MaaT Pharma Receives Positive Opinion from EMA Pediatric Committee on the Pediatric Investigation Plan for MaaT013

- Positive EMA Pediatric Committee opinion has cleared the investigation clinical plan to evaluate the safety and efficacy of MaaT013 in patients from 6 years old to less than 18 years old with aGvHD
- Key regulatory milestone showing alignment with EMA expectations for pediatric investigation confirming MaaT013 is on track towards a marketing authorization submission to the EMA in June 2025
- MaaT013 has the potential to be the first microbiome-driven therapy approved in Europe

Lyon, France, March 11th, 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, announced today that the European Medicines Agency (EMA) Pediatric Committee (PDCO) has approved the Pediatric Investigation Plan (PIP) for MaaT013 for the treatment of acute Graft-versus-Host Disease (aGvHD).

"We are very pleased with the productive dialogue with the EMA Pediatric Committee and the positive PIP opinion. This approval marks a major regulatory milestone towards the submission of our Marketing Authorization dossier with the EMA," **said Gianfranco Pittari, MD, PhD, Chief Medical Officer at MaaT Pharma.** "*Through our Early Access Program, we have already successfully and safely treated two pediatric patients with aGvHD. We are committed to bringing MaaT013 to pediatric patients suffering from aGvHD, who currently have limited options.*"

The EMA PDCO approved the clinical program to evaluate the safety and efficacy of MaaT013 in patients from 6 years old to less than 18 years old, with the initiation, in 2026, of a single-arm trial in third-line treatment for 18 patients with aGvHD and in line with the Company's cash projections.

Based on this positive opinion, MaaT013 would be eligible for up to an additional two years of marketing exclusivity in Europe, on top of the ten-year European market exclusivity as an orphan drug if the Marketing Authorization is granted by the EMA. This also confirms the Company's ability to reach the full patient population.

"With this approval of our Pediatric Investigation Plan, we are now on track to submit our Marketing Authorization dossier in June this year. If approved, the Company could be positioned to generate revenues as soon as late 2026 with MaaT013 in third-line treatment in aGvHD," **stated Hervé Affagard co-founder and CEO of MaaT Pharma**. *"Additionally, the Company will continue to provide the product through its Early Access Program for all patients in need."*

About the Pediatric Committee (PDCO)

The Pediatric Committee (PDCO) is the European Medicines Agency's (EMA) scientific committee responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise and defining pediatric needs. The PDCO issues an opinion on PIP as part of the regulatory process and the EMA adopts a final decision based on the PDCO's opinion.

About the Pediatric Investigation Plan (PIP)

A pediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorization of a medicine for children. As part of the regulatory process for the registration of new medicines in Europe, the EMA requires pharmaceutical companies to provide a PIP detailing their strategy for investigation of the new medicinal product in the pediatric population. An approved PIP is a prerequisite for filing a Marketing Authorization Application (MAA).

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 second-line treatment for steroid-refractory acute graft-versus-host disease (SR aGvHD) is ruxolitinib. Recently, remestemcel—L-rknd was approved in December 2024 in the US specifically for use in the paediatric population as a second-line treatment.

About 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. MaaT013 is a full-ecosystem, off-the-shelf, standardized, pooled-donor, 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). 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. MaaT013 has been granted Orphan Drug Designation by the U.S. 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.

MAAT LISTED EURONEXT

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
Guilhaume DEBROAS, Ph.D.
Head of Investor Relations
+33 6 16 48 92 50
invest@maat-pharma.com

MaaT Pharma – Media Relations
Pauline RICHAUD
Senior PR & Corporate Communications Manager
+33 6 14 06 45 92
media@maat-pharma.com

Rx Communications Group – U.S. Investor Relations
Michael Miller
Managing Director
+1-917-633-6086
mmiller@rxir.com

Catalytic Agency – U.S. Media Relations
Heather Shea
Media relations for MaaT Pharma
+1 617-286-2013
heather.shea@catalyticagency.com