Company to host key opinion leaders' discussion on Monday, December 18 at 6:00 pm CET. To register, please click here.

Lyon, France, December 11th, 2023, 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 of patients with cancer, presented positive results from the Early Access Program (EAP) in Europe involving 111 patients with steroid-refractory (SR) or steroid-dependent (SD) gastrointestinal acute graft-versus-host Disease (GI-aGvHD) treated with MaaT013, at the 2023 American Society of Hematology (ASH) Annual Meeting.

"GvHD remains a significant challenge and source of mortality following allogeneic HSCT," **said Professor Mohty, Professor of Hematology at Sorbonne University, and head of the Clinical Hematology and Cellular Therapy Department at Saint-Antoine Hospital, Paris, France.** *"The clear connection between treatment response and overall survival demonstrates Microbiome Therapies as a potentially life-saving approach, particularly in patients who have failed earlier treatment lines, corticosteroids and ruxolitinib. MaaT013 introduces a novel therapeutic approach by restoring the gut microbiome ecosystem, offering a distinct immuno-restorative option that could complement standard immunosuppressive drugs, and could become a potential breakthrough for patients with limited options."*

"These promising findings pave the way for advancing the treatment landscape for aGvHD, with microbiome-based innovations, especially when they achieve complete responses," **said Hervé Affagard, CEO and co-founder of MaaT Pharma.** *"It reinforces our approach based on restoring patients' immune systems through gut microbiome ecosystem therapies. The efficacy and safety results underscore the strong favourable benefit-risk profile for MaaT013, and we look forward to continuing to investigate MaaT013 with the aim of having it accessible globally for patients in need as soon as possible".*

MaaT013 shown to have a safe profile and translates into increased overall survival:

- GI-ORR of 53% at day 28, with Complete Response observed in more than two thirds of responders (35%); Overall Response Rate (ORR) considering all organs was 50% with 31% Complete Response (CR).
- OS was 56% at 6 months and 47% at 12 months with a median follow up of 355 days.
- OS was significantly higher in patients who responded to MaaT013 compared to non-responders (67% versus 24% at 12 months).

The Company defined a subgroup of 38 patients with similar treatment sequence to the ongoing Phase 3 ARES clinical trial, which included patients previously treated with steroids and ruxolitinib. GI-ORR was 61% at day 28, mainly driven by GI Complete Response (CR) with 58%. ORR was 54% including 51% with CR. Overall Survival (OS) in this group was 55% at 6 months and 52% at 12 months, confirming the CR as a proxy of survival at one year. OS was significantly higher in responders to MaaT013 treatment compared to non-responders (81% versus 8% at 12 months, respectively).

MaaT013, a pooled-donor microbiome ecosystem therapy, displayed a good overall tolerability and safety profile in the EAP population. As of today, MaaT013 has been administered to more than 200 patients. Full details on safety are available here. A Phase 3 trial is currently ongoing in Europe to confirm these results in ruxolitinib-refractory patients (NCT04769895) with ORR expected in mid-2024. The Company has an open-IND granted by the U.S. FDA with active discussions ongoing with potential clinical investigation sites.

MaaT Pharma also presented its ongoing Phase 2b trial design for MaaT033, its second candidate, at the 2023 ASH Annual Meeting. Developed as an adjunctive therapy to enhance OS in HSCT (hematopoietic stem cell transplantation) and cellular therapy recipients, MaaT033 targets optimal microbiota function for a broader patient population in a chronic setting. This international, multi-centre trial (NCT05762211) is the largest randomized controlled study to date of a microbiome-based therapy in oncology, spanning up to 56 sites and enrolling 387 patients.

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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 launched, in March 2022, an open-

label, single arm, phase 3 clinical trial in patients with acute GvHD (aGvHD), 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).

About MaaT013

MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, enema Microbiome Ecosystem TherapyTM for acute, hospital use. It is characterized by a consistently high diversity and richness of microbial species and the presence of Butycore™ (group of bacterial species known to produce anti-inflammatory metabolites). MaaT013 aims to restore the symbiotic relationship between the patient's functional gut microbiome and their immune system to correct the responsiveness and tolerance of immune functions and thus reduce steroid-resistant, gastrointestinal (GI)-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About acute graft-vs-host-disease

aGvHD occurs in patients within 100 days of undergoing a stem cell or bone marrow transplant. The transplanted cells "attack" the recipient, causing inflammation of the skin, liver and/or GI tract. GI-aGvHD results in patients experiencing extensive diarrhea which can be life-threatening. The standard first line therapy for treating aGvHD is the use of systemic steroids. If patients do not respond to steroids, they are considered steroid resistant (SR) and other agents can be administered. Currently, the only agent approved for treating SR aGvHD after failure of steroid treatment is ruxolitinib, which is currently approved for this indication in the USA and has received approval from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on March 25, 2022.

About the Early Access Program

The Early Access Program (EAP) is coordinated and implemented by European Member States, which set their own rules and procedures to grant patients early access to certain medications or treatments, especially when facing life-threatening conditions and lacking alternative options. It allows for the use of these interventions before formal approval, acknowledging the urgent medical needs of individuals who might benefit from them. Healthcare professionals make the formal request to access this treatment. MaaT013 has been used in the EAP since 2019. It encompassed a diverse cohort of patients diagnosed with SR/steroid-dependent (SD) GI-aGvHD, with various aGvHD classifications – mainly grade III (49%) and grade IV (42%).

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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