MaaT Pharma Announces Promising Final Data Readout for Phase 1b Evaluating MaaT033 in Amyotrophic Lateral Sclerosis (ALS)

Lyon, France, May 12, 2025, 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, announced additional findings following full data readout for the exploratory single-arm, open-label Phase 1b clinical trial named IASO (NCT05889572) evaluating MaaT033 in Amyotrophic Lateral Sclerosis (ALS).

In November 2024, the Company announced that the trial had met its primary endpoint assessing the safety and tolerability of MaaT033 with multiple doses, following the independent Data Safety and Monitoring Board (DSMB) conclusion. As a reminder, the exploratory Phase 1b trial enrolled a total of 15 participants across two centers in France Hôpital de la Pitié-Salpêtrière – AP-HP and the University Hospital of Lille. An external Scientific Advisory Committee took place at the end of March 2025 to review the full data. Below are the key takeaways from the Committee's review:

- MaaT033 demonstrated a favorable safety and tolerability profile, supported by biomarker and microbiome analyses.
- A rapid and sustained engraftment of bacterial species from MaaT033 was observed, mostly occurring within the first month and maintained during the 1-month follow-up period.
- A slower rate of disease progression (based on ALSFRS-R slopes) was noted to be interpreted with caution given the short follow up, limited sample size and single-arm Phase 1b design. The ALSFRS-R is a standard functional scale in ALS trials to track the progression of the disease. The slope reflects how many points are "lost" (=disease progression) per month. In the final data readout for the IASO trial, the following was observed for the ALSFRS-R Total score slope:
    - From first symptoms to baseline, the median slope was –0.7 points/month (range: –1.2 to –0.3)
    - From baseline to Day 84 (D84), the median slope slowed to –0.3 points/month (range: –2.4 to +1.0)
- No variation at D84 in the levels of neurofilaments, a marker associated with neuronal injury in ALS.

In addition, the Scientific Advisory Committee provided insights regarding the best population to target in a Phase 2 trial.

"These encouraging findings from the IASO Phase 1b trial confirm the favorable safety and tolerability profile of MaaT033 in ALS patients. They also highlight the therapeutic potential of microbiome modulation beyond oncology and open new avenues for development in neurodegenerative diseases, as evidence continues to grow around the gut-brain connection," **said Gianfranco Pittari, MD, PhD, Chief Medical Officer of MaaT Pharma.**

The study was conducted in close collaboration with the French patient association *Tous en Selles contre la SLA (TECS)*, highlighting the essential role of patients and their advocates in advancing science, and with the support of experts from the French academic networks FILSLAN and ACT4ALS-MND.

"Recognizing the significant unmet medical need in ALS and with the will to support those affected, we applied our discovery platform to this new disease area, demonstrating its potential beyond our primary focus in oncology with encouraging Phase 1 data. In light of the Company's strict financial discipline, and considering the recent successes achieved in oncology, we are actively seeking partners with a focus on ALS and the financial capacity to support new options to fight this disease," **stated Hervé Affagard, CEO and co-founder of MaaT Pharma.**

About MaaT033

MaaT033, a standardized, 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. MaaT033 is developed with the "pooling" technology, which allows pooling donations from multiple donors to create a standardized product with high microbial richness and diversity. 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).

About Amyotrophic Lateral Sclerosis

Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease in the US and Charcot's disease in Europe, is a progressive neurodegenerative disorder affecting motor neurons in the brain and spinal cord. This leads to muscle weakness, loss of voluntary movement, and eventually, paralysis and on an average lead to death in 3 to 5 years. ALS could affect up to 60,000 patients in US and EU by 2040 and has currently no curative treatment and few symptomatic treatments.

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.

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