MaaT Pharma Provides Update on MaaT013 (Xervyteg®) Potential Development Plan Following CHMP Negative Opinion After Re-examination

- The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a negative opinion on the Company's application for a Conditional Marketing Authorization (CMA) for MaaT013 (Xervyteg®), confirming the trend communicated on September 15, 2026, following the Oral Explanation
- During the application process, MaaT Pharma proposed conducting a randomized controlled Phase 3 trial versus Best Available Therapy (BAT), named PHOENIX, which would serve the purpose of regulatory submission in the U.S., Europe and other territories
- Food and Drug Administration (FDA) Type C feedback supports advancement of the pivotal PHOENIX Phase 3 trial which could enable study initiation leading to a potential first patient enrollment in H1 2027, subject to appropriate funding and regulatory clearance

Lyon, France, September 18, 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 maintained its negative opinion on the CMA application 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 following re-examination. The European Commission is expected to issue its final decision following the CHMP opinion in accordance with the applicable regulatory process[1]. The Company also indicates that future developments of MaaT013 (Xervyteg®) will focus on advancing the PHOENIX randomized clinical trial, subject to appropriate financing and regulatory clearance. The Company is actively exploring options to start U.S. focused development plan for MaaT013 (Xervyteg®) with a view to enabling potential global registration.

The CHMP maintained its view in its formal opinion adopted on September 18, 2026 that the available clinical data package based on single arm trial does not allow sufficient characterization of the benefit-risk profile of MaaT013 (Xervyteg®). As part of the re-examination process, MaaT Pharma presented plans for PHOENIX, a global randomized controlled Phase 3 trial intended to generate the additional evidence requested by regulators to further characterize the benefit-risk profile of MaaT013.

MaaT Pharma is advancing the U.S. clinical readiness for PHOENIX, including completion of a feasibility assessment across major clinical trial sites in US and other planned countries. In addition, feedback received following a Type C interaction with the FDA supports advancement of PHOENIX as a registrational Phase 3 trial and provides a framework for finalizing the study protocol and progressing U.S. development activities, including clinical site activation.

Subject to appropriate funding and regulatory clearance, PHOENIX is planned to be conducted across the U.S., Europe and sites in other regions and could also support potential future registration submissions, subject to successful execution and positive results.

PHOENIX is a randomized, controlled, open-label Phase 3 trial evaluating MaaT013 (Xervyteg®) versus pre-specified BAT in patients with corticosteroid- and ruxolitinib-refractory aGvHD. The study is expected to enroll approximately 138 patients randomized 1:1 and will evaluate Day 28 all-organ Overall Response Rate as its primary endpoint, alongside key secondary efficacy and safety endpoints.

In this context, the Company is conducting a strategic review of its assets while taking additional cash preservation measures, to further extend its cash horizon to December 2026 (vs November 2026), based on current operational assumptions.

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. MaaT013 (Xervyteg®) has been granted Orphan Drug Designation by the U.S. 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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[1] *This decision is issued within 67 days of receipt of EMA's recommendation: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines*