



MaaT Pharma Announces Publication of Results in eClinicalMedicine Journal Highlighting Clinical Benefit of MaaT013 in aGvHD

- Data on 76 patients with gastrointestinal acute Graft-versus-Host Disease treated with MaaT013 published in eClinicalMedicine, one of The Lancet Discovery Science suite's journals
- Ongoing Phase 3 trial built on positive data from Phase 2 HERACLES study and ongoing early access program (EAP) in France: both datasets showed that MaaT013 was well-tolerated in immunocompromised patients and had promising clinical benefits

Lyon, France, July 26, 2023, 6:00 pm 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 improving survival outcomes for patients with cancer, today announced that eClinicalMedicine has published clinical data on MaaT013 as a treatment for acute Graft-versus-Host Disease (aGvHD). The data includes results from 24 patients in a Phase 2 clinical trial and 52 patients enrolled in the Early Access Program (EAP) in France. The article entitled “*Pooled allogeneic faecal microbiota MaaT013 for steroid-refractory gastrointestinal acute graft-versus-host disease: a single-arm, multicentre phase 2 trial*” can be accessed [here](#).

“Data show encouraging clinical outcomes and survival rates for very severe patients with acute GvHD, thereby opening new treatment avenues,” **said Pr. Florent Malard, Professor of Hematology at the Saint-Antoine Hospital and Sorbonne University.** *“Based on this promising clinical data, including the good tolerability and safety profile, we eagerly anticipate the results of the ongoing evaluation of MaaT013 in Phase 3.”*

“The publication of our results in a peer-reviewed journal underlines the importance of the microbiome in the hematology-oncology field. Indeed, the data suggests that the successful re-establishment of a functional microbiome through our innovative MET MaaT013 is associated with patient response,” **commented Hervé Affagard, CEO and co-founder of MaaT Pharma.**

The [Phase 2a HERACLES trial](#) evaluated MaaT013's safety and efficacy in patients with grade III-IV steroid-refractory gastrointestinal aGvHD after allogeneic hematopoietic stem cell transplantation. The gastrointestinal Overall Response Rate was 38% in the trial population and 58% in the EAP population. Interestingly, patients responding at day 28 exhibited a higher microbiota richness and greater proportions of MaaT013-derived beneficial species from multiple donors, that could suggest a clinical impact from pooling donors. MaaT013's safety profile was consistent with previous findings. Clinical data in the article were also previously

presented at the [2021 American Society of Hematology Annual Meeting](#). For HERACLES, Overall Survival (OS) in responding patients at the 12-month follow-up was 44%, compared to 13% in non-responders (OS in all included patients was 25% at 12 months). For EAP, the 12-month OS in responding patients was 59%, compared to 7% in non-responders (OS in all included patients was 38% at 12 months). As a reminder, OS in ruxolitinib-resistant patients at 2 months is 22% (REACH1 study). The drug candidate MaaT013 is currently being evaluated in the pivotal ARES study, the first global phase 3 trial in hemato-oncology.

About HERACLES

The HERACLES trial ([NCT03359980](#)), a multi-center, single-arm, open-label study, analyzed the efficacy and safety of MaaT013 in patients with grade III-IV GI-predominant aGvHD after allogeneic-HSCT whose standard failed first-line treatment of high-dose corticosteroids. A total of 24 patients, including 21 in the per-protocol analysis, received at least one, and up to three doses, of MaaT013, and treatment response was evaluated seven days after each administration and on day 28 after the first dose. Patient follow-up was performed at 3 months and 6 months, with a final follow-up at 12 months after study inclusion.

About MaaT013

MaaT013 is a standardized, high-richness, high-diversity Microbiome Ecosystem Therapy™ containing Butycore™ (i.e., a group of bacterial genera known to produce immuno-regulatory metabolites). It 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 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). MaaT013 is an off-the-shelf, healthy-multi-donors-derived product intended for acute, hospital use.

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, an open-label, single-arm Phase 3 clinical trial in patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of 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 listed on Euronext Paris (ticker: MAAT).



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