



## MaaT Pharma Presented Positive Updated Data on MaaT013 in the Early Access Program at ASH 2024 Annual Meeting

**MaaT Pharma to host a KOL webinar on December 17<sup>th</sup>, 2024, to discuss data and the unmet medical need in acute Graft-versus-Host Disease (aGvHD) - Register [here](#).**

- Sustained High Response Rates at Day 28: Gastrointestinal Overall Response Rate (GI-ORR) was 51% and Overall Response Rate (ORR) for all organs was 49%.
- Long-Term Survival: Overall Survival (OS) was 47% at 12 months, and 42% at 24 months.
- [Corrected] Median OS among patients responding to MaaT013 within the ARES-like population was 444 days, compared to 42 days in non-responders. Historically, median OS to best available therapy following Ruxolitinib is 28 days (Abedin et al., 2021).
- Topline results for the ARES pivotal Phase 3 trial anticipated in January 2025.

**Lyon, France, December 10<sup>th</sup>, 2024 2:30am 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 Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, today detailed updated data for 154 patients with acute Graft-versus-Host Disease (aGvHD) treated with MaaT013 in Early Access Program (EAP) in Europe during the 66<sup>th</sup> American Society of Hematology (ASH) Annual Meeting.**

**Speaking on the data, Florent Malard, MD, PhD, highlighted:** *“These findings underscore MaaT013’s potential as a transformative therapy for aGvHD, a condition with poor survival rates and limited treatment options. The high response rates and long-term survival data further validate the critical role of the gut microbiome modulation in managing aGvHD. Additionally, these results highlight the growing interest within the medical community, as demonstrated by ASH’s dedicated symposium on the microbiome’s role in transplantation and cellular therapies.”*

**Hervé Affagard, CEO and co-founder of MaaT Pharma, added:** *“The high demand from clinicians demonstrates growing adoption and trust in MaaT013. The strong real-world data from our Early Access Program not only gives us confidence as we approach Phase 3 results but also validates our immune modulation approach through microbiome-based therapies. Success in GvHD, a severe and complex immune-mediated disease, would pave the way to demonstrate the platform’s potential to address a broad range of complex immune-related diseases.”*

As a reminder, key findings include:

For the full cohort (154 patients) in the EAP

- Durable response: 51% GI-ORR at Day 28 and a 44% GI-ORR at Day 56. ORR for all organs was 49% at D28 and 42% at D56.
- Overall survival (OS): 53% at 6 months, 47% at 12 months, and 42% at 24 months.
- Median survival follow-up: 418 days (range, 27–1644 days).

Subset (n=58) **resembling the population enrolled in the Phase 3 ARES trial** (receiving 2<sup>nd</sup> line ruxolitinib):

- Higher response rate than the full cohort: GI-ORR was 59% at Day 28 and 54% at D56. ORR considering all organ was 55% at D28, and 56% at D56.
- OS was 54% at 6 months, 49% at 12 months, and 40% at 24 months vs 15% at 12 months in published historical data (Abedin et al. Br J Haematol. 2021 Nov).

Full details on data available [here](#).

### Upcoming events & milestones:

- MaaT Pharma will host a webcast on December 17<sup>th</sup>, 2024, at 6.00pm CET/ 12.00pm ET/ 9.00am PT to discuss the latest EAP data, detailing the high unmet medical need and the upcoming milestones for MaaT013. To attend, please register [here](#).
- Topline results for the pivotal Phase 3 ARES trial (NCT04769895), completed in October 2024, are expected in January 2025 and should further validate MaaT013’s potential in meeting high unmet medical need for patients with aGvHD with no therapeutic options.

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### 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.

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