



MaaT Pharma Announces Positive Phase 1b Results, Meeting Primary Endpoint in the Evaluation of MaaT033 in Amyotrophic Lateral Sclerosis (ALS)

- MaaT033 administered for two months confirmed good safety profile and was well tolerated in patients with ALS.
- Other study endpoints will be analysed in the upcoming months with full data readout expected early 2025.

Lyon, France, November 26th, 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, announced that the exploratory single-arm, open-label Phase 1b clinical trial named IASO ([NCT05889572](#)) evaluating MaaT033 in ALS has met its primary endpoint assessing the safety and tolerability of MaaT033 with multiple doses. The independent Data Safety and Monitoring Board (DSMB) concluded that MaaT033 showed good safety and tolerability in ALS patients when dosed for two months. Preliminary microbiome analysis confirms the successful engraftment of MaaT033, the Company’s oral capsule, outlining further the safety and tolerability outcome.

Prof. Gaëlle Bruneteau, Professor of Neurology at Sorbonne University and consultant neurologist at the Paris ALS expert center of the Pitié-Salpêtrière Hospital, Paris, France stated *“I am encouraged by these Phase 1b results, which underscore the strong safety and tolerability profile of MaaT033 in ALS. Preclinical and clinical evidence suggests a role of the gut microbiota in the pathogenesis and variability of ALS and further studies are essential to fully explore the potential of the gut-brain axis in this disease.”*

Additional study endpoints are expected to be analysed in the coming months. Based on the current evidence from the Phase 1b IASO study, the DSMB supports proceeding to Phase 2. MaaT Pharma plans to determine the next steps based on a comprehensive analysis of the study’s overall data, expected in early 2025. These steps may include initiating a larger randomized controlled efficacy study, subject to appropriate funding options.

Hervé Affagard, CEO and co-founder of MaaT Pharma shared *“I want to express my full gratitude to the patients participating in this study while battling a devastating disease. The ALS trial represents a potentially transformative milestone in our mission to improve patient survival through innovative microbiome-based immune modulation therapies. These results demonstrate the potential versatility of our platform to address critical unmet medical needs*

across multiple therapeutic areas. As we look toward expanding the reach and impact of this innovation, we will explore collaboration opportunities to accelerate and broaden its application to benefit even more patients in need."

A total of 15 participants across two centers in France have been enrolled in the Phase 1 trial. This Study has been a collaborative effort involving leading researchers, clinicians from Hôpital de la Pitié-Salpêtrière – AP-HP and University Hospital of Lille, experts from the French academic FILSLAN/ ACT4ALS-MND and the French patients' association [Tous en Selles contre la SLA](#). These results, along with previous data from the Phase 1b CIMON trial in Acute Myeloid Leukemia and the latest DSMB for the ongoing Phase 2b trial PHOEBUS in Europe, bolster confidence in MaaT033's safety profile in continued use.

Key safety and tolerability data will be presented in a poster at the 35th International symposium on ALS/ MND taking place in December 6-8, 2024, in Montreal, Canada.

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. 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.

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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