MaaT Pharma Announces Positive Second DSMB Review of Ongoing Phase 2b Clinical Trial Evaluating MaaT033 for Patients Receiving Allo-HSCT

- The Independent Data Safety and Monitoring Board (DSMB) has recommended that the trial proceeds as planned without modification.
- Consistent good safety profile and tolerability for MaaT033, a pooled donor-derived drug candidate in oral formulation.

Lyon, France, January, 21st, 2025 – 6.00PM 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 that the DSMB completed its second safety assessment of the Phase 2b trial PHOEBUS, the largest randomized controlled trial assessing microbiome therapy in oncology to date, and recommended continuation of the trial without modification. The routine DSMB, which convenes every six months, is composed of 5 independent experts, reviewed safety data on 59 patients (cutoff date as of October 31st, 2024) and concluded that MaaT033 is well tolerated and has an acceptable safety profile.

"We are pleased to see that the safety profile of MaaT033 remains positive, and the trial is advancing as planned. Additionally, we are proud to report that recruitment for our Phase 2b trial is progressing well, with 80 patients enrolled as of end of December 2024", **said Gianfranco Pittari, MD, PhD, Chief Medical Officer of MaaT Pharma.**

Patient enrollment continues to progress at a steady pace in France, Germany, Belgium, Spain, Netherlands and the United Kingdom, with 54 clinical centers open to date. The Phoebus trial is an international, multi-center, randomized, double-blinded study, testing MaaT033, an oral freeze-dried multi-donor formulation, as a potential adjunctive treatment for patients receiving Allogeneic Hematopoietic Stem Cell Transplantation (Allo-HSCT), against placebo. The trial is expected to enroll 387 patients and is set to be conducted in up to 56 clinical investigation sites (NCT05762211).

Upcoming milestones include the routine DSMB review for ongoing safety, conducted every six months, as well as a DSMB assessing mortality imbalance between arms, respectively at 60 patients (expected in Q1 2025) and at 120 patients (expected in Q3 2025), after 90 days of follow-up post Allo-HSCT.

Previous data from a Phase 1b trial in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (HR-MDS) having received intensive chemotherapy (reported in January 2022) and from a Phase 1 trial in patients with Amyotrophic Lateral Sclerosis (ALS) (reported in February 2024) further support MaaT033's favorable safety and tolerability profile.

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 MaaT033

MaaT033, a donor-derived, high-richness, high-diversity oral Microbiome Ecosystem Therapy™ containing anti-inflammatory Butycore™ species, is currently being developed as an adjunctive therapy to improve overall survival in patients receiving HSCT and other cellular therapies. It aims to ensure optimal microbiota function and to address a larger patient population in a chronic setting. MaaT033 has been granted Orphan Drug Designation by 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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