MaaT Pharma Advances Toward Commercialization And Submits Marketing Authorization Application to the European Medicines Agency (EMA) for Xervyteg® (MaaT013) in Acute Graft-versus-Host Disease

- MaaT Pharma submitted today a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its product candidate MaaT013, under the registered brand name of Xervyteg®.
- Xervyteg® has the potential if approved, to become the first microbiota therapeutic approved by the EMA and the first one in hemato-oncology globally.
- The MAA submitted to the EMA is based on data from the Pivotal ARES study, evaluating the safety and efficacy of Xervyteg® in adult patients with acute Graft-versus-Host Disease including gastro-intestinal involvement who received two prior lines of therapy and supported by data from the ongoing Early Access Program.
- MaaT Pharma prepares for a potential 2026 commercial launch through a strategic partnership to address this key unmet need in hemato-oncology.

Lyon, France, June 2, 2025 – 6.30PM 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 submission of the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its lead drug candidate MaaT013, under the registered brand name of Xervyteg®. If approved, the Marketing Authorization would establish Xervyteg® as the first microbiota therapeutic approved by the EMA, and the first one globally for a hematology indication. Xervyteg® would also be the first approved therapy for the treatment of acute Graft-versus-Host Disease including gastro-intestinal involvement (GI-aGvHD) following 2 prior lines of systemic therapy.

"Submitting our MAA to the EMA marks a major regulatory milestone for MaaT Pharma and a meaningful advancement for patients with refractory aGvHD—a life-threatening complication of stem cell transplantation with no approved therapies," **said Hervé Affagard, Co-founder and CEO of MaaT Pharma.** *"We are now closer to providing a much-needed treatment option and remain deeply committed to advancing immunomodulating microbiota technologies in hemato-oncology, where new solutions are urgently needed."*

While advancing toward the commercialization of Xervyteg® (if approved) in Europe, MaaT Pharma is also actively exploring strategic partnerships to ensure broad access in timely fashion. The Company has active discussions with experienced partners who share its mission of delivering meaningful advancements to patients.

In parallel to the MAA submission, MaaT Pharma continues to provide access to Xervyteg® in Europe and the U.S. through its Early Access Program (EAP)[1] for patients with aGvHD and other indications. In 2024, physician demand for Xervyteg® under the EAP (n=107) increased by 75% compared to 2023, driven by growing adoption across Europe and in the U.S. In France where the EAP first started, MaaT Pharma has captured 25% of the addressable market on a yearly basis in 2024. Overall, this position reflects the increasing recognition of Xervyteg® as a valuable treatment option for GI-aGvHD patients.

aGvHD is the most severe complication of allogeneic stem cell transplantation, a standard-of-care treatment with curative intent offered to patients with blood cancers and some non-malignant hematological conditions. aGvHD refractoriness to current treatments is frequently encountered and severely impacts prognosis. In particular, patients with aGvHD failing both steroid and ruxolitinib typically exhibit a dismal prognosis, with a median survival of 28 days and 85% mortality at one year (Abedin et al 2021). Currently, no therapy is approved for third-line aGvHD, underscoring the urgent need for innovative therapies capable of improving survival and quality of life.

The MAA is supported by positive results from the Pivotal ARES study, a single-arm, open-label, multicenter European study evaluating the efficacy and safety of Xervyteg® in GI-aGvHD as third-line therapy in 66 patients. Notably, the study met its primary endpoint, achieving a gastrointestinal overall response rate (GI-ORR) of 62% at Day 28, significantly exceeding the expected 38% response rate, and an overall response rate across all organs of 64% at Day 28. Among responding patients at Day 28, the majority exhibited full resolution of GvHD clinical manifestations (i.e., complete response), an important finding predictive of durable control of aGvHD clinical manifestations over time. The 12-month probability of survival was 54% (vs 15% Abedin et al, 2021). Importantly, patients who exhibited gastrointestinal response at Day 28 had a significantly better probability of survival than non-responders (67% vs 28% respectively, $p < 0.0001$), indicating that Xervyteg®-mediated aGvHD control is associated with a remarkable survival benefit. Additional secondary endpoints, including overall survival, will become available in late H2 2025. The Company also integrated supporting safety and efficacy data from 186 aGvHD patients[2] treated under its ongoing EAP, which aligns with the positive topline results of the ARES trial and further supports Xervyteg®'s strong efficacy and favorable safety profile in aGvHD.

The safety and tolerability of Xervyteg® has been monitored by an independent Data Safety Monitoring Board (DSMB). In March 2025, the DSMB reviewed the overall safety of the trial (after all patients completed Day 28 visit or were discontinued earlier) and confirmed that *"given the remarkable efficacy results, the study results show an acceptable safety profile and a favourable benefit /risk ratio"*. The DSMB members will continue to review safety on an ongoing basis until the 1-year follow-up.

The EMA will review the application under the centralized marketing authorization procedure and potentially a marketing authorization could be granted in H2 2026. This centralized procedure means that a single marketing authorization application can be submitted to the EU, and if granted by the European Commission, the authorization is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

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.

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).

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.

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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[1] *Updated data from the Early Access Program will be presented at the EHA Annual Congress in Milan, June 12–16, 2025*
[2] *The cutoff date was October 3, 2024*