MaaT Pharma Announces Positive Phase 3 Results Evaluating Xervyteg® (MaaT013) in Acute Graft-versus-Host Disease Selected for Oral Presentation at ASH Congress 2025

- Oral presentation at ASH 2025 to feature pivotal Phase 3 results of Xervyteg® (MaaT013), including previously disclosed primary endpoint data (62% GI-ORR at Day 28) and new findings on secondary endpoints (data at Day 56 and 3 months, and duration of response).
- Results highlight strong efficacy and indicate a favorable safety profile for Xervyteg® (MaaT013), reinforcing its potential to become the first third-line treatment for patients with gastrointestinal aGvHD unresponsive to current therapies.
- Xervyteg® (MaaT013) is currently under regulatory review by the European Medicines Agency (EMA), with a decision anticipated in the second half of 2026.

Lyon, France, November 3rd, 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 results from its pivotal Phase 3 ARES trial evaluating Xervyteg® (MaaT013) in patients with gastrointestinal acute Graft-versus-Host Disease refractory to steroids and refractory or intolerant to ruxolitinib (SR GI-aGvHD) will be presented in an oral session at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition that will take place December 6-9, 2025, in Orlando, Florida, USA. This marks the ninth consecutive year that MaaT Pharma's clinical data has been selected for presentation at ASH annual meeting, and the first time the Company will present its Phase 3 results at a medical congress.

"For the ninth consecutive year, MaaT Pharma is proud to present data at ASH, reaffirming our position as the undisputed leader in microbiotherapy for hematology-oncology. The ARES study demonstrated a clinically meaningful and durable benefit in patients with gastrointestinal aGvHD, further validating our approach and its potential to redefine the standard of care in this high unmet need," **said Hervé Affagard, CEO and co-founder of MaaT Pharma.**

The ARES trial met its primary endpoint and topline results were announced in January 2025. At the upcoming ASH annual meeting, the Company will detail secondary endpoints, such as GI-ORR at D56 and Month 3 (M3), and some safety data. Final results, including 1-year overall survival, are expected by the end of 2025.

In the single-arm ARES study, 66 adult patients with GI-aGvHD refractory to steroids and refractory to ruxolitinib were treated with Xervyteg® (MaaT013) as third-line treatment across 50 European sites in 6 countries (Austria, Belgium, France, Germany, Italy and Spain). The vast majority of patients included in the study (91%, n=60) presented with severe gastrointestinal aGvHD, classified as grade III (58%, n=38) or grade IV (33%, n=22). Among them, 86% (n=57) were steroid-resistant and 14% (n=9) steroid-dependent; all were refractory to ruxolitinib.

Efficacy data to be presented at the ASH annual meeting is summarized below (see here for full abstract) - (up to the data cut-off of November 11, 2024):

- GI-Overall Response Rate 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%).
- Overall Response Rate (all organs) at Day 28 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%).
- GI-ORR at Day 56 was maintained in 49% (31/ 63 patients) and prevalently consisted of CR (37%)
- GI-ORR at 3 months was 44% (27/ 62 patients), with a prevalence of GI-CR (36%).
- Average duration of response was 6.4 months
- Probability of overall survival (OS) at 12 months:
    - The estimated OS was 54% with a median follow-up of 140.5 days (median survival not reached).
    - The estimated OS was significantly higher in patients who had a GI response at Day 28 than those who did not respond (67% vs 28% respectively, p <0.0001), demonstrating Xervyteg® (MaaT013)'s significant survival benefit in refractory GI-aGvHD.
    - The median OS of responders was not reached while it was 54 days in non-responders.

Xervyteg® (MaaT013) is currently under review by the European Medicines Agency (EMA) following the submission of a Marketing Authorization Application in June 2025, with a decision anticipated in the second half of 2026.

Details of the Oral Presentation:

- Title: MaaT013 for ruxolitinib-refractory acute graft-versus-host disease with gastrointestinal involvement: Results from the ARES phase III trial
- Publication Number: 817
- Presenting Author: Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, lead investigator for the Phase 3 ARES trial
- Session Date: December 8, 2025
- Presentation Time: 10:30 AM - 10:45 AM
- Session Name: 722. Allogeneic Transplantation: Acute and Chronic GVHD and Immune Reconstitution: Clinical and Translational Insights
- Room: OCCC - Sunburst Room (W340)

Upcoming investor and medical conferences participation

- November 5-9, 2025 – 40th SITC annual meeting in National Harbor, MD, USA
- November 19-21, 2025 – SFGM-TC annual meeting in Geneva, Switzerland
- November 25, 2025 – Investir Day event, Paris, France
- December 6-9, 2025 – 67th ASH annual meeting in Orlando, FL, USA

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 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 Medicines Agency's Committee for Human Medicinal Products (CHMP) on March 25, 2022.

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.

Contacts

MaaT Pharma – Investor Relations
Guilhaume DEBROAS, Ph.D.
Head of Investor Relations
+33 6 16 48 92 50
invest@maat-pharma.com

MaaT Pharma – Media Relations
Pauline RICHAUD
Senior PR & Corporate Communications Manager
+33 6 14 06 45 92
media@maat-pharma.com

Catalytic Agency – U.S. Media Relations
Heather Shea
Media relations for MaaT Pharma
+1 617-286-2013
heather.shea@catalyticagency.com