MaaT Pharma to Present Updates from Early Access Program at the 2024 ASH Annual Meeting Demonstrating Prolonged Long-Term Survival in Patients Receiving MaaT013 in aGvHD

- Efficacy, safety, and long-term follow-up data from 154 patients in the EAP in Europe further reinforce the excellent clinical profile of MaaT013 in GI-aGvHD.
- MaaT013 is a safe and effective treatment for refractory GI-aGvHD particularly in patients who previously received ruxolitinib.
- Long-term follow-up shows that the observed high response rates translate into a prolonged survival at 2 years.
- A pivotal Phase 3 trial evaluating MaaT013 (ARES trial - NCT04769895) in GI-aGvHD patients who previously received steroids and ruxolitinib has been completed in October 2024. Topline results are expected in January 2025; among the 154 patients in the EAP, 58 patients closely resembling the Phase 3 population have shown very promising results.

Lyon, France, November 7th, 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 updated results from its Early Access Program of MaaT013 in 154 patients with steroid-refractory (SR) or dependent (SD) gastrointestinal acute Graft-versus-Host Disease (GI-aGvHD) have been selected for poster presentation at the 66th American Society of Hematology (ASH) Annual Meeting. GI-aGvHD is a major cause of morbidity and mortality following allogeneic hematopoietic stem cell transplantation. These patients previously failed 1 to 6 aGvHD systemic treatment lines and most had grade III (47%) or IV (40%) aGvHD.

Robust response rates that translated in sustained survival and strong safety were observed following MaaT013 treatment, confirming its potential as a transformative therapy for GI-aGVHD patients in urgent need of novel therapies.

Efficacy data is summarized below (see here for full abstract):

Full patient cohort (n=154):

- The gastrointestinal overall response rate (GI-ORR) at day 28 was 51% with complete response (CR) occurring in 46 patients (30%). ORR considering all organs was 49% with CR occurring in 41 patients.
- Overall survival (OS) was 53% at 6 months, 47% at 12 months and 42% at 24 months, indicating long-term benefits survival. Importantly, OS was significantly higher in patients who responded to MaaT013 compared to non-responders (68% versus 24% at 12 months and 58% versus 24% at 24 months).

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

- Compared to the full patient cohort, improved responses were observed. The GI-ORR was 59% at day 28 (CR 48%). ORR considering all organ was 55% (CR 43%).
- In line with the full patient cohort, OS was significantly higher in patients who responded to MaaT013 compared to non-responders (75% versus 11% at 12 months and 61% versus 11% at 24 months).

As a reminder, historical data from Abedin et al. 2021 publication demonstrate that in third-line GI-aGvHD, overall survival rates are critically low: 20% at 6 months, 15% at 12 months, and only 10% at 18 months.

"As we eagerly anticipate the forthcoming results of our Phase 3 ARES trial, we are encouraged by these positive long-term results which underscore MaaT013's potential to address a significant unmet need for patients with refractory GI-aGvHD," **said Dr. Gianfranco Pittari, MD PhD, Chief Medical Officer of MaaT Pharma.** "*The significant survival benefit conferred by MaaT013 reaffirm our commitment to advancing this novel microbiome-based approach, which we believe could become a game-changer in the treatment of aGvHD."*

The Company will host an investor webcast to discuss the data following poster presentation, further details will be announced in the coming days.

Details of the presentation:

- Title: Pooled Fecal Allogenic Microbiotherapy for Refractory Gastrointestinal Acute Graft-Versus-Host Disease: Results from Early Access Program in Europe
- Poster number: 4903
- Presenter: Professor Florent Malard, hematology professor at the Saint-Antoine Hospital and Sorbonne University
- Session: 722. Allogeneic Transplantation: Acute and Chronic GVHD, Immune Reconstitution: Poster III
- Session Date/Time: Monday, December 9, 2024: 6:00pm -8:00pm EST
- Location: San Diego Convention Center, Halls G-H

Upcoming investor and medical conferences participation

- November 6-8, 2024 – 39th SITC annual meeting in Houston, USA
- November 20-22, 2024 – SFGM-TC annual meeting in Toulouse, France

- November 25-27, 2024 – Deutsches Eigenkapitalforum annual meeting in Frankfurt, Germany
- November 26, 2024 – Investir Day event in Paris, France.
- December 5, 2024 – CF&B Midcap Events in Geneva, Switzerland
- December 7-10, 2024 - 66th ASH annual meeting in San Diego, USA, followed by a webinar on the updated dataset from the EAP of MaaT013 in aGvHD.

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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