MaaT Pharma Announces Publication of Retrospective Data in Third-Line Acute GvHD from the CHRONOS Study in Bone Marrow Transplantation Journal

- CHRONOS is one of the largest real-world studies including refractory GI-aGvHD patients (n=59) treated with third-line best available treatments other than microbiome-based therapy
- Results from CHRONOS have been presented at the upcoming EBMT 2026 Annual Congress and included 29% 12-month overall survival (OS) and 37% Day-28 GI-overall response rate (GI-ORR), supporting the urgent need for new therapeutic options
- CHRONOS results have been included in the MaaT013 (Xervyteg®) Marketing Authorization Application filed with the European Medicines Agency (EMA) to contextualize the third-line setting for patients suffering from GI-aGvHD and being resistant to prior lines of treatment
- MaaT013 (Xervyteg®) Marketing Authorization application is currently under regulatory review by the EMA, with feedback anticipated mid-2026, based on EMA's standard timelines

Lyon, France, April 1st, 2026 – 7.30 a.m. 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 the publication of CHRONOS, a large multicenter retrospective cohort study evaluating real-world- outcomes of third-line systemic therapies (excluding microbiotherapy) in 59 patients with steroid- and ruxolitinib-refractory aGvHD with gastrointestinal involvement in the peer-reviewed journal *Bone Marrow Transplantation*, the official journal of the European Society for Blood and Marrow Transplantation (EBMT). The article is available here: Clinical outcomes of third-line therapy for aGvHD with gastrointestinal involvement after steroids and ruxolitinib failure. The CHRONOS

data have also been presented during a poster session by Johannes Clausen, MD, hematologist at Ordensklinikum Linz Elisabethinen, Hematology Department, Linz, Austria and primary author of the publication at the 2026 EBMT Annual Congress.

CHRONOS is a multicenter real-world study offering, to the Company's best knowledge, one of the largest and most current real-world recent benchmarks of third-line systemic treatments (excluding microbiotherapy) in patients with steroid- and ruxolitinib-refractory aGvHD. The study reports limited durability of response and limited survival benefit with currently available off-label therapeutic options in this high-risk patient population. MaaT Pharma sponsored the CHRONOS study to contextualize the final results of the pivotal ARES trial evaluating MaaT013 (Xervyteg®), announced in December 2025 and support its Marketing Authorization Application. This multi-center retrospective study provides real-world evidence on patients with steroid- and ruxolitinib-refractory or -intolerant aGvHD for context on how MaaT013 (Xervyteg®) could potentially support evolving treatment standards in the third-line setting.

"CHRONOS provides a contemporary reference point for third-line GI-aGvHD, underscoring both the gravity of this condition and the persistent lack of standardized, effective therapies. The study highlights the stark limitations of current options and sets a meaningful new benchmark for this challenging clinical setting", **said Johannes Clausen, MD, hematologist at Ordensklinikum Linz Elisabethinen, Hematology Department, Linz, Austria.**

The CHRONOS study retrospectively evaluated 59 adult patients, treated across 16 European transplant centers in Austria, Belgium, France and Spain, in whom treatment with corticosteroids (first-line) and ruxolitinib (second-line) failed.

Most patients presented with a severe form of aGvHD (46% of grade III and 48% of grade IV) and were steroid-resistant (97%) and resistant to ruxolitinib (95%). Twelve different third-line therapies were used, the most frequent being anti-TNF-α (n=20), extracorporeal photopheresis (n=17) and vedolizumab (n=10).

Key findings from CHRONOS study include:

- GI-overall response rate (ORR) at Day 28 was 37% with 22% GI-complete response (n=13), 10% GI-very good partial response (n=6), and 5% GI-partial response (n=3), and all-organ ORR at Day 28 was 36%
- Response rates declined by Day 56 with a GI-ORR of 22% and all-organ ORR of 20%, suggesting rapid loss of response
- 12-month overall survival: 29%
- Median overall survival: 86 days

These findings highlight the poor prognosis of patients progressing beyond ruxolitinib, emphasizing the need for novel treatments and the absence of treatment standardization, the heterogeneity and limited benefits of current third-line interventions.

Until then, the only multicenter benchmark for patients with steroid-refractory aGvHD following ruxolitinib failure or intolerance included a retrospective analysis conducted across nine U.S. centers between 2016 and 2019, reporting modest outcomes in this high-risk population, with an overall response rate of 36% and a 12-month survival of 15% (Abedin et al. (2021)[1]. CHRONOS (Clausen J. et al., *Bone Marrow Transplantation* 2026), a more recent multicenter retrospective study reflecting contemporary standards of care, demonstrated incremental improvement in OS, with an overall response rate of 37% and a 12-month survival of 29%. This progression in OS but not in ORR highlights the evolution of clinical practice in this setting and establishes a critical contemporaneous benchmark for regulatory evaluation of the most innovative therapeutic approaches such as MaaT013 (Xervyteg®), assessed in the ARES registration study.

For contextual information, the results from the single-arm pivotal ARES trial were presented at the ASH 2025 Annual Congress and at the EBMT 2026 Annual Congress, and included for reference:

- GI-ORR at Day 28 occurred in 41/66 patients (62%) and mostly consisted of complete response (CR) (38%, 25/66 patients), and very good partial response (VGPR) (20%, 13/66 patients), substantially higher than the 37% GI-ORR reported in CHRONOS
- 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)
- Response maintained at Day 56 with a GI-ORR of 47% and an all-organ ORR of 45%
- 12 months overall survival: 54% vs 29% reported in CHRONOS
- Median overall survival not reached, indicating that a majority of patients remained alive beyond the longest follow-up period, while CHRONOS reported 86 days

Full dataset available **here**.

"Acute GvHD remains a devastating disease with a profound unmet medical need. There is a clear necessity for evidence-based, standardized strategies in the third-line setting. By providing an updated and credible benchmark, CHRONOS offers critical context to interpret the results of the pivotal ARES trial and the potential clinical benefit observed with MaaT013 (Xervyteg®) in this vulnerable patient population", **stated Prof. Florent Malard, MD, PhD, Professor of Hematology at Saint-Antoine Hospital and Sorbonne University, and lead investigator of the ARES trial.**

Building on these historical benchmarks, the ARES trial demonstrates the potential for MaaT013 (Xervyteg®) contingent to EMA's approval, to offer improvement in patient outcomes and contribute to the evolving treatment landscape in this high-risk population.

About MaaT Pharma

[1] *Abedin S, Rashid N, Schroeder M, Romee R, Nauffal M, Alhaj Moustafa M, Kharfan-Dabaja MA, Palmer J, Hogan W, Hefazi M, Larson S, Holtan S, DeFilipp Z, Jayani R, Dholaria B, Pidala J, Khimani F, Grunwald MR, Butler C, Hamadani M. Ruxolitinib resistance or intolerance in steroid-refractory acute graft-versus-host disease - a real-world outcomes analysis. Br J Haematol. 2021 Nov;195(3):429-432. doi: 10.1111/bjh.17700. Epub 2021 Jul 12. PMID: 34254289; PMCID: PMC9293486.*

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 the CHRONOS Study

CHRONOS is a multicenter, retrospective, non-interventional cohort study based on real-world data collected from medical charts by participating European transplant centers. The study included adult patients (≥18 years) who underwent allogeneic hematopoietic stem cell transplantation (allo-HSCT) and received third-line systemic therapy for acute graft-versus-host disease (aGvHD) with gastrointestinal involvement between May 30, 2019 and September 30, 2024. Eligible patients presented with MAGIC Grade II–IV GI-aGvHD at treatment initiation and were resistant or dependent on high-dose corticosteroids and resistant or intolerant to ruxolitinib used as first- and second-line therapies. Any third-line systemic treatment was permitted, with the exception of fecal microbiotherapy.

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 gastrointestinal 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.

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