Press Release

MaaT Pharma Treats First Acute Myeloid Leukemia Patient in Phase 1 Clinical Trial to Evaluate Capsule Formulation of Microbiome Restoration Biotherapeutic

- MaaT033 is an oral formulation of MaaT Pharma's full-ecosystem biotherapeutic characterized by high microbial diversity and richness

- Study will evaluate safety, dosing regimen and activity of MaaT033 in patients with acute myeloid leukemia receiving intensive chemotherapy

Lyon, France, November 12, 2020 – MaaT Pharma announced today that it treated its first patient in a Phase 1 clinical trial to evaluate the safety and tolerability of MaaT033, a capsule formulation of the company's lead biotherapeutic, MaaT013, characterized by high microbial species diversity and richness. The trial named CIMON will enroll patients with acute myeloid leukemia (AML) or high-risk Myelodysplastic Syndrome (MDS) following intensive chemotherapy. MaaT033 is being developed to provide a complete approach to restoring a functional gut microbiome and re-establishing immune system homeostasis to treat life-threatening diseases. The capsule formulation provides a convenient route of administration for patients who are already undergoing intensive treatment regimens, while providing a high and consistent richness of microbial species, derived from pooling the intestinal ecosystems of healthy donors.

John Weinberg, MD, Chief Medical Officer at MaaT Pharma commented: "As shown in our previous ODYSSEE trial, cancer treatments, in particular chemotherapy, induce a drastic reduction in microbial species networks in the gut, leading to a decline in its protective epithelial layer and disruption of immune system functionality. This in turn can result in multiple complications, some of them severe, especially for leukemia patients. The MaaT033 capsule formulation is designed to restore the microbiome of patients that receive intensive chemotherapy and adds an important treatment modality to our portfolio of microbiome restoration therapeutics. Use in an ambulatory setting will be facilitated, and we will be able to address the needs of a broader patient population."

The CIMON trial (NCT04150393) will enroll 27 patients in 4 centers. It is an open-label Phase 1b study to investigate the maximum tolerated dose of MaaT033, over 7 or 14 days, that supports gut microbiome engraftment in patients with AML or high-risk MDS that are undergoing 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.

"Initiating the clinical evaluation of our capsule formulation is an important milestone for MaaT Pharma, enabling us to expand our therapeutics pipeline with a complementary product candidate to our MaaT013 biotherapeutic. MaaT033 is designed to address a number of different tumor indications where increased ease of administration is important," added Hervé Affagard, CEO and Co-founder of MaaT Pharma. *"Despite the challenges of the COVID-19 pandemic, we continue to meet our development goals for our growing pipeline of microbiome biotherapeutics while ensuring the safety and quality of our product candidates."*

The CIMON Phase 1b trial is expected to be completed in the fourth quarter of 2021.

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 products.

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 ongoing. 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 therapeutics are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators.

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