Press Release

MaaT Pharma Announces First Positive DSMB Safety Review for Phase Ib CIMON Trial Testing Its Microbiome Ecosystem Therapy Capsule Formulation in AML Patients

- Independent Data Safety and Monitoring Board (DSMB) recommends continuing CIMON study and initiating dosing of second patient cohort
- Study is evaluating safety, dosing regimen and activity of MaaT033 in patients with acute myeloid leukemia receiving intensive chemotherapy

Lyon, France, December 22, 2020 – MaaT Pharma announced today that an independent Data Safety and Monitoring Board (DSMB) completed its first analysis of the ongoing Phase Ib CIMON clinical trial with MaaT033, the company's capsule formulation of its lead biotherapeutic, MaaT013, in patients with acute myeloid leukemia (AML) or high-risk Myelodysplastic Syndrome (MDS) following intensive chemotherapy. The DSMB reviewed safety data from the first patient cohort treated with the first dose of MaaT033 and confirmed the absence of safety issues during the trial and recommended that the trial continue without modifications.

Studies have shown that chemotherapy severely reduces the microbial species networks in the gut leading to disruption in its protective epithelial layer and immune system functionality, negatively impacting patient outcomes. MaaT033, which is characterized by high microbial species diversity and richness, has been designed to restore a functional gut microbiome and re-establish immune system homeostasis to improve outcomes for patients in an easy to administer capsule.

"The DSMB's positive assessment supports our data compiled to date and our understanding of the safety of our microbiome ecosystem therapies in this patient population, and we look forward to continuing this trial with the next patient cohort and identifying a dose that will be utilized in the subsequent Phase II study," commented John Weinberg, MD, Chief Medical Officer at MaaT Pharma. "Our goal is to provide a convenient formulation that enables use in a broad group of patients and that complements our first product candidate MaaT013."

The CIMON trial (NCT04150393) is enrolling a total of 27 patients at 4 centers across France. It is an open-label Phase 1b study to investigate the maximum tolerated dose of MaaT033, over 7 or 14 days of therapy, that supports optimal gut microbiome colonization in patients with AML or high-risk MDS who underwent intensive chemotherapy. Overall safety, tolerability, and dose regimen will be evaluated, as will the impact on the gut microbiome, to identify a recommended Phase II dose. The CIMON Phase 1b trial is expected to be completed in the fourth quarter of 2021.

Prof. Christian Recher, PU-PH, Head of the Hematology Department at the University Hospital of Toulouse, France, and coordinator of the CIMON trial added: *"The treatment of hematological malignancies such as acute myeloid leukemia and myelodysplastic syndrome result in substantial negative changes in the content of patients' gut microbiota. These microbiome changes increase the risk of poor outcomes, by allowing for negative effects such as gut or systemic infections or GvHD in patients who do go on to receive a hematopoietic stem cell transplant. Therefore, we believe that reconstituting the microbiome with a rich and highly diverse microbial therapy such as MaaT033 offers an opportunity to improve outcomes for these patients."*

About MaaT033
MaaT033 is an oral, full-ecosystem, off-the-shelf, standardized, pooled-donor, high-richness microbiome biotherapeutic. It is manufactured at MaaT Pharma's centralized European cGMP production facility. MaaT033 is designed to restore the gut ecosystem to full functionality in order to improve clinical outcomes as well as control adverse events related to conventional treatments for cancer. The capsule formulation eases administration while maintaining the high and consistent richness and diversity of microbial species, including anti-inflammatory "Butycore" species, which characterize MaaT Pharma's microbiome ecosystem therapies.

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 a Phase 2 clinical trial in acute GvHD is completed. Supporting the development and expansion of our pipeline, 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.

Contacts

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

Media Requests for MaaT Pharma
Stephanie May or Laura Mittmann
Trophic Communications
Phone: +49 89 9093 3803
E-Mail: maat@trophic.eu