MaaT Pharma Presents Pivotal ARES Phase 3 Results for MaaT013 (Xervyteg®) in Acute GvHD at ASH 2025 Annual Congress and Announces 54% 1-Year Overall Survival

- Presentation included previously disclosed primary results from the pivotal ARES Phase 3 single-arm trial evaluating MaaT013 (Xervyteg®) in treating refractory severe acute Graft-versus-Host Disease (aGvHD) patients with gastrointestinal involvement following corticosteroid and ruxolitinib failure.
- MaaT Pharma announces final pivotal ARES results including a confirmed 1-year overall survival of 54%.
- Oral presentation and results confirm durable survival benefit in this high-risk patient population known for extremely poor prognosis.
- MaaT013 (Xervyteg®) is currently under regulatory review by the European Medicines Agency (EMA) for Market Approval, with a decision expected mid-2026.

Lyon, France, December 8th, 2025 – 6.00PM 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 that Prof. Malard, MD, PhD, hematology professor at Saint-Antoine Hospital and Sorbonne University and ARES Trial lead investigator, presented the results for the pivotal ARES, single arm, open label trial evaluating MaaT013 (Xervyteg®) in aGvHD during an oral session at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition currently taking place in Orlando, Florida, USA. In addition, the Company announced new data from the pivotal ARES trial including a 1-year overall survival rate of 54%, confirming the global clinical benefit of MaaT013 (Xervyteg®).

"These results confirm that MaaT013 (Xervyteg®) offers a durable clinical benefit for patients with GI-aGvHD who have exhausted all currently approved treatment options. Achieving a 62% gastrointestinal response at Day 28, maintaining responses over time, and reaching a 54% one-year overall survival represent a meaningful step forward in addressing this critical unmet need," **said Prof. Florent Malard, MD, PhD, Professor of Hematology at Saint-Antoine Hospital and Sorbonne University, and lead investigator of the ARES trial who presented the findings.**

Prof. Malard detailed primary and secondary endpoints, noting that GI-Overall Response Rate (GI-ORR) at Day 28 (62% including 38% of complete response) remains high over time, indicating a durable response with a GI-ORR of 47% and all-organ ORR of 45% at Day 56. At three months, GI-ORR and all-organ ORR were both still high at 44%. These results indicate that responses to MaaT013 (Xervyteg®) are durable and result in improved survival outcomes, which translates into a 54% 1-year overall survival rate in the study population.

Final efficacy data of MaaT013 (Xervyteg®) in the ARES study are summarized below.
The ARES trial is a single-arm, open label trial evaluating MaaT013 (Xervyteg®) as third-line treatment in 66 adult patients with severe GI-aGvHD refractory to corticosteroids and ruxolitinib across 50 sites in six European countries:

Patient profile:

- 91% (n=60) presented with Grade III–IV aGvHD with GI involvement
- 86% (n=57) were steroid-resistant and 14% (n=9) steroid-dependent; all were refractory to ruxolitinib
- Male: 53%, Female: 47%

Final results:

- GI-ORR at Day 28 occurred in 41/66 patients (62%) and prevalently consisted of complete response (CR) (38%, 25/66 patients), and very good partial response (VGPR) (20%, 13/66 patients).
- All-organ ORR at Day 28 occurred in 42/66 patients (64%) patients and was similarly driven by high rates of CR (36%, 24/66 patients) and VGPR (18%, 12/66 patients).
- GI-ORR at Day 56 was maintained at 47% (31/ 66 patients) and prevalently consisted of CR (35%, 23/66 patients).
- All-organ ORR at Day 56 was 45% (30/66 patients) and prevalently consisted of CR (35%, 23/66 patients).
- GI-ORR and all-organ ORR at 3 months were both 44% (29/ 66 patients), with a prevalence of CR (36%, 24/66 patients).
- Overall survival (OS) at 12 months was 54% (median survival not reached), this confirms the 12-month probability of survival of 54% announced in January 2025 for the topline results.
- Median overall survival was not reached, indicating that more than half of the patients were still alive at the end of the study. This suggests a durable survival benefit and reinforces the strong efficacy signal observed in the pivotal ARES study. The median OS of responders was not reached, while it was only 54 days for non-responders.

- The OS was significantly higher in patients who had a GI response at Day 28 than those who did not respond: 68% vs 28% respectively ($p < 0.0001$), indicating a strong association between early GI response and improved survival in refractory GI-aGvHD.
- Safety data showed that MaaT013 (Xervyteg®) was associated with an acceptable tolerability profile in severe aGvHD patient population (as reviewed continuously by a Data and Safety Monitoring Board).

The pivotal ARES trial results will soon be submitted for publication in a leading peer-reviewed medical journal. MaaT013 (Xervyteg®) is currently under review by the European Medicines Agency (EMA) following the submission of a marketing authorization application in June 2025, with a decision expected in mid- 2026, as previously announced. If approved, MaaT013 (Xervyteg®) would become the first microbiotherapy in oncology in the world and the first 3rd-line therapy in aGvHD addressing a critical unmet need.

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 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 second-line treatment for steroid-refractory acute graft-versus-host disease (SR aGvHD) is ruxolitinib and remestemcel—L-rknd was approved in December 2024 in the US specifically for use in the paediatric population as a second-line treatment.

About Xervyteg® (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. Xervyteg® (MaaT013) is a full-ecosystem, off-the-shelf, standardized, pooled-donors, 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). Xervyteg® (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. Xervyteg® (MaaT013) has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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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