



MaaT Pharma Presents Updated Positive Data in Early Access Program for Xervyteg® at the EHA Congress Validating High Efficacy Observed in Pivotal ARES Study in Acute Graft-versus-Host Disease

- Oral presentation highlights updated data in Early Access Program (EAP) for 173 patients with acute Graft-vs-Host Disease (aGvHD) treated with Xervyteg®
- Independent dataset from EAP reinforces the findings from the pivotal ARES trial and has also been included in the EMA Marketing Authorization Application submitted on June 2nd, 2025
- EAP for Xervyteg® in aGvHD is currently running in 11 countries* providing expanded access to patients with high unmet medical needs

Lyon, France, June 13, 2025 – 7.30AM 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 Professor Mohamad Mohty, Professor of Hematology and Head of the Hematology and Cellular Therapy Department at Saint-Antoine Hospital and Sorbonne University, will present updated data for Xervyteg® (MaaT013) in treating acute Graft-versus-Host Disease (aGvHD) under the Early Access Program (EAP) at the European Hematology Association (EHA) Annual Congress 2025. This independent EAP dataset further supports the efficacy and safety profile of Xervyteg® previously shown in the [pivotal ARES trial](#). It also confirms the breakthrough potential of Xervyteg® for aGvHD patients with limited treatment options and it also serves as supportive data within the [Marketing Authorization Application \(MAA\)](#) recently submitted to the European Medicines Agency (EMA).

Key highlights:

- aGvHD is a major cause of morbidity and mortality following allogeneic hematopoietic stem cell transplantation. The patients (N=173) treated in EAP previously failed 1 to 6 aGvHD systemic treatment lines and most had grade III (49%) or IV (38%) aGvHD. The real-world

data presented underscores the favorable safety profile of Xervyteg® the strong and durable responses, translating into increased overall survival:

- Gastrointestinal Overall Response Rate (GI-ORR) of 53% at D28, with Complete Response (CR) observed in 30% of patients; all-organ Overall Response Rate (ORR) was 50% with 26% CR.
- Response is maintained at D56 indicating a long-term disease control with a GI-ORR of 47% and an ORR considering all organs of 46%.
- Overall Survival (OS) in all patients was 55% at 6 months, 48% at 12 months, 44% at 24 months.
- Xervyteg® displayed a good overall safety profile in the EAP population.
- OS was significantly higher in patients who responded to Xervyteg® (MaaT013) compared to non-responders (69% versus 25% at 12 months, and 61% versus 25% at 24 months).
- Median survival in all patients was 312 days. In responder patients, median survival was 834 days vs 69 days in non-responders.

A subset of patients (n=70) failing both steroid resistant (SR) and ruxolitinib resistant (RR) and thus resembling the cohort enrolled in the pivotal Phase 3 ARES trial ([NCT04769895](#)), exhibited a significant and consistent efficacy profile:

- At both Day 28 and Day 56, Xervyteg® demonstrated durable efficacy in SR/RR aGvHD patients, with GI-ORRs of 57% and Complete Response (CR) observed in 44% of patients at D28 and 51% at D56. All-organs ORR was 54% with 41% CR at D28, and 55% with 48% CR at D56.
- OS was 55% at 6 months, 51% at 12 months, 40% at 24 months.
- OS was significantly higher in patients who responded to Xervyteg® compared to non-responders (77% versus 14% at 12 months, and 59% versus 14% at 24 months).
- Median survival in all 70 patients was 445 days. In responder patients, median survival was 834 days vs 53 days in non-responders.

The complete data may be found [here](#).

*“The consistency between the real-world Early Access Program data and our pivotal ARES trial underscores Xervyteg®’s clinical benefit for patients with severe, treatment-resistant aGvHD,” said **Dr. Gianfranco Pittari, PhD, Chief Medical Officer at MaaT Pharma.** “This is particularly meaningful for clinicians and patients, as it confirms the potential of microbiome therapies to deliver long-term survival benefits in a population with historically poor outcomes.”*

In comparison, historical data from [Abedin et al. 2021](#) demonstrated that in a similar population of patients, i.e. third-line aGvHD patients receiving additional treatment after ruxolitinib failure, the median survival was only 28 days.

*“Among patients who responded by Day 28, the majority achieved a complete resolution of aGvHD symptoms – a strong predictor of sustained disease control over time. The overall safety profile is favorable in this high-risk patient population,” outlines **Professor Mohty, Professor of Hematology and Head of the Hematology and Cellular Therapy Department at Saint-Antoine Hospital and Sorbonne University.***

Details of the Oral Presentation:

- **Title:** Pooled Fecal Allogeneic Microbiotherapy for Refractory Gastrointestinal Acute Graft-Versus-Host Disease: Results from the Early Access Program in Europe
- **Abstract number:** S260
- **Presenting Author:** Mohamad Mohty, Professor of Hematology and Head of the Hematology and Cellular Therapy Department at Saint-Antoine Hospital and Sorbonne University
- **Session title:** s424 Stem cell transplantation - Session 2
- **Date & Time:** 13/06/2025 (17:00 - 17:15 CEST) - Brown Hall 3

MaaT Pharma also presented a poster on the design of its ongoing Phase 2b trial (PHOEBUS) evaluating MaaT033 to enhance overall survival in allo-HSCT. This international, multi-center trial ([NCT05762211](#)) is the largest randomized controlled study to date of a microbiome-based therapy in oncology, enrolling up to 387 patients across 60 sites.

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.



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