MaaT Pharma Announces Plan to Request Re-Examination Following Negative CHMP Opinion for MaaT013 for the treatment of acute Graft-versus-Host Disease

- The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a negative opinion on the conditional Marketing Authorization Application (MAA) for MaaT013 (Xervyteg®), confirming the trend communicated in May 2026 after the Oral Explanation
- MaaT Pharma plans to seek re-examination of the opinion and request that a Scientific Advisory Group (SAG) be convened
- Second opinion upon re-examination expected during CHMP session in September 2026

Lyon, France, June 26, 2026 – 7.30 am 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 the CHMP of the EMA has adopted a negative opinion on the conditional MAA for MaaT013, under the brand name Xervyteg®, for the treatment of acute Graft-versus-Host Disease (aGvHD) in adult patients with gastrointestinal involvement refractory to prior lines of therapy. This confirms the previously announced negative trend opinion disclosed on May 20, 2026. The Company has reviewed grounds cited by the CHMP and confirms its plan to seek re-examination of the opinion as previously announced.

Under EMA procedures, the re-examination includes the appointment of a new rapporteur and co-rapporteur who will conduct a new and independent evaluation of the dossier. MaaT Pharma will also request a Scientific Advisory Group (SAG) hearing with hematology experts on aGvHD to provide input and insights to the CHMP into, among other things, the clinical reality of

managing aGvHD with complex concomitant therapies and patients in high need of solutions due to the severity of the disease and the lack of any other efficient third-line therapy so far.

In its opinion of June 25, 2026, the CHMP maintained the position that, given the use of concomitant therapies to manage aGvHD, the data package, primarily based on the ARES single-arm study, does not allow sufficient attribution of the observed clinical effect and safety to the study treatment alone.

Based on current EMA procedural timelines, a new CHMP opinion is expected within 60 days following validation of the re-examination request, with a second decision anticipated in the CHMP September Session (September 14-17, 2026).

MaaT Pharma remains confident in the clinical profile of MaaT013 (Xervyteg®), to treat a population with very limited treatment options and poor prognosis. This is supported by data from the ARES study, as well as data from the CHRONOS study (Clausen et al., 2026) and real-world evidence from its Early Access Program, active in 13 countries, with more than 300 patients treated since 2019. The Company also confirms that the re-examination process has no impact on the ongoing Early Access Program, as of today, and that MaaT013 (Xervyteg®) remains available to eligible patients.

MaaT Pharma's strategy also extends beyond MaaT013 (Xervyteg®), supported by the development of MaaT033, an oral microbiome therapy, currently evaluated in a randomized controlled Phase 2 trial for broader prophylactic and outpatient use in hemato-oncology, and by the expansion of its platform into immuno-oncology with the next generation product MaaT034.

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 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, ruxolitinib is the standard second-line treatment for steroid-refractory acute graft-versus-host disease. More recently, remestemcel-L (rknd) was approved in December 2024 in the United States, specifically for use in the pediatric population as a second-line treatment.

About MaaT013 (Xervyteg®)

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. MaaT013 (Xervyteg®) 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 the symptoms of 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
Eric Soyer
Chief Financial Officer
+33 4 28 29 14 00
invest@maat-pharma.com

MaaT Pharma – Media Relations
Pauline Richaud
Head of Communications
+33 6 14 06 45 92
media@maat-pharma.com