MaaT Pharma Announces Positive Outcome Following DSMB Review Reinforcing Confidence in Phase 3 On-Going Trial in Acute Graft-versus-Host Disease with MaaT013

- The independent Data Safety Monitoring Board (DSMB), after careful review of safety, efficacy, and protocol adherence, has unanimously recommended that the trial continues without modification.
- The DSMB concluded on a positive benefit/risk ratio based on a good safety profile and positive preliminary efficacy results with an Overall Response Rate higher than pre-defined protocol assumptions.

Lyon, France, October 26, 2023, 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, today announced that the DSMB unanimously recommended that the open-label, single arm pivotal Phase 3 clinical trial evaluating MaaT013 in acute Graft-versus-Host Disease (aGvHD), named ARES, continues without modification. The Overall Response Rate (ORR) was superior to pre-defined protocol assumptions. Therefore, the DSMB concluded that the benefit/risk ratio with *"high efficacy and low toxicity"* was favorable in this patient population.

"*We are delighted to report significant progress in the development of therapeutic solutions for patients battling severe acute GvHD. Modulation of the microbiota is increasingly proving to be a breakthrough in the oncology field,*" **stated Hervé Affagard, CEO and co-founder of MaaT Pharma.**

The DSMB is responsible for assessing the benefit/risk ratio with a particular focus on safety that is continuously reviewed throughout the course of the study. As per protocol, the DSMB met to review a specific safety and efficacy data analysis at Day 28, after inclusion of 30 patients. The recruitment of patients in the ARES trial has continued while the DSMB reviewed the data. **The conclusions of the DSMB review are as follow:**

- **Safety validation:** No safety concerns were identified to date, based on the data from 30 patients reviewed. MaaT013 was well-tolerated, and the adverse event profile was consistent with the previously observed safety profile of MaaT013 (170+ patients treated to date within Phase 2 study and in the ongoing Early Access Program) and with patients with aGvHD, in general. In addition, infections were specifically monitored and the

DSMB concluded that no increased infectious risk was observed, and no fatal events were attributed to MaaT013.

- **Efficacy assessment:** The efficacy profile of MaaT013 was seen by the independent group of experts to be higher than expected in the protocol assumptions, signaling potential benefits for treatment-refractory aGvHD patients. The results from this prospective pivotal clinical trial confirm and strengthen previous results in a comparable patient population in the Early Access Program of MaaT013.
- **Positive benefit/risk ratio:** The DSMB's comprehensive evaluation concluded that the benefit/risk ratio in the Phase 3 trial was favorable with *"high efficacy and low toxicity"*.

Next milestones for the ARES Phase 3 trial include:

- Mid-2024, primary endpoint evaluation: Gastrointestinal Overall Response Rate (GI-ORR) at day 28
- Mid-2025, secondary endpoint evaluation: One-year Overall Survival

As a reminder, ARES is a pivotal Phase 3 multicenter, international, open-label, single-arm study assessing the safety and efficacy of MaaT013 in 75 patients with Grade II-IV GI-aGvHD who are refractory to steroids and are resistant or are intolerant to ruxolitinib. To learn more about the study, visit www.clinicaltrials.gov.

About MaaT Pharma

MaaT Pharma, a leading clinical-stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma initiated an open-label, single-arm Phase 3 clinical trial in patients with acute GvHD, building on the positive results of its Phase 2 proof-of-concept. Its powerful discovery and analysis platform, gutPrint®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of biomarkers for microbiome-related conditions. The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice. MaaT Pharma is listed on Euronext Paris (ticker: MAAT).

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

Trophic Communications – Corporate Communications
Charlotte SPITZ or
Stephanie MAY
+49 171 351 2733
maat@trophic.eu