MaaT Pharma Completes Recruitment of its ARES Phase 3 Trial for MaaT013 to Treat Acute Graft-versus-Host Disease

- Last patient treated in MaaT Pharma's Phase 3 ARES clinical trial
- Topline results publication now expected in January 2025
- Positive DSMB review of Phase 3 ARES trial announced in Q4 2023, with a favourable benefit/risk ratio and *"high efficacy and low toxicity"*
- Registration process to commence with submission expected in 2025 in Europe

Lyon, France, October 15, 2024 7:30am 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 full recruitment of its Phase 3 clinical trial designed to evaluate efficacy and safety of its lead asset MaaT013 in the treatment of steroid refractory and ruxolitinib refractory or intolerant acute Graft-versus-Host Disease (aGvHD) (NCT04769895). This achievement is one of the most significant milestones in the Company's development and the study's topline results, including the primary endpoint (Gastrointestinal aGvHD Overall Response Rate) are now expected to be released in January 2025.

Hervé Affagard, CEO and co-founder of MaaT Pharma stated*: "Completing the enrolment of this Phase 3 marks a major milestone in our mission to improve outcomes for blood cancer patients and underscores our continued commitment to the GvHD community. MaaT013 enables immune modulation by optimizing the gut microbiota balance while lowering the risk of adverse events associated with conventional immunosuppressive therapies. We are confident that MaaT013 could become the first-ever approved therapy harnessing microbiome-driven immune modulation in oncology, opening the door to the creation of a new therapeutic pillar across a broad range of cancer types."*

ARES is a pivotal Phase 3 multicenter, European, open-label, single-arm study assessing the safety and efficacy of MaaT013 in patients with GI-aGvHD refractory to steroids and ruxolitinib. The study anticipated recruiting a maximum of 75 patients to account for potential dropouts and the Company has reached its goal by enrolling 66 evaluable patients, the number required for an accurate assessment of the primary endpoint. The Company previously announced in Q4 2023 the positive outcome of the interim Data Safety Monitoring Board (DSMB) of the Phase 3 ARES trial, including a favourable benefit/risk ratio, with "*high*

efficacy and low toxicity." In parallel, MaaT013 has been available for the past 5 years in Early Access Program in 6 countries in Europe to treat acute Graft-versus-Host Disease, with over 180 patients safely treated as of today.

Next steps and milestones for MaaT013 in GvHD:

- **Early December 2024:** Company to host Key Opinion Leaders discussion on updated data from Early Access Program in Europe for MaaT013 in treating aGvHD.
- **January 2025:**
  - Topline results with primary endpoint evaluation: GI Overall Response Rate (GI-ORR) at day 28
  - Company to host Key Opinion Leaders discussion on Phase 3 data
- **By end of 2025**: Secondary endpoint evaluation including One-year Overall Survival

---

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 MaaT013

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™ (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)-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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. The transplanted cells attack the recipient, causing inflammation of the skin, liver and/or gastro-intestinal tract. GI-aGvHD results in patients experiencing very high volumes of diarrhea which can be life-threatening. 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.

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