



MaaT Pharma Presents Compelling Consolidated MaaT013 Clinical Data at the 64th ASH Annual Meeting

- Oral presentation at 64th American Society of Hematology Annual Meeting includes promising results from 81 patients with steroid-resistant, gastrointestinal acute Graft-versus-Host Disease (GI-aGvHD) treated with MaaT013 as part of compassionate use program (Early Access Program or EAP) in France.
- Results showed a GI-Overall Response Rate (ORR) of 56% including 30 complete responses (37%), 11 very good partial responses (14%), 4 partial response (5%) in GI-aGvHD patients 28 days after treatment initiation; 12-month overall survival was 59% in patients responding to MaaT013 treatment.
- A 65% ORR was observed in 31 patients treated with MaaT013 as 3rd-line therapy after failure to 2nd-line ruxolitinib treatment; 12-month overall survival in this group responding to MaaT013 treatment was 74%; similar patient population is being treated in MaaT Pharma's ongoing pivotal Phase III ARES clinical trial in Europe.

Company to host investor webcast on Monday, December 12 at 6:00 pm CET.

To register and access the webcast, please click [here](#). A replay will be made available shortly after the conclusion of the webcast and archived on MaaT Pharma's website for at least 90 days.

Lyon, France December 10th, 2022 – 5:30pm CET – [MaaT Pharma](#) (EURONEXT: MAAT – the “Company”), a French clinical-stage biotech and a pioneer in the development of Microbiome Ecosystem Therapies™ (MET) dedicated to improving survival outcomes for patients with cancer, today presented data from the continuing compassionate use program (EAP) in France for MaaT013 at the Annual Society of Hematology (ASH) Annual Meeting in New Orleans, U.S. [To see the abstract, click here.](#)

The EAP consolidated results, presented in an oral format on December 10 at 5:15 pm CET/ 10.15am CST by **Prof. Mohamad Mohty**, Head of the Clinical Hematology and Cellular Department at the Saint-Antoine Hospital and Sorbonne University, include data from 81 patients treated with MaaT013, the company's high-richness, high-diversity lead Microbiome Ecosystem Therapy™ (MET) for hospital use in an acute setting. Patients developing refractory acute Graft-versus-Host Disease with gastrointestinal involvement (GI-aGvHD) following hematopoietic cell transplantation demonstrated an overall response rate (GI-ORR) of 56% at day 28 following MaaT013 treatment. In patients responding to MaaT013 therapy, the overall survival (OS) rate at 12 months was 59% (compared to 14% for non-responders) indicating a significant clinical benefit with MaaT013.

In aGvHD patients refractory to 1st-line (steroids) and 2nd-line (ruxolitinib) treatments (n=31) and receiving MaaT013 as a 3rd-line therapy, 65% demonstrated a GI-ORR at day 28. The 12-month OS rate in the MaaT013-responding group was 74%. This patient population resembles the ongoing Phase 3 ARES clinical trial ([NCT04769895](https://clinicaltrials.gov/ct2/show/study/NCT04769895)) being conducted in Europe.

“The clinical benefits we continue to observe with MaaT013 are promising and reinforce the potential for our MET to improve survival outcomes for aGvHD patients when early treatment lines are unsuccessful,” said Hervé Affagard, CEO and co-founder of MaaT Pharma. “The year 2022 will be remembered as a turning point for the microbiome therapeutics industry as it continues to mature. We expect to see an acceleration in the field following the first FDA approval for a microbiome-based product in preventing C. difficile infection as well as promising clinical results in various infectious disease and oncology indications.”

Prof. Mohamad Mohty added, *“Patients with severe acute GvHD that have undergone several lines of treatments have a high mortality risk with no currently proven salvage treatment options. The results observed with MaaT013 are very encouraging especially in the 3rd-line setting where we see that the survival outcome is significantly improved. Since the patient population being treated with MaaT013 in the company’s Phase III ARES pivotal study in Europe is similar to those treated in the EAP, we are hopeful that the clinical trial results will corroborate these positive results and will provide an important benefit to all patients who are in need.”*

Key clinical findings with MaaT013 in compassionate use in France (Early Access Program or ‘EAP’)

In the EAP, 81 patients with steroid-dependent or steroid-resistant, Grade II-IV, gastrointestinal aGvHD were treated with MaaT013 from July 2018 to May 2022

- 45 out of 81 (56%) showed objective GI response at day 28 of which 30 patients (37%) had a complete response, 11 patients (14%) had a very good partial response, and 4 patients (5%) showed a partial response.
- Overall survival (OS) in MaaT013-responding patients at the 12-month follow-up was 59%, compared to 14% in non-responders (OS in all included patients was 39% at 12 months).
- Considering GvHD response in all organs (GI, skin, liver), 38 out of 78 patients (49%) showed an objective response rate (ORR) at day 28, of which 24 patients (31%) had a complete response, 11 patients (14%) had a very good partial response, and 3 patients (4%) showed a partial response.
- At the time of treatment, all patients had either Grade II (11%), Grade III (51%) or Grade IV (38%) aGvHD (MAGIC Classification).
- Patients received MaaT013 after 1 to 6 (median: 2; 66/81 received ruxolitinib) lines of treatment
- 68 out of 81 patients (84%) were steroid resistant of which 33 out of 68 (49%) showed an objective GI response at day 28; among these patients, 21 patients (31%) had a complete response, 9 patients (13%) had a very good partial response, and 3 patients (4%) showed a partial response.
- 66 out of 81 patients (81%) were refractory to ruxolitinib (any treatment line), of which, 37 out of 66 (56%) showed an objective GI response at day 28; of these 25 patients (38%) had a complete response, 9 patients (14%) had a very good partial response, and 3 patients (5%) showed a partial response

- 31 out of 66 patients were ruxolitinib-refractory in 2nd-line and MaaT013 was administered as a 3rd-line treatment; 20 out of 31 patients (65%) showed an objective GI response at day 28; among these patients, 19 patients (61%) had a complete response, and 1 patient (3%) had a very good partial response.
- 13 out of 81 patients (16%) were steroid-dependent of which 12 out of 13 patients (92%) showed an objective GI response at day 28; among these patients, 9 patients (69%) had a complete response, 2 patients (15%) had a very good partial response, and 1 patient (8%) showed a partial response.

Evaluation of MaaT013 in the Phase III pivotal clinical trial ARES

MaaT Pharma announced the [first patient](#) enrolled in the Phase III, open label, single arm, ARES pivotal trial for MaaT013 in March 2022, with a safety and data review by an independent data safety and monitoring board (DSMB), after enrollment of half of the patients in the study, expected in the first half of 2023.

As of today, MaaT013 has been safely administered to more than 160 patients in Europe in clinical trials and in the Expanded Access Program in France. Indeed, additionally to clinical trials, MaaT Pharma has been pursuing, since 2019, the compassionate use program in France, approved by the ANSM, to faster access to MaaT013 for patients with unmet medical need, mainly for indications in acute Graft-versus-Host disease. This program also allows the Company to strengthen its supply chain and production capacities to safely provide MaaT013, on a regular basis to 24 transplantation centers in France.

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-predominant aGvHD. MaaT013 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About MaaT Pharma

MaaT Pharma, a clinical stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has launched, in March 2022, a Phase 3 clinical trial for patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, supports the development and expansion of its pipeline by determining novel disease targets, evaluating drug candidates, and identifying biomarkers for microbiome-related conditions. The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome, in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice.

MaaT Pharma is the first company developing microbiome-based therapies listed on Euronext Paris (ticker: MAAT).



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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