MaaT Pharma Announces Positive Topline Results from the Pivotal Phase 3 ARES Study Evaluating MaaT013 in acute Graft-versus-Host Disease

The study met its primary endpoint with a significant gastrointestinal overall response rate at Day 28 of 62% and demonstrates the unprecedented efficacy of MaaT013 as third-line treatment of aGvHD with gastrointestinal involvement (GI-aGvHD)

- High gastrointestinal overall response rate (GI-ORR) exceeding the expected response rate of 38%. Complete response (CR), only, was 38% and very good partial response (VGPR) was 20%.
- Frequent and strong all-organ responses (ORR), prevalently consisting of complete response (CR) of 36% and very good partial response (VGPR) of 18%, reflecting systemic effects beyond the gastrointestinal tract.
- 54% probability of survival at 1 year driven by clinical response, highlighting MaaT013's potential to overcome the short-term mortality of third-line GI-aGvHD.
- Company anticipates MAA submission in Europe in mid-2025, earlier than initially planned.

Conference call and webcast to be held on Thursday, January 9, 2025, at 4.00PM CET/ 7.00 AM PST/ 10.00AM EST/ 7.00PM GST
To register, please click here.

Lyon, France, January, 8 2025 – 7.30 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 through immune modulation, today announced topline results from ARES, a pivotal, single-arm, open-label, multicenter European Phase 3 study evaluating the efficacy and safety of MaaT013 in acute Graft-versus-Host Disease patients with gastrointestinal involvement (GI-aGvHD) in third-line treatment, meaning refractory to steroids and refractory or intolerant to ruxolitinib. Notably, the study met its primary endpoint, with a significant gastrointestinal overall response rate (GI-ORR) at 28 Days of 62%, exceeding the expected 38% response rate. Responses reviewed by an Independent

Review Committee (IRC), exceed the per-protocol prespecified threshold and confirm the unprecedented clinical efficacy of MaaT013 for the treatment of third-line GI-aGvHD.

"Gastrointestinal involvement in aGvHD is a devastating condition, particularly for patients who do not respond to ruxolitinib. These individuals face an urgent unmet medical need, with alarmingly low survival rates and a critical lack of effective treatment options," **stated Professor Mohamad Mohty, Professor of Hematology and Head of the Hematology and Cellular Therapy Department at Saint-Antoine Hospital and Sorbonne University.** *"The results for MaaT013 in this Phase 3 trial represent a groundbreaking advancement in third-line treatment for GI-aGvHD. By directly targeting the gut-immune interface, this innovative therapy has the potential to redefine disease management, bringing new hope to patients and clinicians, alike."*

"We would like to thank all patients who participated in this landmark study. These positive topline results strongly position MaaT013 as a first-in-class therapeutic for GI-aGvHD, potentially bringing a new option for patients in need of effective treatments when both steroids and ruxolitinib have failed. ARES represents the first-ever positive pivotal clinical study for an immunosuppressant-sparing, microbiome-based approach, confirming MaaT Pharma's leadership in the field, validating the Company's therapeutic platform, supporting its programs, and broadens potential applications in oncology, inflammation, and other therapeutic areas." **said Gianfranco Pittari, MD PhD, Chief Medical Officer, MaaT Pharma.**

The therapeutic options for patients with GI-aGvHD refractory to steroids and refractory or intolerant to ruxolitinib remain very limited despite the poor prognosis for this condition, which has 1-year survival rates of just 15% (Abedin et al., 2021). MaaT013 has the potential to be the first approved third-line treatment option and thereby transform the survival outcomes and redefine long-term prospects for approximately 3,000 third-line GI-aGvHD patients per year in the U.S., Canada and Europe.

Top-line Data Highlights:

- In the single-arm ARES study, 66 adult patients with GI-aGvHD refractory to steroids and refractory or intolerant to ruxolitinib were treated with MaaT013 as third-line treatment across 50 European sites (Austria, Belgium, France, Germany, Italy and Spain).
- Patients' characteristics:
    - Gender: 47% females, 53% males.
    - Median age: 55.5 years (24-76)
    - At baseline, aGvHD grading (according to both IRC and investigators' assessments):
        - Grade II: 9.1%
        - Grade III: 57.6%
        - Grade IV: 33.3%
    - Steroid refractory: 86.4%
    - Steroid dependent: 13.6%
    - Ruxolitinib refractory: 100%
    - Ruxolitinib intolerant: 0
- The study **met its primary endpoint** of GI-ORR at Day 28 of treatment with MaaT013 ($p < 0.0001$), as assessed by the Independent Review Committee (IRC).

- **Frequent, strong and durable response rates translating into prolonged survival**
    - GI-ORR at Day 28 occurred in 41/66 patients (62%) and prevalently consisted of complete response (CR) (25/66 patients, 38%) and very good partial response (VGPR) (13/66 patients, 20%).
    - ORR in all evaluable organs occurred in 42/66 patients (64%) patients and was similarly driven by high rates of CR (24/66 patients, 36%) and VGPR (12/66 patients, 18%).
    - The 12-month probability of survival was 54% (median survival not reached). The 12-month probability was significantly higher in patients who responded at Day 28 than those who did not respond (67% vs 28% respectively, p <0.0001), demonstrating MaaT013's significant survival benefit in refractory GI-aGvHD.

Enrolled patients will continue to be followed for secondary and exploratory endpoints for the duration of the study. Results are expected to be presented at future scientific conferences.

MaaT013's safety has already been confirmed by the ARES Data Safety Monitoring Board (DSMB) in October 2023 for the first 30 patients, showing it was well tolerated with no increased infection risk or treatment-related fatal events (Full details here). Pharmacovigilance and DSMB surveillance for the study remain ongoing.

With robust data supporting efficacy and safety, MaaT Pharma is pursuing the regulatory submission of MaaT013, in Europe, as a treatment for GI-aGvHD in third-line, aiming for a Centralized Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) in mid-2025, earlier than previously expected. The centralized procedure enables a single authorization across the EU (27 members), thus facilitating patient access and market launch.

In line with its mission to offer new treatment options for high unmet medical needs, MaaT Pharma will continue to ensure availability of MaaT013 in Europe, for patients with aGvHD (and other indications) as part of its Early Access Program (EAP), which exceeded 100 requests for patients in 2024. The EAP will continue during the regulatory evaluation phase and up to commercialization, anticipated for end of 2026. The Early Access Program, has been expanded to the United States in December 2024, will continue as the Company advances readiness for the U.S. Phase 3 clinical trial, which is expected to be launched in 2025, upon securing financing.

Conference Call and Webcast Information

MaaT Pharma will host a conference call and a webcast tomorrow on Thursday, January 9th, 2025, at 4.00PM CET/ 7.00AM PST/ 10.00AM EST/ 7.00PM GST. Hervé Affagard, Chief Executive Officer and co-founder, Gianfranco Pittari, MD, PhD, Chief Medical Officer, Eric Soyer, Chief Financial Officer, Sian Crouzet, Chief of Staff, will further discuss the impact of the ARES Phase 3 results and the related perspectives for MaaT Pharma. To register, please click here. Participants can also join the conference by phone by dialling the following number: +33 1 78 42 94 76 and using the PIN code 85 99 53.

About MaaT Pharma

MaaT Pharma is a leading, late-stage clinical company focused on developing innovative gut microbiome-driven therapies to modulate the immune system and enhance cancer patient survival. Supported by a talented team committed to making a difference for patients worldwide, the Company was founded in 2014 and is based in Lyon, France. As a pioneer, MaaT Pharma is leading the way in bringing the first microbiome-driven immunomodulator in oncology. Using its proprietary pooling and co-cultivation technologies, MaaT Pharma develops high diversity, standardized drug candidates, aiming at extending life of cancer patients. MaaT Pharma has been listed on Euronext Paris (ticker: MAAT) since 2021.

About MaaT013

MaaT Pharma's Microbiome Ecosystem Therapies (MET) are designed to leverage a full microbiome ecosystem to restore balance and maximize clinical benefits for patients with severe, treatment-induced dysbiosis in acute diseases. MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, enema Microbiome Ecosystem Therapy™ for acute, hospital use. It is characterized by a consistently high diversity and richness of microbial species and the presence of Butycore™ (a 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)-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-versus-Host Disease

Acute Graft-versus-Host Disease occurs in patients within 100 days of undergoing a stem cell or bone marrow transplant, where the transplanted cells initiate an immune response and attack the transplant recipient's organs, causing inflammation of the skin, liver and/or gastro-intestinal tract and leading to significant morbidity and mortality. GI involvement is associated with severe complications such as profound diarrhea, abdominal pain, intestinal bleeding, and death. These complications are often life-threatening, with increased mortality risk, due to the challenges of managing severe GI inflammation and the associated risks of infection, malnutrition, and organ failure. 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 USA and has received approval from the European Medical Agency's Committee for Human Medicinal Products (CHMP) on March 25, 2022.

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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