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MaaT Pharma Announces Publication of Results from Completed Phase 1/2 ODYSSEE Clinical Trial in *Nature Communications*

- The trial of the autologous microbial therapy, MaaT011, met its primary endpoints through demonstration of restored gut microbiota balance and diversity as well as reduction of antibiotic resistance gene carriage
- MaaT011 was safe after induction chemotherapy in acute myeloid leukemia patients
- MaaT011 formed the basis of the company's full ecosystem therapeutic approach that was continued with product candidates MaaT013 (in acute graft-vs-host disease) and MaaT033 (in acute myeloid leukemia)

Lyon, France, May 25, 2021 – MaaT Pharma announced today that final results from its Phase 1/2 ODYSSEE clinical trial have been published in the journal, *Nature Communications*. The data demonstrated that the company's initial product candidate, MaaT011, an autologous fecal microbiota transfer treatment, was safe and effective in fully restoring the gut microbiota in the 20 per-protocol analyses set of acute myeloid leukemia (AML) patients. In addition, the MaaT011 treatment showed short- and long-term signs of positive clinical outcomes including the reduction of both intestinal inflammation and gut carriage of antibiotic resistance genes. Topline data from the study had been previously presented in a poster presentation at the 60th American Society of Hematology (ASH) Annual Meeting in December 2018.

Follow-up results from the trial also showed that only 17% (3/18) of the AML patients who received the MaaT011 intervention and subsequent allogeneic hematopoietic stem cell transplantation (allo-HSCT) developed gastrointestinal- graft -versus-host disease (GI-GvHD), a serious complication often resulting in high morbidity and mortality rates of up to 80%, suggesting a potential long-term protective effect of MaaT011 in these patients. The overall survival (OS) rate in the trial was 92% at six months and 72% at two years, which compares favorably with previously published studies in which the two-year OS ranged from 41.9% to 60% in this setting[1].

"The publication of peer-reviewed data in this renowned journal is a validation of the scientific rigor behind MaaT Pharma's full-ecosystem restoration approach. The initial positive data from ODYSSEE paved the way for our enema and capsule formulations, MaaT013 and MaaT033, respectively, which are derived from pooling the intestinal microbial ecosystems of healthy donors. The full results from the study support

[1] See for instance: Castaigne, S. *et al. Lancet (London, England)* **379**, 1508-1516, (2012); Burnett, A. K. *et al. Blood* **125**, 3878-3885 (2015) for data in similar populations.

our premise that a full-ecosystem microbiome therapeutic that can restore the high diversity and richness of the gut microbiota can provide a positive impact for patients with liquid tumors, including possibly in a prophylactic setting," commented John Weinberg, MD, Chief Medical Officer of MaaT Pharma. *"We recently announced positive results for MaaT013 from our Phase 2 HERACLES clinical trial in graft-vs-host disease and our oral formulation, MaaT033, is currently being evaluated in a Phase 1b clinical study in acute myeloid leukemia patients; we expect to complete that trial in the fourth quarter of this year."*

The standard treatment regimen for AML relies on intensive induction chemotherapy and treatment with antibiotics, which has been shown to dramatically alter the rich and diverse composition of the gut microbiome. As a result, host-microbiome interactions can be disrupted, resulting in pathological conditions including uncontrolled local immune responses, systemic inflammation, and increased incidence of comorbidities and complications. The study demonstrated that MaaT011 treatment successfully reestablished the disrupted gut microbiota back to baseline levels, qualitatively and quantitatively. Moreover, it drastically reduced proinflammatory bacteria that have been shown to dominate after intensive chemotherapy.

Professor Mohamad Mohty, MD, PhD, Professor of Hematology at Sorbonne University and Head of the Hematology and Cellular Therapy Department at the Saint Antoine Hospital in Paris, and senior corresponding author of the article added: "*The results from the ODYSSEE study are profound because they suggest that restoring a functional gut microbiome ecosystem in heavily pre-treated acute myeloid leukemia patients can improve their outcomes. It is also impressive that MaaT011 treatment could likely reduce the risk of GvHD in the patients that received stem cell transplantation compared to standard expectations in this population*."

The article titled, "Restoration of gut microbiota diversity with autologous fecal microbiota transfer in acute myeloid leukemia patients " summarizes the findings of the ODYSSEE trial (NCT02928523), a Phase 1/2 single-arm, multicenter, prospective, interventional trial in hospitalized patients with AML or high-risk myelodysplastic syndrome (MDS). A total of 25 patients were treated with MaaT011 and the efficacy results published were from those 20 patients that met the per-protocol analysis profile.

The *Nature Communications* publication is available online.

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a rare and aggressive cancer of the myeloid cells – immune cells that fight bacterial infections, defend the body against parasites, and prevent the spread of tissue damage – that progresses quickly and aggressively, and usually requires immediate treatment. The risk of developing AML increases with age; it is most common in people over 75 years.

About MaaT Pharma

MaaT Pharma, a clinical stage company, has established the most complete approach to restoring patient-microbiome symbiosis to improve survival outcomes in life-threatening diseases. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has already achieved proof of concept in acute myeloid leukemia patients and successfully completed a positive Phase 2 clinical trial in acute GvHD. Supporting the further expansion of our pipeline into larger indications, we have built a powerful discovery and analysis platform, GutPrint®, to evaluate drug candidates, determine novel disease targets and identify biomarkers for microbiome-related conditions. Our 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 spearhead microbiome treatment integration into clinical practice.

About MaaT011

MaaT011 is a full-ecosystem autologous fecal microbiota transfer product manufactured under cGMP conditions. It was evaluated in the company's ODYSSEE clinical trial to establish proof-of-concept for a full-ecosystem microbiome-based therapeutic approach in severe diseases. The study demonstrated that reintroducing the patient's own microbiome post chemotherapy can reestablish the gut microbiome and have a beneficial impact in acute myeloid leukemia patients. MaaT011 formed the basis of the company's full ecosystem therapeutic approach that was continued with product candidates MaaT013 (enema) and MaaT033 (oral), which are standardized, full-ecosystem, off-the-shelf, high-richness, pooled-from-healthy-donors microbiome biotherapeutic products. Positive topline data for MaaT013 for the treatment of acute graft-versus-host-disease was recently announced. MaaT033 is currently in Phase 1 testing in patients with acute myeloid leukemia.

Contacts

Hervé Affagard, CEO
Phone: +33 4 2829 1400
E-Mail: haffagard@maat-pharma.com

Media Requests for MaaT Pharma

Jacob Verghese or Stephanie May
Trophic Communications
Phone: +49 89 2388 7735
E-Mail: maat@trophic.eu