



MaaT Pharma Provides an Update on the Application for Marketing Authorization of MaaT013 (Xervyteg®) in the treatment of acute Graft-versus-Host Disease

- During the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) Oral Explanation, the Company received a “negative trend” opinion for the upcoming June CHMP vote
- Subject to the formal CHMP vote expected in the June Meeting, the Company plans to request a re-examination procedure for the application

Lyon, France, May 20, 2026 – 8.45pm 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, that it has been informed by the CHMP of the EMA of a “negative trend” opinion on its conditional Marketing Authorization Application (MAA) for MaaT013 (Xervyteg®) for the treatment of acute Graft-versus-Host Disease (aGvHD), following its recent CHMP oral explanation.

The CHMP formal vote is expected at the upcoming June Meeting, and subject to the formal vote, the Company intends to request a re-examination of the application, a standard procedure enabling a new independent scientific assessment by a different set of reviewers. The EMA’s procedure provides that the CHMP shall re-examine its opinion within 60 calendar days following receipt of the Company’s official request for re-examination.

*“We continue to strongly believe in the potential for registration of MaaT013 (Xervyteg®). We remain committed to working closely with the EMA to progress this application, encouraged by the therapy’s potential to address the significant unmet medical need in patients with aGvHD and by the continued support from the hematology community,” said **Hervé Affagard, CEO and co-founder of MaaT Pharma.** “Our application remains under review, and we are fully committed to engaging constructively in the re-examination process.”*

For context, the CHMP feedback shared during the Oral Explanation reflects challenges, in the Company's view, expected for first-in-class therapies based on a novel therapeutic approach, particularly those based on a single-arm pivotal trial. The application for MaaT013 (Xervyteg®) is assessed under the Conditional Marketing Authorization (CMA) pathway, which is designed to facilitate earlier access to medicines addressing unmet medical needs while confirmatory data is generated post-approval.

The Company is taking cash management measures to extend its financial visibility into November 2026 (vs August 2026), covering the upcoming regulatory milestones including the re-examination process, while continuing to advance its pipeline.

MaaT013 (Xervyteg®) is supported by clinical data from the pivotal ARES study, and real-world data with the ongoing Early Access Program active in 13 countries and with 300+ patients globally treated to date since 2019. Data supporting MaaT013 (Xervyteg®) has previously been presented at major international congresses and in peer-reviewed publications. The Company remains committed to advancing MaaT013 (Xervyteg®) through the European regulatory process, expanding patient access and progressing its broader pipeline in microbiome-based in oncology.

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 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 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 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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